# FEDERAL TRADE COMMISSION DECISIONS

## FINDINGS, OPINIONS, AND ORDERS JANUARY 1, 2006 TO JUNE 30, 2006

PUBLISHED BY THE COMMISSION

## **VOLUME 141**



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## MEMBERS OF THE FEDERAL TRADE COMMISSION DURING THE PERIOD JANUARY 1, 2006 TO JUNE 30, 2006

DEBORAH PLATT MAJORAS, *Chairman* Took oath of office August 16, 2004.

PAMELA JONES HARBOUR, *Commissioner* Took oath of office August 4, 2003.

JON LEIBOWITZ, *Commissioner* Took oath of office September 3, 2004.

WILLIAM E. KOVACIC, *Commissioner* Took oath of office January 4, 2006.

J. THOMAS ROSCH, *Commissioner* Took oath of office January 5, 2006.

DONALD S. CLARK, *Secretary* Appointed August 28, 1988.

## **CONTENTS**

Members of the Commission	Page II
Table of Cases	
Findings, Opinions, and Orders	1
Interlocutory, Modifying, Vacating, and Miscellaneous Orders	454
Responses to Petitions to Quash or Limit Compulsory Process	. 498
Table of Commodities	508

## **TABLE OF CASES**

## Volume 141

The names in SOLID CAPITALS refer to cases in which orders to cease and desist have been entered by the Commission, and to interlocutory proceedings, which are indicated in parentheses. The names in italics are cases which the Commission has dismissed.

ALLERGAN, INC	Page 165
DSW INC DYNAMIC HEALTH OF FLORIDA, LLC	
EVANSTON NORTHWESTERN HEALTHCARE (Interlocutory Orders)	54, 472, 484
FRESENIUS AG	343
GAS PRICING INVESTIGATION	498
HEALTH CARE ALLIANCE OF LAREDO, L.C	133
JOHNSON & JOHNSON (Modifying Order)	487
NATIONS TITLE AGENCY, INC NORTH TEXAS SPECIALTY PHYSICIANS	323
(Interlocutory and Modifying Orders)	456, 469
RAMBUS, INC. (Interlocutory Order)	476
TEVA PHARMACEUTICALS INDUSTRIES, LTDTIME WARNER INC., ET AL. (Modifying Order)	
VALASSIS COMMUNICATIONS, INC	247

## FEDERAL TRADE COMMISSION DECISIONS

FINDINGS, OPINIONS, AND ORDERS JANUARY 1, 2006, TO JUNE 30, 2006

## IN THE MATTER OF

## TEVA PHARMACEUTICAL INDUSTRIES LTD.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4155; File No. 051 0214 Complaint, January 20, 2006--Decision, March 2, 2006

This consent order addresses the acquisition of IVAX Corporation ("IVAX") by Teva Pharmaceutical Industries Ltd. ("Teva"), which would make Teva the world's largest generic pharmaceutical supplier and would lessen competition in the U.S. markets for the manufacture and sale of certain generic pharmaceutical products. The order requires the respondents to divest rights and assets related to the relevant products to Par Pharmaceutical Companies, Inc. and Barr Pharmaceuticals, Inc. or to other Commission-approved acquirers. To ensure that the divestitures are successful, Teva and IVAX are required to provide transitional services to enable the acquirers to obtain all necessary approvals from the U.S. Food and Drug Administration until the acquirers are able to manufacture and sell all formulations and dosages of the products independently. These transitional services include technology transfer assistance to manufacture the products in substantially the same manner and quality employed or achieved by Teva and IVAX. Furthermore, Teva and IVAX are required to supply the acquirers until they receive approval to manufacture the products on their own. The Commission will select an Interim Monitor to monitor respondents' compliance with the order, and if necessary, the Commission may appoint a Divestiture Trustee to assign, grant, license, divest, transfer, deliver or otherwise convey the relevant assets.

## **Participants**

For the Commission: Jeffrey W. Brennan, Sylvia M. Brooks, Richard H. Cunningham, Daniel P. Ducore, Leslie Farber, Mark Frankena, Andrew P. Konove, Stephanie A. Parks, Thomas D. Mays, Michael R. Moiseyev, Christine Naglieri, David A. von Nirschl, David Schmidt, and Kari A. Wallace.

For the Respondent: William H. Rooney and Theodore C. Whitehouse, Willkie Farr & Gallagher LLP; and Brian R. Dunlap and Richard Liebeskind, Pillsbury Winthrop Shaw Pittman LLP.

## **COMPLAINT**

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Respondent Teva Pharmaceutical Industries Ltd. ("Teva"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire IVAX Corporation ("IVAX"), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act ("FTC Act"), as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

## I. DEFINITIONS

- 1. "Commission" means the Federal Trade Commission.
- 2. "FDA" means the United States Food and Drug Administration.
- 3. "Respondents" means Teva and IVAX individually and collectively.
  - 4. "LA" means long-acting formulation.

## II. RESPONDENTS

5. Respondent Teva is a corporation organized, existing, and doing business under and by virtue of the laws of Israel, with its office and principal place of business located at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel. Teva's principal subsidiary in the United States, Teva Pharmaceuticals USA, Inc., is located at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva,

among other things, is engaged in the research, development, manufacture, and sale of generic pharmaceutical products.

- 6. Respondent IVAX is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Florida, with its office and principal place of business located at 4400 Biscayne Boulevard, Miami, Florida 33137. IVAX, among other things, is engaged in the research, development, manufacture, and sale of generic pharmaceutical products.
- 7. Respondents are, and at all times relevant herein have been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and are corporations whose business is in or affects commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

## III. THE PROPOSED ACQUISITION

8. On July 25, 2005, Teva and IVAX entered into an Agreement and Plan of Merger (the "Merger Agreement") whereby Teva proposes to acquire all of the issued and outstanding shares of IVAX in a transaction valued at approximately \$7.4 billion (the "Acquisition").

## IV. THE RELEVANT MARKETS

- 9. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the manufacture and sale of the following generic pharmaceutical products:
  - a. Amoxicillin clavulanate potassium;
  - b. Cefaclor LA tablets;
  - c. Pergolide mesylate tablets;

- d. Estazolam tablets;
- e. Leuprolide acetate injection kits;
- f. Nabumetone tablets:
- g. Amoxicillin;
- h. Propoxyphene hydrochloride capsules;
- i. Nicardipine hydrochloride capsules;
- j. Flutamide capsules;
- k. Clozapine tablets;
- 1. Tramadol/Acetaminophen tablets;
- m. Glipizide & metformin hydrochloride tablets;
- n. Calcitriol injectables; and
- o. Cabergoline tablets.
- 10. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant lines of commerce.

## V. THE STRUCTURE OF THE MARKETS

11. Amoxicillin clavulanate potassium ("amox/clav") is a commonly-prescribed penicillin antibiotic used to treat infections. Currently, Teva, IVAX, Sandoz Inc. ("Sandoz"), and Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy") are the only suppliers of various formulations of generic amox/clav in the United States. Teva and IVAX, however, are the only suppliers of the 600 mg powder formulation of generic amox/clav. The Acquisition would leave only

Teva, Sandoz, and Ranbaxy in the generic amox/clav market, and increase Teva's market share in all formulations to over 50 percent. The Herfindahl-Hirschman Index ("HHI") would increase by 1,360 points, resulting in a post-acquisition HHI of 4,438 points.

- 12. Teva dominates the U.S. market for the manufacture and sale of generic cefaclor LA tablets, with a share of over 65 percent. Cefaclor LA tablets are cephalosporin antibiotics. The only other supplier of this product is IVAX. The Acquisition would create a monopoly in this market, and increase the HHI concentration by 4,422 points, resulting in a post-acquisition HHI of 10,000 points.
- 13. The market for the manufacture and sale of generic pergolide mesylate tablets is highly concentrated, with a pre-acquisition HHI of 6,568 points. Pergolide mesylate tablets are used to treat Parkinson's disease. Only Teva and IVAX offer this product in the United States. The Acquisition would create a monopoly in this market and increase the HHI concentration by 3,432 points, resulting in a post-acquisition HHI of 10,000 points.
- 14. Teva is the leading supplier in the market for the manufacture and sale of generic estazolam tablets in the United States, with 52 percent of the market. Estazolam tablets are used to treat seizure disorders. IVAX and Watson Pharmaceuticals, Inc. are the only other suppliers of this product. The Acquisition would create a duopoly, with Teva accounting for approximately 65 percent of the generic estazolam tablet market. The HHI would increase by 1,352 points to a post-acquisition HHI of 5,450 points.
- 15. Leuprolide acetate is an injectable drug used to treat prostate cancer. Teva is the leading supplier in the U.S. market for the manufacture and sale of generic leuprolide acetate. IVAX and Sandoz are the only other suppliers of this product. The Acquisition would create a duopoly, with Teva accounting for over 50 percent of the market. The HHI would increase 100 points to a post-acquisition HHI of 5,002 points.

- 16. Teva is the leading supplier in the market for the manufacture and sale of generic nabumetone tablets, with a share of over 60 percent. Nabumetone tablets are used to treat inflammation. IVAX and Sandoz are the only other suppliers of generic nabumetone tablets in the United States. The Acquisition would create a duopoly in this market, and increase the HHI concentration by 360 points, resulting in a post-acquisition HHI of 5,338 points.
- 17. Teva dominates the U.S. market for the manufacture and sale of generic amoxicillin. Amoxicillin is a penicillin antibiotic used to treat infections. Teva, IVAX, Ranbaxy, Stada Pharmaceuticals, Inc., and Sandoz are the only suppliers of various formulations of generic amoxicillin in the United States. Teva, IVAX, and Ranbaxy, however, are the only suppliers of the 200 mg and 400 mg oral suspensions and the 875 mg tablet formulations of the drug. The Acquisition would increase Teva's market share in the amoxicillin formulations to over 55 percent, and increase the HHI concentration by 110 points, resulting in a post-acquisition HHI of 4,094 points.
- 18. The market for the manufacture and sale of generic propoxyphene hydrochloride capsules in the United States is highly concentrated, with a pre-acquisition HHI of 4,696 points. Propoxyphene hydrochloride capsules are analgesics used to relieve severe pain. Currently, Teva, IVAX, Mylan Pharmaceuticals ("Mylan"), and Qualitest Pharmaceuticals, Inc. ("Qualitest") are the only suppliers in this market. After the Acquisition, Mylan and Qualitest would be the only competitors to Teva in this market, and the HHI concentration would increase by 663 points to a post-acquisition HHI of 5,359 points.
- 19. The market for the manufacture and sale of generic nicardipine hydrochloride capsules is highly concentrated. Nicardipine hydrochloride capsules are used to treat heart conditions. Teva, IVAX, Mylan, and Par Pharmaceutical Companies, Inc. ("Par") are the only suppliers of this product in the United States. After the Acquisition, Mylan and Par would be the

only competitors to Teva in this market, and the HHI would increase by 216 points to a post-acquisition HHI of 3,592 points.

- 20. Teva and IVAX are the two leading suppliers of generic flutamide capsules in the United States, with 26 percent and 36 percent of the market, respectively. Flutamide capsules are used to treat cancer. Currently, Sandoz and Barr Pharmaceuticals, Inc. ("Barr") are the only other suppliers of this product. After the Acquisition, Teva would control over 60 percent of the generic flutamide capsule market, and Sandoz and Barr would be the only remaining competitors to Teva. The HHI would increase 1,015 points to a post-acquisition HHI of 3,702 points.
- 21. IVAX, Mylan, and Caraco Pharmaceuticals Ltd. ("Caraco") are the only suppliers in the U.S. market for the manufacture and sale of generic clozapine tablets. Clozapine tablets are used to treat psychotic and maniac disorders. Teva has FDA approval to sell this drug, and has recently begun offering it to customers. In the absence of its pending acquisition of IVAX, Teva would have offered lower prices to attract customers and ultimately caused the market price of generic clozapine tablets to decrease. The Acquisition would leave only the combined Teva/IVAX entity, Mylan, and Caraco as suppliers in this market.
- 22. Par, IVAX, and Caraco are currently the only suppliers in the U.S. market for the manufacture and sale of generic tramadol/acetaminophen ("tramadol/apap") tablets. Tramadol/apap tablets are analgesics used to treat severe pain. Caraco only recently received FDA approval to sell this drug, and has begun offering it to customers. Teva is in the process of entering this market and is the only other supplier capable of entering this market in a timely manner. The Acquisition would eliminate Teva's planned entry into the generic tramadol/apap tablet market.
- 23. The market for the manufacture and sale of generic glipizide & metformin hydrochloride tablets is highly concentrated. Glipizide & metformin tablets are blood glucose regulators used to treat type II diabetes. Currently, Teva and Sandoz are the only suppliers of this

product in the United States. IVAX is in the process of entering this market and is one of a limited number of suppliers capable of entering this market in a timely manner. The Acquisition would eliminate IVAX's planned entry into the generic glipizide & metformin tablet market.

- 24. Calcitriol is an injectable form of vitamin D that is used in dialysis patients. Teva and American Pharmaceutical Partners, Inc. are the only suppliers in the U.S. market for the manufacture and sale of generic calcitriol. IVAX (through a distribution agreement with Genix Therapeutics, Inc.) is in the process of entering this market as a distributor of the Genix product and is the only supplier capable of entering this market in a timely manner. The Acquisition would eliminate IVAX's potential entry into the generic calcitriol market.
- 25. Cabergoline tablets are used to treat Parkinson's disease. The patent for the branded version of the drug expired in December 2005. Teva and IVAX are in the process of entering this market and are two of a limited number of suppliers who are capable of entering the future market for generic cabergoline tablets.

## VI. ENTRY CONDITIONS

26. Entry into each of the relevant product markets described in Paragraph 9 would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Developing and obtaining FDA approval for the manufacture and sale of these products takes at least two years due to substantial regulatory, technological, and intellectual property barriers.

## VII. EFFECTS OF THE ACQUISITION

27. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as

amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. by eliminating actual, direct, and substantial competition between Teva and IVAX, and reducing the number of competitors, in the markets for the manufacture and sale of generic amox/clav, cefaclor LA tablets, pergolide mesylate tablets, estazolam tablets, leuprolide acetate injection kits, nabumetone tablets, amoxicillin, propoxyphene hydrochloride capsules, nicardipine hydrochloride capsules, flutamide capsules, and clozapine tablets thereby: (1) increasing the likelihood that Teva will be able to unilaterally exercise market power in these markets, (2) increasing the likelihood and degree of coordinated interaction between or among competitors, and (3) increasing the likelihood that customers would be forced to pay higher prices;
- b. by eliminating potential competition between Teva and IVAX in the markets for the manufacture and sale of generic tramadol/apap tablets, glipizide & metformin hydrochloride tablets, and calcitriol injectables, thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of Teva's tramadol/apap product, and IVAX's glipizide & metformin and calcitriol products, and (2) increasing the likelihood that the combined entity would delay or eliminate the significant additional price competition that would have resulted from Teva's independent entry into the market for generic tramadol/apap, and IVAX's independent entry into the markets for generic glipizide & metformin and generic calcitriol; and
- c. by eliminating potential competition between Teva and IVAX in the future market for the manufacture and sale of generic cabergoline tablets, thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of IVAX's cabergoline product, and (2)

increasing the likelihood that the combined entity would delay or eliminate the substantial additional price competition that would have resulted from IVAX's independent entry into the future market for generic cabergoline.

## VIII. VIOLATIONS CHARGED

- 28. The Merger Agreement described in Paragraph 8 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.
- 29. The Acquisition described in Paragraph 8, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twentieth day of January, 2006, issues its Complaint against said Respondents.

By the Commission.

## **DECISION AND ORDER**

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Teva Pharmaceutical Industries Limited ("Teva") of Respondent IVAX Corporation ("IVAX"), hereinafter referred to as "Respondents," and Respondents having been furnished thereafter with a copy of a draft Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and that, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets (attached to this Order as Appendix I), and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

- 1. Respondent Teva is a corporation organized, existing and doing business under and by virtue of the laws of the State of Israel, with its offices and principal place of business located at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131 Israel.
- 2. Respondent IVAX is a corporation organized, existing and doing business under and by virtue of the laws of the State of Florida, with its offices and principal place of business located at 4400 Biscayne Boulevard, Miami, Florida 33137.
- 3. The Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

## **ORDER**

I.

**IT IS ORDERED** that, as used in the Order, the following definitions shall apply:

- A. "Teva" means Teva Pharmaceutical Industries Limited, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Teva (including, but not limited to, Ivory Acquisition Sub, Inc., Ivory Acquisition Sub II, Inc., Teva Pharmaceuticals USA Inc. and Novopharm Limited), and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each. After the Acquisition, Teva shall include IVAX.
- B. "IVAX" means IVAX Corporation, its directors, officers, employees, agents, representatives,

predecessors, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by IVAX (including, but not limited to, IVAX Pharmaceuticals, Inc.), and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.

- C. Respondents" means Teva and IVAX, individually and collectively.
- D. "Acquisition" means the acquisition contemplated by the "Agreement and Plan of Merger" dated as of July 25, 2005, by and among IVAX Corporation, Teva Pharmaceutical Industries Limited, Ivory Acquisition Sub, Inc. and Ivory Acquisition Sub II, Inc.
- E. "Commission" means the Federal Trade Commission.
- F. "Agency(ies)" means any Government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term "Agency" includes, but is not limited to, the United States Food and Drug Administration ("FDA").
- G. "Application," "Investigational New Drug Application ("IND"), "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug Application" ("SNDA"), or "Marketing Authorization Application" ("MAA") means the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Respondent(s) and the FDA.

- H. "Assignment Product(s)" means a Product that is the subject of an assignment of rights under this Order, *i.e.*, the GSK Authorized Generic Products, the Genzyme Leuprolide Products, and the Genix Calcitriol Products, individually and collectively.
- I. "Barr" means Barr Laboratories, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, having its principal place of business located at Two Quaker Road, P.O. Box 2900, Pomona, New York 10970.
- J. "Cabergoline" means all Products Developed, manufactured, marketed or sold by Respondent Teva pursuant to Respondent Teva's ANDA No. 77-843 and any supplements, amendments, or revisions thereto.
- K. "Categorized Assets" means the following assets related to the specified Divestiture Product(s):
  - 1. all Product Intellectual Property related to such Divestiture Product(s);
  - perpetual, fully paid-up and royalty-free license(s) with rights to sublicense to all Product Licensed Intellectual Property to use, make, distribute, offer for sale, promote, advertise, sell, import, export, or have used, made, distributed, offered for sale, promoted, advertised, sold, imported, or exported the Divestiture Product(s) within the specified Geographic Territory;
  - 3. all Product Registrations related to such Divestiture Product(s);

- 4. all Product Manufacturing Technology related to such Divestiture Product(s);
- 5. all Product Marketing Materials related to such Divestiture Product(s);
- 6. a list of all of the NDC Numbers related to such Divestiture Product(s), and rights, to the extent permitted by Law:
  - a. to require Respondents to discontinue the use of those NDC Numbers in the sale or marketing of Products other than with respect to returns, rebates, allowances, and adjustments for Divestiture Products sold prior to the Effective Date;
  - to prohibit Respondents from seeking from any customer any type of cross- referencing of those NDC Numbers with any Retained Product(s);
  - c. to seek to change any cross-referencing by a customer of those NDC Numbers with the Retained Product(s) (including the right to receive notification from Respondents of any such cross-referencing that is discovered by Respondents);
  - d. to seek cross-referencing from a customer of those NDC Numbers with the relevant Commission-approved Acquirer's NDC Numbers related to the Divestiture Product(s);
  - e. to approve the timing of Respondents' discontinued use of those NDC Numbers in the sale or marketing of Products other than with respect to returns, rebates, allowances, and

adjustments for Divestiture Products sold prior to the Effective Date;

- f. to approve any notification(s) from the Respondents to any customer(s) regarding the use or discontinued use of such numbers by the Respondents prior to such notification(s) being disseminated to the customer(s);
- 7. all rights to all of the relevant Respondent's Applications related to such Divestiture Product(s);
- 8. Right of Reference or Use to the Drug Master Files related to the above-described Applications including, but not limited to, the pharmacology and toxicology data contained in all Application(s);
- 9. all Product Development Reports related to such Divestiture Product(s);
- 10. at the relevant Commission-approved Acquirer's option, all Product Assumed Contracts related to such Divestiture Product(s) (copies to be provided to the relevant Commission-approved Acquirer on or before the Closing Date);
- 11. all strategic safety program(s) submitted to the FDA related to such Divestiture Product(s) that is designed to decrease product risk by using one or more interventions or tools beyond the package insert;
- 12. all patient registries related to such Divestiture Product(s), and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by the FDA to facilitate

the investigation of adverse effects related to the such Divestiture Product(s);

- 13. list of all customers and/or targeted customers for such Divestiture Product(s) and the net sales (in either units or dollars) of such Divestiture Products to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of such Divestiture Products on behalf of the High Volume Account and his or her business contact information;
- 14. at the relevant Commission-approved Acquirer's option and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to such Divestiture Product(s);
- 15. copies of all unfilled customer purchase orders for the Divestiture Product(s) as of the Closing Date, to be provided to the relevant Commission-approved Acquirer not later than two (2) days after the Closing Date;
- 16. at the relevant Commission-approved Acquirer's option, subject to any rights of the customer, all unfilled customer purchase orders for the Divestiture Products; and
- 17. all of the specified Respondent's books, records, and files directly related to the foregoing or to such Divestiture Product(s);

provided, however, that "Categorized Assets" shall not include documents relating to Respondents' general business strategies or practices relating to research, development, manufacture, marketing or sales of generic pharmaceutical Products, where such documents do not discuss with particularity the Divestiture Products;

provided further, the "Categorized Assets" shall not include administrative, financial, and accounting records;

provided further, the Respondents may exclude from the "Categorized Assets" quality control records that are determined by the Interim Monitor or the Commission-approved Acquirer not to be material to the manufacture of the Divestiture Product(s);

provided further, that in cases in which documents or other materials included in the relevant assets to be divested contain information: (1) that relates both to such Divestiture Product(s) and to other Products or businesses of the specified Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to such Divestiture Product(s); or (2) for which the specified Respondent has a legal obligation to retain the original copies, the specified Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the relevant Commissionapproved Acquirer, the specified Respondent shall provide such Commission-approved Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that the Respondent(s) provides the relevant Commission-

approved Acquirer with the above-described information without requiring the Respondent(s) completely to divest itself of information that, in content, also relates to Products and businesses other than such Divestiture Product(s).

- L. "Cefaclor ER" means all Products Developed, manufactured, marketed or sold by Respondent IVAX pursuant to Respondent IVAX's ANDA No. 65-057 and any supplements, amendments, or revisions thereto.
- M. "Closing Date" means, as to each Divestiture Product and as to each Assignment Product, the date on which the Respondent(s) (or a Divestiture Trustee) consummate a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to a Commission-approved Acquirer pursuant to this Order.
- N. "Clozapine" means all Products Developed, manufactured, marketed or sold by Novopharm Limited pursuant to Novopharm Limited's ANDA No. 75-162 and any supplements, amendments, or revisions thereto.
- O. "Commission-approved Acquirer" means the following:
  (1) an entity specified by name in this Order to acquire particular assets or rights that the Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final; or
  (2) an entity approved by the Commission to acquire particular assets or rights that the Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.

- P. "Confidential Business Information" means all information owned by, or in the possession or control of, Respondents that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support or use of the Divestiture Product(s); *provided however*, that the restrictions contained in this Order regarding the use, conveyance, provision or disclosure of "Confidential Business Information" shall not apply to the following:
  - 1. information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by Respondents;
  - 2. information related to the IVAX Generic Divestiture Products (Group 1) or the IVAX Generic Divestiture Products (Group 2) that Respondent Teva can demonstrate it obtained without the assistance of Respondent IVAX prior to the Acquisition;
  - 3. information related to the Teva Generic Divestiture Products (Group 1), the Teva Generic Divestiture Products (Group 2) or the Novopharm Generic Divestiture Product that Respondent IVAX can demonstrate it obtained without the assistance of Respondent Teva prior to the Acquisition;
  - 4. information that is required by Law to be publicly disclosed;
  - 5. information that does not directly relate to the Divestiture Product(s);
  - 6. information relating to Respondents' general business strategies or practices relating to research,

development, manufacture, marketing or sales of generic pharmaceutical Products that does not discuss with particularity the Divestiture Product(s); or

- 7. information specifically excluded from the Categorized Assets.
- Q. "Contract Manufacture" means the manufacture of a Divestiture Product to be supplied by Respondent or a Designee to a Commission-approved Acquirer.
- R. "Designee" means any entity other than Respondents that will manufacture a Divestiture Product for a Commission-approved Acquirer.
- S. "Development" means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any Government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. "Develop" means to engage in Development.
- T. "Direct Cost" means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent they are directly incurred to provide the relevant assistance or service. "Direct Cost" to the Commission-approved Acquirer for its use of any of the Respondents'

employees' labor shall not exceed the average hourly wage rate for such employee.

- U. "Divestiture Product(s)" means a Product(s) the assets and business of which is the subject of a divestiture under this Order, *i.e.*, the IVAX Generic Divestiture Products (Group 1), the IVAX Generic Divestiture Products (Group 2), the Teva Generic Divestiture Products (Group1), the Teva Generic Divestiture Products (Group2) and the Novopharm Generic Divestiture Product, individually and collectively.
- V. "Divestiture Product Core Employees" means the Product Research and Development Employees and the Product Manufacturing Employees related to each Divestiture Product(s).
- W. "Divestiture Product Releasee(s)" means the Commission-approved Acquirer for the assets related to a particular Divestiture Product(s) or any entity controlled by or under common control with such Commission-approved Acquirer, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of such Commission-approved Acquirer, or of such Commission-approved Acquirer-affiliated entities.
- X. "Divestiture Trustee" means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- Y. "Drug Master Files" means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- Z. "Effective Date" means the earlier of the following dates:

- 1. the date the Respondents close on the Acquisition pursuant to the Acquisition Agreement; or
- 2. the date the merger contemplated by the Acquisition Agreement becomes effective by filing the certificate of merger with the Secretary of State of the State of Florida.
- AA. "Estazolam" means all Products Developed, manufactured, marketed or sold by Respondent IVAX pursuant to Respondent IVAX's ANDA No. 74-826 and any supplements, amendments, or revisions thereto.
- BB. "Flutamide" means all Products Developed, manufactured, marketed or sold by Respondent Teva pursuant to Respondent Teva's ANDA No. 75-298 and any supplements, amendments, or revisions thereto.
- CC. "Genix" means Genix Therapeutics, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Illinois, having its principal place of business located at 505 North Wolf Road, Wheeling, Illinois 60090.
- DD. "Genix Calcitriol Products" means the Products that are the subject of the Genix Calcitriol Products Agreement.
- EE. "Genix Calcitriol Products Agreement" means the "Distribution and Supply Agreement (Calcitriol Injectable 1mcg/ml)" by and between IVAX Pharmaceuticals, Inc. and Genix Therapeutics, Inc. dated as of October 1, 2004, and all amendments, exhibits, attachments, agreements, and schedules thereto. The Genix Calcitriol Products Agreement is attached to this Order and contained in non-public Appendix V.
- FF. "Genix Calcitriol Products Assignment Agreement" means the "Assignment and Assumption Agreement"

between Par Pharmaceutical, Inc. and IVAX Pharmaceuticals, Inc., dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto. The Genix Calcitriol Assignment Agreement is attached to this Order and contained in non-public Appendix V.

- GG. "Genzyme" means Genzyme Corporation, a corporation organized, existing, and doing business under and by virtue of the laws of the State of Massachusetts, having its principal place of business located at 500 Kendall Street, Cambridge, Massachusetts 02142.
- HH. "Genzyme Leuprolide Products" means the Products that are the subject of the Genzyme Leuprolide Products Agreement.
- II. "Genzyme Leuprolide Products Agreement" means the "Supply Agreement (Leuprolide Acetate)" between Zenith Goldline Pharmaceuticals, Inc. and Genzyme Corporation, dated as of July 13, 2000, and all amendments, exhibits, attachments, agreements, and schedules thereto. The Genzyme Leuprolide Products Agreement is attached to this Order and contained in non-public Appendix IV.
- JJ. "Genzyme Leuprolide Products Assignment Agreement" means the "Assignment and Assumption Agreement (Leuprolide Supply Agreement)" between Par Pharmaceutical, Inc. and IVAX Pharmaceuticals, Inc., dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto. The Genzyme Leuprolide Products Assignment Agreement is attached to this Order and contained in non-public Appendix IV.

- KK. "Geographic Territory" shall mean the United States of America (including all of the territories within its jurisdiction or control) unless otherwise specified.
- LL. "Glipizide & Metformin" means all Products Developed, manufactured, marketed or sold by Respondent IVAX pursuant to Respondent IVAX's ANDA No. 76-345 and any supplements, amendments, or revisions thereto.
- MM. "Government Entity" means any Federal, state, local or non-U.S. government, or any court, legislature, Government agency, or Government commission, or any judicial or regulatory authority of any government.
- NN. "GSK" means SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, a corporation organized, existing, and doing business under and by virtue of the laws of the State of Pennsylvania, having its principal place of business located at One Franklin Plaza, Philadelphia, Pennsylvania 19102.
- OO. "GSK Authorized Generic Products" means the Products that are the subject of the GSK Authorized Generic Products Agreements.
- PP. "GSK Authorized Generic Products Agreements" means the following agreements: (1) "Supply Agreement" among SmithKline Beecham Corporation, SmithKline Beecham P.L.C. and IVAX Pharmaceuticals, Inc. dated as of June 22, 2004, a/k/a., GSK IVAX Generic Augmentin ES-600 Supply Agreement, and all amendments, exhibits, attachments, agreements, and schedules thereto; and (2) "Supply Agreement" between SmithKline Beecham Corporation and IVAX Pharmaceuticals, Inc. dated as of December 2, 2003, a/k/a., GSK IVAX Amoxicillin Supply Agreement, and all amendments, exhibits, attachments, agreements, and schedules thereto. The GSK Authorized Generic

Agreements are attached to this Order and contained in non-public Appendix III.

- QQ. "GSK Authorized Generic Products Assignment Agreements" means the following agreements: (1) "Consent and Agreement" by and among Teva Pharmaceuticals USA, Inc., IVAX Pharmaceuticals, Inc., Beecham Corporation, SmithKline GlaxoSmithKline, and SmithKline Beecham P.L.C. dated as of December 14, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto; and (2) "Assignment, Assumption and Consent Agreement between Par Pharmaceuticals, Inc., IVAX Pharmaceuticals, Inc., SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, and SmithKline Beecham P.L.C. dated as of December 14, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto. The GSK Consent and Agreement is attached to this Order and contained in non-public Appendix III.
- RR. "High Volume Account(s)" means any retailer, wholesaler or distributor whose annual and/or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States from the divesting Respondent was, is, or is projected to be among the top twenty highest of such purchase amounts by Respondent's U.S. customers on any of the following dates: (1) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (2) the end of the last quarter that immediately preceded the Effective Date; (3) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or 4) the end of the last quarter following the Acquisition and/or the Closing Date.

- SS. "Interim Monitor" means any monitor appointed pursuant to Paragraph VI of this Order or Paragraph III of the related Order to Maintain Assets.
- TT. "IVAX Generic Divestiture Products (Group 1)" means the following Products, individually and collectively: Cefaclor ER, Estazolam, Nabumetone, and Propoxyphene.
- UU. "IVAX Generic Divestiture Products (Group 1) Agreement(s)" means the "Asset Purchase Agreement" between IVAX Pharmaceuticals, Inc. and Par Pharmaceutical, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, the "Supply Agreement" between IVAX Pharmaceuticals, Inc. and Par Pharmaceutical, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, and the "Supply Agreement" between Teva Pharmaceutical Industries Ltd. and Par Pharmaceutical, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto related to the IVAX Generic Divestiture Products (Group 1) that have been approved by the Commission to accomplish the requirements of this Order. The IVAX Generic Divestiture Products (Group 1) Agreements are attached to this Order and contained in non-public Appendix II.A.
- VV. "IVAX Generic Divestiture Products (Group 1) Assets" means all of Respondent IVAX's rights, title and interest in and to all assets related to Respondent IVAX's business within the Geographic Territory related to the IVAX Generic Divestiture Products (Group 1) to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the IVAX Generic Divestiture Products (Group 1), including, without limitation, the Categorized Assets

related to the IVAX Generic Divestiture Products (Group 1).

- WW. "IVAX Generic Divestiture Products (Group 2)" means the following Products, individually and collectively: Glipizide & Metformin, and Nicardipine.
- XX. "IVAX Generic Divestiture Products (Group 2) Agreement(s)" means the "Asset Purchase Agreement" between IVAX Pharmaceuticals, Inc. and Barr Laboratories, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto and the "Supply Agreement" between IVAX Pharmaceuticals Inc. and Barr Laboratories, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, and the "Supply Agreement" between Pharmaceutical Industries Ltd. and Barr Laboratories, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the IVAX Generic Divestiture Products (Group 2) that have been approved by the Commission to accomplish the requirements of this Order. The IVAX Generic Divestiture Products (Group 2) Agreements are attached to this Order and contained in non-public Appendix II.B.
- YY. "IVAX Generic Divestiture Products (Group 2) Assets" means all of Respondent IVAX's rights, title and interest in and to all assets related to Respondent IVAX's business within the Geographic Territory related to the IVAX Generic Divestiture Products (Group 2) to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the IVAX Generic Divestiture Products (Group 2), including, without limitation, the Categorized Assets

- related to the IVAX Generic Divestiture Products (Group 2).
- ZZ. "Law" means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- AAA. "Nabumetone" means all Products Developed, manufactured, marketed or sold by Respondent IVAX pursuant to Respondent IVAX's ANDA No. 76-009 and any supplements, amendments, or revisions thereto.
- BBB. "NDC Numbers" means the National Drug Code numbers(s), including both the labeler code assigned by the FDA and the additional numbers assigned by the Application holder as a product code for a specific Product.
- CCC. "Nicardipine" means all Products Developed, manufactured, marketed or sold by Respondent IVAX pursuant to Respondent IVAX's ANDA No. 74-439 and any supplements, amendments, or revisions thereto.
- DDD. "Novopharm Generic Divestiture Product" means Clozapine.
- EEE. "Novopharm Generic Divestiture Product Agreement(s)" the "Asset Purchase Agreement" between Novopharm Limited and Par Pharmaceutical, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto and the "Supply Agreement" between Novopharm Limited and Par Pharmaceutical, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Novopharm Generic Divestiture Product that have been approved by the Commission to accomplish the requirements of this Order. The Novopharm Generic Divestiture Product

Agreements are attached to this Order and contained in non-public Appendix II.A.

- FFF. "Novopharm Generic Divestiture Product Assets" means all of Respondent Teva's rights, title and interest in and to all assets related to Respondent Teva's business within the Geographic Territory related to the Novopharm Generic Divestiture Product to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Novopharm Generic Divestiture Product, including, without limitation, the Categorized Assets related to the Novopharm Generic Divestiture Product.
- GGG. "Order to Maintain Assets" means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders. The Order to Maintain Assets is attached to this Order and contained in Appendix I.
- HHH. "Par" means Par Pharmaceutical, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, having its principal place of business located at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.
- III. "Patents" means all patents, patent applications, including provisional patent applications, and statutory invention registrations, in each case existing as of the Closing Date (except where this Order specifies a different time), and includes all reissues, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any Product of or owned by

- Respondent(s) as of the Closing Date (*except* where this Order specifies a different time).
- JJJ. "Pergolide Mesylate" means all Products Developed, manufactured, marketed or sold by Respondent Teva pursuant to Respondent Teva's ANDA No. 76-061 and any supplements, amendments, or revisions thereto.
- KKK. "Person" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, joint venture, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- LLL. "Product" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient.
- MMM. "Product Assumed Contracts" means all of the following contracts or agreements (copies of each such contract to be provided to the Commission-approved Acquirer on or before the relevant Closing Date and segregated in manner that clearly identifies the purpose(s) of each such contract):
  - 1. that makes specific reference to the Divestiture Product(s) and pursuant to which any Third Party is obligated to purchase the Divestiture Product(s) from the specified Respondent unless such contract applies generally to the divesting Respondent's sales of generic Products to that Third Party;
  - pursuant to which the specified Respondent purchases the active pharmaceutical ingredient(s) or had planned to purchase the active pharmaceutical ingredient(s) from any Third Party for use in

connection with the manufacture of the Divestiture Product(s);

- 3. relating to any clinical trials involving the Divestiture Product(s);
- 4. with universities or other research institutions for the use of the Divestiture Product(s) in scientific research;
- 5. relating to the particularized marketing of the Divestiture Product(s) or educational matters relating solely to the Divestiture Product(s);
- pursuant to which a Third Party manufactures the Divestiture Product(s) on behalf of the specified Respondent;
- 7. pursuant to which a Third Party provides the Product Manufacturing Technology or related equipment to the specified Respondent;
- 8. constituting confidentiality agreements involving the Divestiture Product(s);
- 9. involving any royalty, licensing, or similar arrangement involving the Divestiture Product(s);
- 10. pursuant to which a Third Party provides any specialized services necessary to the research, Development, or manufacture of the Divestiture Products to the Respondents, including consultation arrangements; and/or
- 11. pursuant to which any Third Party collaborates with the specified Respondent in the performance of research, Development, marketing or selling of the

Divestiture Product(s) or the Divestiture Product(s) business;

provided, however, that where any such contract or agreement also relates to a Retained Product(s), Respondent(s) shall assign the Commission-approved Acquirer all such rights under the contract or agreement as are related to the Divestiture Product(s), but concurrently may retain similar rights for the purposes of the Retained Product(s).

NNN. "Product Copyrights" means rights to all original works of authorship of any kind directly related to the Divestiture Product(s) and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers; all promotional materials for patients; educational materials for the sales force; copyrights in all pre-clinical, clinical and process development data and reports relating to the research and Development of the Divestiture Product(s) or of any materials used in the research, Development, manufacture, marketing or sale of the Divestiture Product(s), including all raw data relating to clinical trials of the Divestiture Product(s), all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; customer information, promotional and marketing materials, the Divestiture Product(s) sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees who accept employment with the Commission-approved Acquirer (excluding any personnel records the transfer

of which is prohibited by applicable Law); all records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all data contained in laboratory notebooks relating to the Divestiture Product(s) or relating to its biology; all adverse experience reports and files related thereto (including source documentation) and all periodic adverse experience reports and all data contained in electronic data bases relating to adverse experience reports; all analytical and quality control data; and all correspondence with the FDA.

# OOO. "Product Development Reports" means:

- 1. Pharmacokinetic study reports related to the specified Divestiture Product(s);
- 2. Bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product(s);
- 3. Bioequivalence study (including reference listed drug information) related to the specified Divestiture Product(s);
- 4. all correspondence to the specified Respondent from the FDA and from the specified Respondent to the FDA relating to the Application(s) submitted by, on behalf of, or acquired by, the specified Respondent related to the specified Divestiture Product;
- 5. annual and periodic reports related to the above-described Application(s), including any safety update reports;

- 6. FDA approved Product labeling related to the specified Divestiture Product(s);
- 7. currently used product package inserts (including historical change of controls summaries) related to the specified Divestiture Product(s);
- 8. FDA approved patient circulars and information related to the specified Divestiture Product(s);
- 9. adverse event/serious adverse event summaries related to the specified Divestiture Product(s);
- 10. summary of Product complaints from physicians related to the specified Divestiture Product(s);
- 11. summary of Product complaints from customers related to the specified Divestiture Product(s); and
- 12. Product recall reports filed with the FDA related to the specified Divestiture Product(s).
- PPP. "Product Employee Information" means the following, for each Divestiture Product Core Employee, as and to the extent permitted by the Law:
  - 1. a complete and accurate list containing the name of each relevant employee (including former employees who were employed by Respondent(s) within ninety (90) days of the execution date of any Remedial Agreement);
  - 2. with respect to each such employee, the following information:
    - a. the date of hire and effective service date;
    - b. job title or position held;

- c. a specific description of the employee's responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, Respondent(s) may provide the employee's most recent performance appraisal;
- d. the base salary or current wages;
- e. the most recent bonus paid, aggregate annual compensation for the Respondent's last fiscal year and current target or guaranteed bonus, if any;
- f. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and
- g. any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
- 3. at the Commission-approved Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.
- QQQ. "Product Intellectual Property" means all of the following related to a Divestiture Product (other than Product Licensed Intellectual Property):
  - 1. Patents;
  - 2. Product Copyrights;

- 3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and
- 4. rights to obtain and file for patents and copyrights and registrations thereof;

provided, however, "Product Intellectual Property" does not include the names or trade dress of "Teva", "IVAX,", "Novopharm", or the names or trade dress of any other corporations, companies, or brands owned or sold by Respondents or related logos to the extent used on Respondent Teva's or Respondent IVAX's Retained Products.

- RRR. "Product Licensed Intellectual Property" means the following:
  - 1. Patents that are related to a Divestiture Product that Respondent(s) can demonstrate have been routinely used, prior to the Effective Date, by either Respondent Teva or Respondent IVAX (as applicable) for a Retained Product(s) that: 1) have been marketed or sold on an extensive basis by the relevant Respondent within the two-year period immediately preceding the Acquisition; or 2) for which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell such a Retained Product on an extensive basis by the Respondents; and
  - 2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in any jurisdiction to limit the use or disclosure thereof,

that are related to a Divestiture Product and that Respondent(s) can demonstrate have been routinely used, prior to the Effective Date, by either Respondent Teva or Respondent IVAX (as applicable) for Retained Product(s) that: 1) have been marketed or sold on a extensive basis by the relevant Respondent within the two-year period immediately preceding the Acquisition; or 2) for which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell such a Retained Product on an extensive basis by the Respondents;

provided however, that, in cases where the aggregate retail sales in dollars within the two-year period immediately preceding the Acquisition of the Retained Product(s) collectively are less than the aggregate retail sales in dollars within the same period of the Divestiture Product(s) collectively, the above-described intellectual property shall be considered, at the Commission-approved Acquirer's option, to be Product Intellectual Property and, thereby, subject to assignment to the Commission-approved Acquirer; provided further, however, that in such cases, Respondents may take a license back from the Commission-approved Acquirer for such intellectual property for use in connection with the Retained Products.

SSS. "Product Manufacturing Employees" means all salaried employees of Respondent(s) who have directly participated in the planning, design, implementation or use of the Product Manufacturing Technology of the specified Divestiture Product(s) (irrespective of the portion of working time involved unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the

eighteen (18) month period immediately prior to the Closing Date;

provided, however, the Respondents may exclude from the "Product Manufacturing Employees" those employees that are determined by the Interim Monitor or the Commission-approved Acquirer not to be material to the planning, design, implementation or use of the Product Manufacturing Technology of the specified Divestiture Product(s).

- TTT. "Product Manufacturing Technology" means all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of the Divestiture Product(s) for those instances in which the (including. manufacturing equipment is not readily available from a Third Party, at the Commission-approved Acquirer's option, all such equipment used to manufacture the Divestiture Product(s)), including, but not limited to, the following: all product specifications, processes, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and current good manufacturing practices compliance, and labeling and all other information related to the manufacturing process, and supplier lists.
- UUU. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of a Divestiture Product(s) in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (e.g., detailing reports,

vendor lists, sales data), marketing information, (e.g., competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research, customer information (including customer net purchases information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists), promotional and marketing materials, artwork for the production of packaging components, television masters and other similar materials related to the Divestiture Product(s); provided however, "Product Marketing Materials" excludes the pricing of the Divestiture Product to customers.

VVV. "Product Registrations" means all registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, or sale of the Product within the Geographic Territory, including all Applications in existence for the Product as of the Closing Date.

WWW. "Product Research and Development Employees" means all salaried employees of Respondent(s) who directly have participated in the research, Development, or regulatory approval process, or clinical studies of the specified Divestiture Product(s) (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date;

provided, however, the Respondents may exclude from the "Product Research and Development Employees" those

employees that are determined by the Interim Monitor or the Commission-approved Acquirer not to be material to the research, Development, or regulatory approval process, or clinical studies of the specified Divestiture Product(s).

- XXX. "Product Trade Dress" means the current trade dress of the Divestiture Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.
- YYY. "Product Trademark(s)" means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for the Product(s).
- ZZZ. "Proposed Acquirer" means an entity proposed by the Respondent(s) (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by Respondent(s) pursuant to this Order.
- AAAA. "Propoxyphene" means all Products Developed, manufactured, marketed or sold by Respondent IVAX pursuant to Respondent IVAX's ANDA No. 80-269 and any supplements, amendments, or revisions thereto.
- BBBB. "Remedial Agreement(s)" means the following: (1) any agreement between Respondent(s) and a Commission-approved Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or

rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final; (2) any agreement between Respondent(s) and a Third Party to effect the assignment of assets or rights of the Respondent(s) related to a Divestiture Product or an Assignment Product to the benefit of a Commission-approved Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final; (3) any agreement between the Respondent(s) and a Commission-approved Acquirer (or between a Divestiture Trustee and a Commission-approved Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of this Order; and/or (4) any agreement between Respondent(s) and a Third Party to effect the assignment of assets or rights of the Respondent(s) related to a Divestiture Product or an Assignment Product to the benefit of a Commission-approved Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

- CCCC. "Retained Product" means any Product(s) other than a Divestiture Product.
- DDDD. "Right of Reference or Use" means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an Application, including the ability to make available the underlying raw data from the investigation for FDA audit.
- EEEE. "Supply Cost" means a cost not to exceed the manufacturer's average direct per unit cost of manufacturing the Divestiture Product for the twelve (12) month period immediately preceding the Effective Date. "Supply Cost" shall expressly exclude any intracompany business transfer profit.
- FFFF. "Teva Generic Divestiture Products (Group 1)" means the following Products, individually and collectively: Clozapine, Flutamide, and Pergolide Mesylate.
- GGGG. "Teva Generic Divestiture Products (Group 1) Agreement(s)" means the "Asset Purchase Agreement" between Teva Pharmaceutical Industries Ltd. and Par Pharmaceutical, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto and the "Supply Agreement" between Teva Pharmaceutical Industries Ltd. and Par Pharmaceutical, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Teva Generic Divestiture Products (Group 1) that have been approved by the Commission to accomplish the requirements of this Order. The Teva Generic Divestiture Products (Group 1) Agreements

are attached to this Order and contained in non-public Appendix II.A.

- HHHH. "Teva Generic Divestiture Products (Group 1)
  Assets" means all of Respondent Teva's rights, title
  and interest in and to all assets related to Respondent
  Teva's business within the Geographic Territory
  related to the Teva Generic Divestiture Products
  (Group 1) to the extent legally transferable, including
  the research, Development, manufacture,
  distribution, marketing, and sale of the Teva Generic
  Divestiture Products (Group 1), including, without
  limitation, the Categorized Assets related to the Teva
  Generic Divestiture Products (Group 1).
- IIII. "Teva Generic Divestiture Products (Group 2)" means the following Products, individually and collectively: Cabergoline and Tramadol/Acetaminophen.
- JJJJ. "Teva Generic Divestiture Products (Group 2) Agreement(s)" means the "Asset Purchase Agreement" between Teva Pharmaceutical Industries Ltd. and Barr Laboratories, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, the "Supply Agreement" between Teva Pharmaceutical Industries Ltd. and Barr Laboratories, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto and "Supply Agreement" between IVAX the Pharmaceuticals Inc. and Barr Laboratories, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Teva Generic Divestiture Products (Group 2) that have been approved by the Commission to accomplish the requirements of this

Order. The Teva Generic Divestiture Products (Group 2) Agreements are attached to this Order and contained in non-public Appendix II.B.

- KKKK. "Teva Generic Divestiture Products (Group 2)
  Assets" means all of Respondent Teva's rights, title
  and interest in and to all assets related to Respondent
  Teva's business within the Geographic Territory
  related to the Teva Generic Divestiture Products
  (Group 2) to the extent legally transferable, including
  the research, Development, manufacture,
  distribution, marketing, and sale of the Teva Generic
  Divestiture Products (Group 2), including, without
  limitation, the Categorized Assets related to the Teva
  Generic Divestiture Products (Group 2).
- LLLL. "Third Party(ies)" means any private entity other than the following: (1) the Respondents; or (2) the relevant Commission-approved Acquirer for the affected assets, rights and Divestiture Product(s).
- MMMM. "Tramadol/Acetaminophen" means all Products Developed, manufactured, marketed or sold by Respondent Teva pursuant to Respondent Teva's ANDA No. 76-914 and any supplements, amendments, or revisions thereto.

II.

# IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Effective Date, Respondents shall divest the IVAX Generic Divestiture Products (Group 1) Assets, the Teva Generic Divestiture Products (Group 1) Assets, and the Novopharm Generic Divestiture Product Assets, absolutely and in good faith, to Par pursuant to and in accordance with, respectively, the IVAX Generic Divestiture Products (Group 1)

Agreements, the Teva Generic Divestiture Products (Group 1) Agreements, and the Novopharm Generic Product Asset Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Par or to reduce any obligations of the Respondents under such agreements), and each such agreement, if it becomes the Remedial Agreement related to the IVAX Generic Divestiture Products (Group 1) Assets, the Teva Generic Divestiture Products (Group 1) Assets, or the Novopharm Generic Divestiture Product Assets respectively, is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the IVAX Generic Divestiture Products (Group 1) Assets, the Teva Generic Divestiture Products (Group 1) Assets, or Novopharm Generic Divestiture Product Assets to Par prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Par is not an acceptable purchaser of the IVAX Generic Divestiture Products (Group 1) Assets, the Teva Generic Divestiture Products (Group 1) Assets, or the Novopharm Generic Divestiture Product Assets then Respondents shall immediately rescind the transaction with Par and shall divest the IVAX Generic Divestiture Products (Group 1) Assets, the Teva Generic Divestiture Products (Group 1) Assets, or the Novopharm Generic Divestiture Product Assets as is required, within one hundred eighty (180) days from the date the Order becomes final, absolutely and in good faith, at no minimum price, to a Commission-approved Acquirer(s) and only in a manner that receives the prior approval of the Commission;

provided further that if the Respondents have divested the IVAX Generic Divestiture Products (Group 1) Assets, the Teva Generic Divestiture Products (Group 1) Assets or the Novopharm

Generic Divestiture Product Assets to Par prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies the Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct the Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the IVAX Generic Divestiture Products (Group 1) Assets, the Teva Generic Divestiture Products (Group 1) Assets or the Novopharm Generic Divestiture Product Assets to Par (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

Not later than ten (10) days after the Effective Date, B. Respondents shall divest the IVAX Generic Divestiture Products (Group 2) Assets and the Teva Generic Divestiture Products (Group 2) Assets, absolutely and in good faith, to Barr pursuant to and in accordance with, respectively, the IVAX Generic Divestiture Products (Group 2) Agreements and the Teva Generic Divestiture Products (Group 2) Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Barr or to reduce any obligations of the Respondents under such agreements), and each such agreement, if it becomes the Remedial Agreement related to the IVAX Generic Divestiture Products (Group 2) Assets or the Teva Generic Divestiture Products (Group 2) Assets, respectively, is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the IVAX Generic Divestiture Products (Group 2) Assets or the Teva Generic Divestiture Products (Group 2) Assets to Barr prior to the date this Order becomes final, and if, at the time the

Commission determines to make this Order final, the Commission notifies Respondents that Barr is not an acceptable purchaser of the IVAX Generic Divestiture Products (Group 2) Assets or the Teva Generic Divestiture Products (Group 2) Assets, then Respondents shall immediately rescind the transaction with Barr and shall divest the IVAX Generic Divestiture Products (Group 2) Assets or the Teva Generic Divestiture Products (Group 2) Assets, as is required, within one hundred eighty (180) days from the date the Order becomes final, absolutely and in good faith, at no minimum price, to a Commission-approved Acquirer(s) and only in a manner that receives the prior approval of the Commission;

provided further that if the Respondents have divested the IVAX Generic Divestiture Products (Group 2) Assets or the Teva Generic Divestiture Products (Group 2) Assets to Barr prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies the Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct the Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the IVAX Generic Divestiture Products (Group 2) Assets or the Teva Generic Divestiture Products (Group 2) Assets to Barr (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- C. Any Remedial Agreement shall be deemed incorporated into this Order, and any failure by Respondents to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- D. After the Closing Date for the assets related to a specified Divestiture Product(s), Respondents shall not receive any payment or other compensation from the relevant Commission-approved Acquirer that is: (1)

based on the actual amount of sales or profits of such Divestiture Product(s) realized at any time after the Closing Date or (2) due upon the realization of any aggregate amount of sales or profits of such Divestiture Product(s), *provided however*, Respondents may receive payments from the Commission-approved Acquirer based on units of Divestiture Product(s) supplied to the relevant Commission-approved Acquirer pursuant to a Remedial Agreement to Contract Manufacture such Divestiture Product(s).

- E. Respondents shall include in each Remedial Agreement for each Divestiture Product a specific reference to this Order and the remedial purpose thereof and shall include among the provisions in those Remedial Agreement(s) the following provisions:
  - 1. upon reasonable notice and request from the Commission-approved Acquirer to the Respondents, Respondents shall Contract Manufacture and deliver to the Commission-approved Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the relevant Divestiture Products at the divesting Respondent's Supply Cost, for a period of time sufficient to allow the Commissionapproved Acquirer (or the Designee of the Commission-approved Acquirer) to obtain all of the relevant Agency approvals necessary to manufacture in commercial quantities the relevant finished drug product independently of Respondents and to secure sources of supply of the relevant active pharmaceutical ingredients, excipients, and other ingredients specified in the relevant Respondent's Application(s) for the Product from entities other than the Respondents; provided, however, that in each instance where: (1) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (2) such agreement becomes a

Remedial Agreement for a Divestiture Product, Supply Cost shall be determined as specified in such Remedial Agreement;

2. Respondents shall make representations and warranties to the Commission-approved Acquirer that the Product(s) supplied through Contract Manufacture pursuant to the Remedial Agreement meet the relevant Agency-approved specifications. For the Product(s) to be marketed or sold in the Geographic Territory, Respondents shall agree to indemnify, defend and hold the Commissionapproved Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Product(s) supplied to the Commission-approved Acquirer pursuant to the Remedial Agreement by the Respondents to meet current good manufacturing practices of the FDA, as set forth in 21 C.F.R. Parts 210 and 211. This obligation may be made contingent upon the Commission-approved Acquirer giving Respondents prompt, adequate notice of such claim and cooperating fully in the defense of such claim. The Remedial Agreement shall be consistent with the obligations assumed by Respondents under this Order; provided, however, that Respondents may reserve the right to control the defense of any such litigation, including the right to settle the litigation, so long as such settlement is consistent with the Respondents' responsibilities to supply the ingredients in the manner required by this Order; provided further that this obligation shall not require Respondents to be liable for any negligent act or omission of the Commission-approved Acquirer or for any representations and warranties, express or implied, made by the Commission-approved Acquirer that exceed the representations and

warranties made by the Respondents to the Commission-approved Acquirer; provided further that in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on Respondents' aggregate liability resulting from the failure of the Products supplied to the Commission-approved Acquirer pursuant to such Remedial Agreement by the Respondents to meet current good manufacturing practices of the FDA (as set forth in 21 C.F.R. Parts 210 and 211);

- 3. Respondents shall make representations and warranties to the Commission-approved Acquirer that Respondents shall hold harmless and indemnify the Commission-approved Acquirer for any liabilities or loss of profits resulting from the failure by Respondents to deliver the Products in a timely manner as required by the Remedial Agreement unless the Respondents can demonstrate that their failure was entirely beyond the control of the Respondents and in no part the result of negligence or willful misconduct by Respondents; provided, however, that in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on Respondents' aggregate liability for such a breach;
- 4. during the term of the Contract Manufacture between Respondent(s) and the Commission-approved Acquirer, upon request of the Commission-approved Acquirer or Interim Monitor (if applicable), Respondents shall make available to the

Commission-approved Acquirer and the Interim Monitor (if applicable) all records that relate to the manufacture of the relevant Divestiture Products that are generated or created after the Closing Date;

- 5. upon reasonable notice and request from the Commission-approved Acquirer to the Respondents, Respondents shall provide in a timely manner at no greater than Direct Cost the following:
  - assistance and advice to enable the Commissionapproved Acquirer (or the Designee of the Commission-approved Acquirer) to obtain all necessary permits and approvals from any Agency or Government Entity to manufacture and sell the relevant Divestiture Products;
  - b. assistance to the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to manufacture the relevant Divestiture Product(s) in substantially the same manner, quality, and quantity(ies) employed or achieved by either Respondent IVAX or Respondent Teva for the relevant Divestiture Product; and
  - c. consultation with knowledgeable employees of Respondents and training, at the request of the Commission-approved Acquirer and at a facility chosen by the Commission-approved Acquirer, until the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) obtains all FDA approvals necessary to manufacture in commercial quantities the relevant Divestiture Product(s) independently of the Respondents and sufficient to satisfy management of the Commission-approved Acquirer that its personnel (or the Designee's

personnel) are adequately trained in the manufacture of the relevant Divestiture Product(s);

- d. personnel, assistance and training as the Commission-approved Acquirer(s) might reasonably need to transfer the assets related to the Divestiture Products;
- 6. The foregoing provisions II.E.1-5 shall remain in effect until the relevant Commission-approved Acquirer(s) (or the Designee(s) of such Commission-approved Acquirer(s)) is fully validated, qualified, and approved by the FDA, and able to manufacture in commercial quantities each of the relevant Divestiture Products independently of Respondents;
- 7. the relevant Commission-approved Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture in commercial quantities each such Divestiture Product and to manufacture such quantities of each such Divestiture Product independently of Respondents, all as soon as reasonably practicable;
- 8. upon reasonable notice and request from the Commission-approved Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of the Respondents to assist the Commission-approved Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Product Intellectual Property related to the relevant Divestiture Product(s);
- 9. for any patent infringement suit in which a Respondent is a party prior to the Closing Date or for which a Respondent has prepared or is preparing as

of the Closing Date to be a party, and where such a suit would have the potential to interfere with the Commission-approved Acquirer's freedom to practice in the research, Development, manufacture, use, import, export, distribution or sale of the relevant Divestiture Product(s), the respective Respondent shall:

- a. cooperate with the Commission-approved Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from Respondent in connection with obtaining resolution of any pending patent litigation involving a Divestiture Product;
- b. waive conflicts of interest, if any, to allow Respondent's outside legal counsel to represent the Commission-approved Acquirer in any ongoing patent litigation involving a Divestiture Product; and
- c. permit the transfer to the Commission-approved Acquirer of all of the litigation files and any related attorney work-product in the possession of respective Respondent's outside counsel relating to such Divestiture;
- 10. Respondents shall covenant to the relevant Commission-approved Acquirer that Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the Commission-approved Acquirer under Patents that: (1) are owned or licensed by Respondents as of the Effective Date; or (2) may be assigned, granted, licensed, or otherwise conveyed to Respondents after the Effective Date, if such suit would have the potential to interfere with the Commission-approved Acquirer's freedom to

practice in the research, Development, manufacture, use, import, export, distribution or sale of the relevant Divestiture Product(s);

- 11. Respondents shall covenant to the Commissionapproved Acquirer that: (1) as a condition of any assignment, transfer or license to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue the Divestiture Product Releasees under such Patents, if the suit would have the potential to interfere with the Commissionapproved Acquirer's freedom to practice in the research, Development, manufacture, use, import, export, distribution or sale of the relevant Divestiture Product(s); and (2) with respect to any Third Party rights licensed to Respondents as of or after the Effective Date, and as to which Respondents do not control the right of prosecution of any legal action, Respondents shall not actively induce, assist or participate in any legal action or proceeding relating to the relevant Product(s) against the Divestiture Product Releasees, unless required by Law or contract (such contract not to be solicited or entered into for the purpose of circumventing any of the requirements of this Order); and
- 12. Respondents shall not seek pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement a decision the result of which would be inconsistent with the terms of this Order and/or the remedial purposes thereof.

# F. Respondents shall:

1. submit to the Commission-approved Acquirer, at Respondents' expense, all Confidential Business

Information related to the relevant Divestiture Product(s);

- 2. deliver such Confidential Business Information as follows: (1) in good faith; (2) as soon as practicable, avoiding any delays in transmission of the respective information; and (3) in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
- 3. pending complete delivery of all such Confidential Business Information to the Commission-approved Acquirer, provide the Commission-approved Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the relevant Divestiture Product(s) that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
- 4. not use, directly or indirectly, any such Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the relevant Divestiture Product(s) other than as necessary to comply with the following: (1) the requirements of this Order; (2) the Respondents' obligations to the Commission-approved Acquirer under the terms of any Remedial Agreement related to relevant Divestiture Product(s); or (3) applicable Law;
- 5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any

person except the Commission-approved Acquirer; and

- 6. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the relevant Divestiture Products to the employees associated with business related to those Retained Products that are approved by the FDA for the same or similar indications as the relevant Divestiture Products.
- G. Respondents shall not enforce any agreement against a Third Party or the Commission-approved Acquirer to the extent that such agreement may limit or otherwise impair the ability of the Commission-approved Acquirer to acquire the Product Manufacturing Technology related to the relevant Divestiture Product(s) or related equipment from the Third Party. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology.
- H. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to an agreement as described in Paragraph II.G. that allows the Third Party to provide the relevant Product Manufacturing Technology or related equipment to the Commission-approved Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to the Commission-approved Acquirer for the relevant assets.

# I. Respondents shall:

1. for a period of at least six (6) months from the relevant Closing Date, provide the relevant Commission-approved Acquirer with the opportunity

to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by such Commission-approved Acquirer. Each of these periods is hereinafter referred to as the "Divestiture Product Employee Access Period(s)"; and

2. not later than the earlier of the following dates: (1) ten (10) days after notice by staff of the Commission to the Respondents to provide the Product Employee Information; or (2) ten (10) days after the relevant Closing Date, provide the relevant Commission-approved Acquirer or the relevant Proposed Acquirer with the Product Employee Information related to the relevant Divestiture Product Core Employees. Failure by Respondents to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Employee Access Period(s) with respect to that employee in an amount equal to the delay.

# J. Respondents shall:

1. during the Divestiture Product Employee Access Period(s), not interfere with the hiring or employing by the relevant Commission-approved Acquirer of the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by such Commission-approved Acquirer, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with the relevant Commission-approved Acquirer, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondents that would affect

the ability or incentive of those individuals to be employed by the relevant Commission-approved Acquirer. In addition, Respondents shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from the relevant Commission-approved Acquirer;

provided, however, that this Paragraph II.J.1 shall not prohibit the Respondents from making offers of employment to or employing any Divestiture Product Core Employee during the Divestiture Product Employee Access Period;

2. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, and manufacture the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for such Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product(s) has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

provided, however, that nothing in this Order requires or shall be construed to require the Respondents to terminate the employment of any employee or prevents the Respondents from continuing the employment of the Divestiture Product Core Employees (other than those conditions of continued employment prescribed in this Order) in connection with the Acquisition; and

- 3. for a period of one (1) year from the relevant Closing Date, not:
  - a. directly or indirectly, solicit or otherwise attempt to induce any employee of the Commissionapproved Acquirer with any amount of responsibility related to a Divestiture Product ("Divestiture Product Employee") to terminate his or her employment relationship with the relevant Commission-approved Acquirer; or
  - b. hire any Divestiture Product Employee; provided, however, Respondents may hire any former Divestiture Product Employee whose employment has been terminated by the relevant Commission-approved Acquirer or who independently applies for employment with the Respondents, as long as such employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided, however, Respondents may do the following: (1) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (2) hire a Divestiture Product Employee who contacts Respondents on his or her own initiative without any direct or indirect solicitation or encouragement from the Respondents.

K. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit the Respondents to divest the assets required to be divested pursuant this Order to the relevant Commission-approved Acquirer(s), and/or to permit such Commission-approved Acquirer to continue

the research, Development, manufacture, sale, marketing or distribution of the Divestiture Products;

provided, however, Respondents may satisfy this requirement by certifying that the relevant Commission-approved Acquirer has executed all such agreements directly with each of the relevant Third Parties.

- L. Respondents shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each Divestiture Product Core Employee retained by Respondents, the direct supervisor(s) of any such employee, and any other employee retained by Respondents and designated by the Interim Monitor (if applicable) sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondents (other than as necessary to comply with the requirements of this Order).
- M. Not later than thirty (30) days after the Effective Date, Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to the Divestiture Products by Respondents' personnel to all of Respondents' employees who:
  - 1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of the Divestiture Products;
  - 2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that are approved by the FDA for

the same or similar indications as the relevant Divestiture Products prior to the Acquisition; and/or

3. may have Confidential Business Information related to the Divestiture Products.

Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the relevant Closing Date. Respondents shall provide a copy of such notification to the Commission-approved Acquirer. Respondents shall maintain complete records of all such agreements at Respondents' corporate headquarters and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondents shall provide the Commission-approved Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

N. Upon reasonable notice and request by the Commissionapproved Acquirer(s), Respondents shall make available to the Commission-approved Acquirer(s), at no greater than Direct Cost (or, in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, then at such cost as may be provided therein) such personnel, assistance and training the Commission-approved Acquirer(s) might reasonably need to transfer the assets related to the Divestiture Product(s) and shall continue providing such personnel, assistance and training, at the request of the Commission-approved Acquirer(s), until the relevant Commission-approved Acquirer(s) (or the Designee(s) of such Commission-approved Acquirer(s)) is fully validated, qualified, and approved by the FDA, and able

to manufacture in commercial quantities each of the relevant Divestiture Products independently of the Respondents.

- O. Pending divestiture of the assets required to be divested pursuant to this Order, Respondents shall take such actions as are necessary to maintain the full economic viability and marketability of the business associated with such assets, to minimize any risk of loss of competitive potential for such business, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of these assets except for ordinary wear and tear.
- P. Respondents shall maintain manufacturing facilities necessary to manufacture each Divestiture Product in finished form until the relevant Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) is fully validated, qualified and approved by the FDA and able to manufacture in commercial quantities the relevant Divestiture Product in finished form in a facility that is independent of Respondents;

provided, however, the Commission may eliminate, or limit the duration of, the Respondents' obligation under this provision if the Commission determines that the relevant Commission-approved Acquirer is not using commercially reasonable efforts to secure the FDA approvals necessary to manufacture in commercial quantities each such Divestiture Product in finished form in a facility that is independent of Respondents and to enable itself to manufacture such quantities of each such Divestiture Product independently of Respondents.

Q. Counsel for Respondents (including in-house counsel under appropriate confidentiality arrangements) may retain unreducted copies of all documents or other materials provided to the Commission-approved

Acquirer(s) and may have access to original documents (under circumstances where copies of documents are insufficient or otherwise unavailable) provided to the Commission-approved Acquirer(s) only in order to do the following:

- 1. comply with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- 2. defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or assets and businesses associated with those Products; provided, however, that Respondents may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement or arrangement;

provided, however, that pursuant to this Paragraph II.Q., Respondents shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Commission-approved Acquirer (but shall not be deemed to have violated this requirement if the relevant Commission-approved Acquirer withholds such agreement unreasonably); and (2) use their best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

R. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the relevant

Commission-approved Acquirer(s) or the Divestiture Product Releasee(s) for the research, Development, manufacture, use, import, export, distribution, or sale of the relevant Divestiture Product(s) under the following:

- 1. any Patents owned or licensed by Respondents as of the Effective Date that claim the use of the respective Divestiture Product;
- 2. any Patents owned or licensed at any time after the Effective Date by Respondents that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the respective Divestiture Products, other than such Patents that claim inventions conceived by and reduced to practice after the Effective Date.
- S. Respondents shall not, in the Geographic Territory: (1) use the Product Trademarks related to the Divestiture Products or any mark confusingly similar to such Product Trademarks, as a trademark, trade name, or service mark; (2) attempt to register such Product Trademarks; (3) attempt to register any mark confusingly similar to such Product Trademarks; (4) challenge or interfere with the Commission-approved Acquirer(s)'s use and registration of such Product Trademarks; or (5) challenge or interfere with the Commission-approved Acquirer(s)'s efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties; provided however, that nothing in this Order shall preclude Respondents from continuing to use those trademarks, tradenames, or service marks related to the Retained Products as of the Effective Date.
- T. The purpose of the divestiture of the IVAX Generic Divestiture Products (Group 1) Assets, the Teva Generic Divestiture Products (Group 1) Assets, the Novopharm

Divestiture Products (Group 2) Assets, and the Teva Generic Divestiture Products (Group 2) Assets, and the Teva Generic Divestiture Products (Group 2) Assets is to ensure the continued use of such assets in the same business, independent of Respondents, in which such assets were engaged at the time of the announcement of the Acquisition, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

## III.

## **IT IS FURTHER ORDERED** that:

Α. Not later than ten (10) days after the Effective Date, Respondents shall assign their rights under the GSK Authorized Generic Products Agreements, absolutely and in good faith, to Par pursuant to and in accordance with the GSK Authorized Generic Products Assignment Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Par or to reduce any obligations of the Respondents under such agreements), and such agreement, if it becomes the Remedial Agreement related to the GSK Authorized Generic Products is incorporated by reference into this Order and made a part hereof;

provided however, that if the Respondents have assigned their rights under the GSK Authorized Generic Products Agreements to Par prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies the Respondents that the manner in which the assignment was accomplished is not acceptable, the Commission may direct the Respondents, or appoint a

Divestiture Trustee, to effect such modifications to the manner of assignment of such rights to Par (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. The GSK Authorized Generic Products Assignment Agreements shall be deemed incorporated by reference into this Order and made a part hereof, and any failure by Respondents to comply with any term of the GSK Authorized Generic Products Assignment Agreements, if such agreements are approved by the Commission in connection with the Commission's determination to make this Order final shall constitute a failure to comply Any other Remedial Agreement with this Order. related to the GSK Authorized Generic Products shall also be deemed incorporated into this Order, and any failure by Respondents to comply with any term of such Remedial Agreement related to the GSK Authorized Generic Products shall constitute a failure to comply with this Order.
- C. After the Closing Date for the assignment of rights related to the GSK Authorized Generic Products, Respondents shall not receive any payment or other compensation from the Commission-approved Acquirer that is: (1) based on the actual amount of sales or profits of such Product(s) realized at any time after the Closing Date or (2) due upon the realization of any aggregate amount of sales or profits of such Product(s), provided however, Respondents may receive payments from the Commission-approved Acquirer based on units of such Product(s) supplied to the relevant Commission-approved Acquirer pursuant to a Remedial Agreement to Contract Manufacture such Product(s).
- D. The purpose of Paragraph III of this Order is to ensure the continued manufacture, marketing and sale of the

GSK Authorized Generic Products independently of Respondents and for the same purposes for which the Products were researched, Developed, manufactured, marketed and sold by IVAX and GSK at the time of the announcement of the Acquisition, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

## IV.

## IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Effective Date, Respondents shall assign their rights under the Genzyme Leuprolide Products Agreement, absolutely and in good faith, to Par pursuant to and in accordance with the Genzyme Leuprolide Products Assignment Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Par or to reduce any obligations of the Respondents under such agreement), and such agreement, if it becomes the Remedial Agreement related to the Genzyme Leuprolide Products is incorporated by reference into this Order and made a part hereof;

provided however, that if the Respondents have assigned their rights under the Genzyme Leuprolide Products Agreement to Par prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies the Respondents that the manner in which the assignment was accomplished is not acceptable, the Commission may direct the Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of assignment of such rights to Par (including, but not limited to, entering into additional agreements or arrangements) as the

Commission may determine are necessary to satisfy the requirements of this Order.

- B. The Genzyme Leuprolide Products Assignment Agreement shall be deemed incorporated by reference into this Order and made a part hereof, and any failure by Respondents to comply with any term of the Genzyme Leuprolide Products Assignment Agreement, if such agreement is approved by the Commission in connection with the Commission's determination to make this Order final shall constitute a failure to comply with this Order. Any other Remedial Agreement related to the Genzyme Leuprolide Products shall also be deemed incorporated into this Order, and any failure by Respondents to comply with any term of such Remedial Agreement related to the Genzyme Leuprolide Products shall constitute a failure to comply with this Order.
- C. After the Closing Date for the assignment of rights related to the Genzyme Leuprolide Products, Respondents shall not receive any payment or other compensation from the Commission-approved Acquirer that is: (1) based on the actual amount of sales or profits of such Product(s) realized at any time after the Closing Date or (2) due upon the realization of any aggregate amount of sales or profits of such Product(s), provided however, Respondents may receive payments from the Commission-approved Acquirer based on units of such Product(s) supplied to the relevant Commission-approved Acquirer pursuant to a Remedial Agreement to Contract Manufacture such Product(s).
- D. The purpose of Paragraph IV of this Order is to ensure the continued manufacture, marketing and sale of the Genzyme Leuprolide Products independently of Respondents and for the same purposes for which the Products were researched, Developed, manufactured,

marketed and sold by IVAX and Genzyme at the time of the announcement of the Acquisition, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

V.

### IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Effective Date, Respondents shall assign their rights under the Genix Calcitriol Products Agreement, absolutely and in good faith, to Par pursuant to and in accordance with the Genix Calcitriol Products Assignment Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Par or to reduce any obligations of the Respondents under such agreements), and such agreement, if it becomes the Remedial Agreement related to the Genix Calcitriol Products is incorporated by reference into this Order and made a part hereof;

provided however, that if the Respondents have assigned their rights under the Genix Calcitriol Products Agreement to Par prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies the Respondents that the manner in which the assignment was accomplished is not acceptable, the Commission may direct the Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of assignment of such rights to Par (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. The Genix Calcitriol Products Assignment Agreement shall be deemed incorporated by reference into this Order and made a part hereof, and any failure by Respondents to comply with any term of the Genix Calcitriol Products Assignment Agreement, if such agreement is approved by the Commission in connection with the Commission's determination to make this Order final shall constitute a failure to comply with this Order. Any other Remedial Agreement related to the Genix Calcitriol Products shall also be deemed incorporated into this Order, and any failure by Respondents to comply with any term of such Remedial Agreement related to the Genix Calcitriol Products shall constitute a failure to comply with this Order.
- C. After the Closing Date for the assignment of rights related to the Genix Calcitriol Products, Respondents shall not receive any payment or other compensation from the Commission-approved Acquirer that is: (1) based on the actual amount of sales or profits of such Product(s) realized at any time after the Closing Date or (2) due upon the realization of any aggregate amount of sales or profits of such Product(s), *provided however*, Respondents may receive payments from the Commission-approved Acquirer based on units of such Product(s) supplied to the relevant Commission-approved Acquirer pursuant to a Remedial Agreement to Contract Manufacture such Product(s).
- D. The purpose of Paragraph V of this Order is to ensure the continued manufacture, marketing and sale of the Genix Calcitriol Products independently of Respondents and for the same purposes for which the Products were researched, Developed, manufactured, marketed and sold by IVAX and Genix at the time of the announcement of the Acquisition, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

### VI.

### **IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent Teva, which consent shall not be unreasonably withheld. If Respondent Teva has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent Teva of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.
- D. If an Interim Monitor is appointed, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:

- 1. The Interim Monitor shall have the power and authority to monitor Respondents' compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.
- 2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
- 3. The Interim Monitor shall serve until the later of:
  - a. the completion by Respondents of:
    - (1) the divestiture of all Divestiture Assets in a manner that fully satisfies the requirements of this Order; and
    - (2) notification by each of the relevant Commission-approved Acquirers to the Interim Monitor that it is fully capable of manufacturing, independently of Respondents, the relevant Divestiture Product(s) in commercial quantities and in a manner consistent with current good manufacturing practices of the FDA; and
  - b. the completion by Respondents of the last obligation under the Orders pertaining to the Interim Monitor's service;

*provided, however,* that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- 4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with their obligations under the Order, including, but not limited to, their obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Order.
- 5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of the Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
- 6. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses

result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.

- 7. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by the Commission-approved Acquirer with respect to the performance of Respondents' obligations under the Order or the Remedial Agreement. Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Order.
- 8. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.

- G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- H. The Interim Monitor appointed pursuant to this Order may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

## VII.

### **IT IS FURTHER ORDERED** that:

Α. If Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey relevant assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver or otherwise convey the assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed pursuant to each of the relevant Paragraphs in a manner that satisfies the requirements of each such Paragraph. In the event that the Commission or the Attorney General brings an action pursuant to  $\S 5(l)$  of the Federal Trade Commission Act, 15 U.S.C. § 45(*l*), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey the relevant assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to  $\S 5(l)$  of the Federal Trade Commission Act,

or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent Teva, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent Teva has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent Teva of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
  - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.

- 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
- 3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall Develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
- 4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price.

The divestiture shall be made in the manner and to an acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondent from among those approved by the Commission; and, *provided further, however*, that Respondent shall select such entity within five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

- 6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
- 7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however,* that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of the Order to Maintain Assets in this matter.
- 8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
- 9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided*, *however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the

Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.

F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

### VIII.

## IT IS FURTHER ORDERED that:

- A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the date this Order becomes final, and every sixty (60) days thereafter until Respondents have fully complied with, the following:
  - 1. Paragraphs II.A, Paragraphs II.B., III.A., IV.A. and V.A. (*i.e.*, has assigned, licensed, divested, transferred, delivered or otherwise conveyed all relevant assets to the relevant Commission-approved Acquirer in a manner that fully satisfies the requirements of the Order);
  - 2. Paragraphs II.F., II.G., and II.H; and
  - 3. and all of its responsibilities to render transitional services to the relevant Commission-approved Acquirer as provided by this Order and the Remedial Agreement(s),

Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order. Respondents shall submit at the same time a copy of their report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant Paragraphs of the Order, including a full description of all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all Persons contacted, including, copies of all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning completing the obligations.

C. One (1) year after the date this Order becomes final, annually for the next nine years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which they have complied and are complying with the Order.

## IX.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed (1) dissolution of such Respondent(s), (2) acquisition, merger or consolidation of Respondent(s), or (3) any other change in the Respondent(s) that may affect compliance obligations arising out of the Order, including, but not limited to, assignment and the creation or dissolution of subsidiaries.

## X.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents made to their principal United States offices, Respondents shall permit any duly authorized representative of the Commission:

- A. access, during business office hours of Respondent(s) and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondent related to compliance with this Order; and
- B. upon five (5) days' notice to Respondent(s) and without restraint or interference from Respondent, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

## XI.

**IT IS FURTHER ORDERED** that this Order shall terminate ten (10) years from the date on which the Order becomes final.

By the Commission.

## APPENDIX I PUBLIC

## **ORDER TO MAINTAIN ASSETS**

## APPENDIX II.A. NON-PUBLIC

AGREEMENTS RELATED TO THE IVAX GENERIC DIVESTITURE PRODUCTS (GROUP 1) ASSETS

AND

THE TEVA GENERIC DIVESTITURE PRODUCTS (GROUP 1) ASSETS

AND

THE NOVOPHARM GENERIC DIVESTITURE PRODUCT ASSETS

[Redacted From the Public Record Version But Incorporated By Reference]

# APPENDIX II.B. NON-PUBLIC

AGREEMENTS RELATED TO THE IVAX GENERIC DIVESTITURE PRODUCTS (GROUP 2) ASSETS AND THE TEVA GENERIC DIVESTITURE PRODUCTS (GROUP 2) ASSETS

[Redacted From the Public Record Version But Incorporated By Reference]

## APPENDIX III NON-PUBLIC

## AGREEMENTS RELATED TO THE GSK AUTHORIZED GENERIC PRODUCTS

[Redacted From the Public Record Version But Incorporated By Reference]

## APPENDIX IV NON-PUBLIC

# AGREEMENTS RELATED TO GENZYME LEUPROLIDE PRODUCTS

[Redacted From the Public Record Version But Incorporated By Reference]

## APPENDIX V NON-PUBLIC

# AGREEMENTS RELATED TO THE GENIX CALCITRIOL PRODUCTS

[Redacted From the Public Record Version But Incorporated By Reference]

## **ORDER TO MAINTAIN ASSETS**

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Teva Pharmaceutical Industries Limited ("Teva") of Respondent IVAX Corporation ("IVAX"), hereinafter referred to as "Respondents," and Respondents having been furnished thereafter with a copy of a draft Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and that, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

1. Respondent Teva is a corporation organized, existing and doing business under and by virtue of the laws of the State of Israel, with its offices and principal place of

business located at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131 Israel.

- 2. Respondent IVAX is a corporation organized, existing and doing business under and by virtue of the laws of the State of Florida, with its offices and principal place of business located at 4400 Biscayne Boulevard, Miami, Florida 33137.
- 3. The Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

## **ORDER**

I.

IT IS ORDERED that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final, the Decision and Order), which are attached hereto as Appendix A and incorporated herein by reference and made a part hereof, shall apply:

- A. "Teva" means Teva Pharmaceutical Industries Limited, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Teva (including, but not limited to, Ivory Acquisition Sub, Inc., Ivory Acquisition Sub II, Inc., Teva Pharmaceuticals USA, Inc., and Novopharm Limited), and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each. After the Acquisition, Teva shall include IVAX.
- B. "IVAX" means IVAX Corporation, its directors, officers, employees, agents, representatives,

predecessors, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by IVAX (including, but not limited to, IVAX Pharmaceuticals, Inc.), and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.

- C. "Respondents" means Teva and IVAX, individually and collectively.
- D. "Acquisition" means the acquisition contemplated by the "Agreement and Plan of Merger" dated as of July 25, 2005, by and among IVAX Corporation, Teva Pharmaceutical Industries Limited, Ivory Acquisition Sub, Inc. and Ivory Acquisition Sub II, Inc.
- E. "Closing Date" means, as to each Divestiture Product and as to each Assignment Product, the date on which the Respondent(s) (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to a Commission-approved Acquirer pursuant to the Decision and Order.
- F. "Commission" means the Federal Trade Commission.
- G. "Commission-approved Acquirer" means the following:
  (1) an entity specified by name in the Decision and Order to acquire particular assets or rights that the Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to the Decision and Order and that has been approved by the Commission to accomplish the requirements of the Decision and Order in connection with the Commission's determination to make the Decision and Order final; or (2) an entity approved by the Commission to acquire particular assets or rights that the Respondents

are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to the Decision and Order.

- H. "Confidential Business Information" means all information owned by, or in the possession or control of, Respondents that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support or use of the Divestiture Product(s); *provided however*, that the restrictions contained in this Order to Maintain Assets regarding the use, conveyance, provision or disclosure of "Confidential Business Information" shall not apply to the following:
  - 1. information that subsequently falls within the public domain through no violation of this Order to Maintain Assets or breach of confidentiality or non-disclosure agreement with respect to such information by Respondents;
  - 2. information related to the IVAX Generic Divestiture Products (Group 1) or the IVAX Generic Divestiture Products (Group 2) that Respondent Teva can demonstrate it obtained without the assistance of Respondent IVAX prior to the Acquisition;
  - 3. information related to the Teva Generic Divestiture Products (Group 1), the Teva Generic Divestiture Products (Group 2) or the Novopharm Generic Divestiture Product that Respondent IVAX can demonstrate it obtained without the assistance of Respondent Teva prior to the Acquisition;
  - 4. information that is required by Law to be publicly disclosed;

- 5. information that does not directly relate to the Divestiture Product(s);
- 6. information relating to Respondents' general business strategies or practices relating to research, development, manufacture, marketing or sales of generic pharmaceutical Products that does not discuss with particularity the Divestiture Product(s); or
- 7. information specifically excluded from the Categorized Assets.
- I. "Divestiture Assets" means the IVAX Generic Divestiture Products (Group 1) Assets, IVAX Generic Divestiture Products (Group 2) Assets, Teva Generic Divestiture Products (Group 1) Assets, and the Teva Generic Divestiture Products (Group 2) Assets, and the Novopharm Generic Divestiture Product Assets, individually and collectively, as defined in the attached Decision and Order.
- J. Divestiture Product(s)" means a Product(s) the assets and business of which is the subject of a divestiture under the Decision and Order, *i.e.*, the IVAX Generic Divestiture Products (Group 1), IVAX Generic Divestiture Products (Group 2), Teva Generic Divestiture Products (Group 1), and the Teva Generic Divestiture Products (Group 2), and the Novopharm Generic Divestiture Product, individually and collectively.
- K. "Divestiture Product Business(es)" means the relevant Respondent's business within the Geographic Territory specified in the Decision and Order related to each of the Divestiture Products, including the research, Development, manufacture, distribution, marketing, and

sale of each Divestiture Product and the assets related to such business, including, but not limited to, the Divestiture Assets.

- L. "Divestiture Product Core Employees" means the Product Research and Development Employees and the Product Manufacturing Employees related to each Divestiture Product(s), individually and collectively.
- M. "Effective Date" means the earlier of the following dates:
  - 1. the date the Respondents close on the Acquisition pursuant to the Acquisition Agreement; or
  - 2. the date the merger contemplated by the Acquisition Agreement becomes effective by filing the certificate of merger with the Secretary of State of the State of Florida.
- N. "Interim Monitor" means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph VI of the Decision and Order.
- O. "Orders" means the Decision and Order and this Order to Maintain Assets.
- P. "Pre-Acquisition Marketing Plan" means any marketing or sales plan that was planned or implemented within the period immediately prior to the Acquisition and without consideration of the influence of the pending Acquisition for the Divestiture Product Businesses.
- Q. "Remedial Agreement" means the following: (1) any agreement between Respondent(s) and a Commission-approved Acquirer that is specifically referenced and attached to the Decision and Order, including all amendments, exhibits, attachments, agreements, and

schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Decision and Order in connection with the Commission's determination to make the Decision and Order final; (2) any agreement between Respondent(s) and a Third Party to effect the assignment of assets or rights of the Respondent(s) related to a Divestiture Product or an Assignment Product to the benefit of a Commission-approved Acquirer that is specifically referenced and attached to the Decision and Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Decision and Order in connection with the Commission's determination to make the Decision and Order final; (3) any agreement between the Respondent(s) and a Commission-approved Acquirer (or between a Divestiture Trustee and a Commissionapproved Acquirer) that has been approved by the Commission to accomplish the requirements of the Decision and Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Decision and Order; and/or (4) any agreement between Respondent(s) and a Third Party to effect the assignment of assets or rights of the Respondent(s) related to a Divestiture Product or an Assignment Product to the benefit of a Commission-approved Acquirer that has been approved by the Commission to accomplish the requirements of the Decision and Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

### II.

**IT IS FURTHER ORDERED** that from the date this Order to Maintain Assets becomes final:

- A. Respondents shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses, to minimize any risk of loss of competitive potential for the Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of the Divestiture Product Businesses except for ordinary wear and tear. Respondents shall not sell, transfer, encumber or otherwise impair the Divestiture Assets (other than in the manner prescribed in the Decision and Order) nor take any action that lessens the full economic viability, marketability or competitiveness of the Divestiture Product Businesses.
- Respondents shall maintain the operations of the B. Divestiture Product Businesses in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such businesses) and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Divestiture Product Businesses and shall use their best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors, including, but not limited to, the High Volume Accounts; customers; Agencies; employees; and others having business relations with the Divestiture Product Businesses. Respondents' responsibilities shall include, but are not limited to, the following:
  - 1. providing the Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls

with respect to such businesses and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for the Divestiture Product Businesses;

- 2. continuing, at least at their scheduled pace, any additional expenditures for the Divestiture Product Businesses authorized prior to the date the Consent Agreement was signed by Respondents including, but not limited to, all research, Development, manufacture, distribution, marketing and sales expenditures;
- 3. provide such resources as may be necessary to respond to competition against the Divestiture Products and/or to prevent any diminution in sales of the Divestiture Products during and after the Acquisition process and prior to divestiture of the related Divestiture Assets;
- 4. provide such resources as may be necessary to maintain the competitive strength and positioning of the Divestiture Products at the High Volume Accounts;
- 5. making available for use by the Divestiture Product Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such business, including the Divestiture Assets;
- 6. providing the Divestiture Product Businesses with such funds as are necessary to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses; and

- 7. providing such support services to the Divestiture Product Businesses as were being provided to these businesses by Respondents as of the date the Consent Agreement was signed by Respondents.
- C. Respondents shall maintain a work force at least as equivalent in size, training, and expertise to what has been associated with the Divestiture Products for the relevant Divestiture Product's most recent Pre-Acquisition Marketing Plan.
- D. Until the Closing Date for each respective set of Divestiture Assets, Respondents shall provide all the related Divestiture Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, and manufacture the relevant Divestiture Products consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of such Divestiture Products pending divestiture and to ensure successful execution of the Pre-Acquisition Marketing Plans related to the relevant Divestiture Products. Such incentives shall include a continuation of all employee benefits offered by Respondents until the Closing Date for the divestiture of the respective Divestiture Assets has occurred, including regularly scheduled raises, bonuses, vesting of pension benefits (as permitted by Law), and additional incentives as may be necessary to prevent any diminution of the relevant Divestiture Product's competitiveness.
- E. Respondents shall, during the Divestiture Product Employee Access Period, not interfere with the hiring or employing by the relevant Commission-approved Acquirer of Divestiture Product Core Employees, and shall remove any impediments within the control of Respondents that may deter these employees from

accepting employment with such Commission-approved Acquirer, including, but not limited to, any noncompete provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by such Commission-approved Acquirer. In addition, Respondents shall not make any counteroffer to a Divestiture Product Core Employee who receives a written offer of employment from the relevant Commission-approved Acquirer;

provided, however, that this Paragraph II.E. shall not prohibit the Respondents from making offers of employment to or employing any Divestiture Product Core Employee during the Divestiture Product Employee Access Period.

- F. Pending divestiture of the relevant Divestiture Assets, Respondents shall:
  - 1. not use, directly or indirectly, any such Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the relevant Divestiture Product(s) other than as necessary to comply with the following: (1) the requirements of the Orders; (2) the Respondents' obligations to the Commission-approved Acquirer under the terms of any Remedial Agreement related to relevant Divestiture Product(s); or (3) applicable Law;
  - 2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any person except the relevant Commission-approved Acquirer; and
  - 3. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business

Information related to the marketing or sales of the relevant Divestiture Products to the employees associated with business related to those Retained Products that are approved by the FDA for the same or similar indications as the relevant Divestiture Products.

- 4. shall institute procedures and requirements to ensure that the above-described employees:
  - a. do not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Order to Maintain Assets; and
  - b. do not solicit, access or use any Confidential Business Information that they are prohibited under this Order to Maintain Assets from receiving for any reason or purpose;
- G. Not later than thirty (30) days following the Effective Date, Respondents shall provide to all of Respondents' employees and other personnel who may have access to Confidential Business Information related to each of the respective Divestiture Products written or electronic notification of the restrictions on the use of such information by Respondents' personnel. At the same time, if not provided earlier, Respondents shall provide a copy of such notification by e-mail with return receipt requested or similar transmission, and keep an electronic file of such receipts for one (1) year after the Closing Date. Respondents shall provide a copy of the form of such notification to the Commission-approved Acquirer, the Interim Monitor(s), and the Commission. Respondents shall also obtain from each employee covered by this Paragraph II.G. an agreement to abide by the applicable restrictions. Respondents shall maintain complete records of all such agreements at Respondents'

corporate headquarters and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondents shall monitor the implementation by their employees and other personnel of all applicable restrictions, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets. Respondents shall provide the Commission-approved Acquirer with copies of all certifications, notifications and reminders sent to Respondents' employees and other personnel.

- H. Respondents shall adhere to and abide by the Remedial Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of the Orders, it being understood that nothing in the Orders shall be construed to reduce any obligations of Respondents under such agreement(s)), which are incorporated by reference into this Order to Maintain Assets and made a part hereof.
- I. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses through their respective transfer to the Commission-approved Acquirer(s), to minimize any risk of loss of competitive potential for the Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Assets except for ordinary wear and tear.

III.

IT IS FURTHER ORDERED that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint an Interim Monitor to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by the Orders and the Remedial Agreements. The Commission may appoint one or more Interim Monitors to assure Respondents' compliance with the requirements of the Orders, and the related Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent Teva, which consent shall not be unreasonably withheld. If Respondent Teva has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) Days after notice by the staff of the Commission to Respondent Teva of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) Days after the appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. If one or more Interim Monitors are appointed pursuant to this Paragraph or pursuant to the relevant provisions of the Decision and Order in this matter, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of each Interim Monitor:

- 1. The Interim Monitor shall have the power and authority to monitor Respondents' compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission;
- 2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission;
- 3. The Interim Monitor shall serve until the later of:
  - a. the completion by Respondents of:
    - (1) the divestiture of all Divestiture Assets in a manner that fully satisfies the requirements of the Orders; and
    - (2) notification by each of the relevant Commission-approved Acquirers to the Interim Monitor that it is fully capable of manufacturing, independently of Respondents, the relevant Divestiture Product(s) in commercial quantities and in a manner consistent with current good manufacturing practices of the FDA; and
  - b. the completion by Respondents of the last obligation under the Orders pertaining to the Interim Monitor's service;

provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of this Order to Maintain Assets.

- E. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with their obligations under the Orders, including, but not limited to, their obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Orders.
- F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of the Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
- G. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.

- H. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order to Maintain Assets and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by the Commission-approved Acquirer with respect to the performance of Respondents' obligations under the Orders or the Remedial Agreement. Within one (1) month from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Orders.
- I. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement;

provided, however, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.

- J. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- K. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph or the

relevant provisions of the Decision and Order in this matter.

- L. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- M. The Interim Monitor appointed pursuant to this Order to Maintain Assets or the relevant provisions of the Decision and Order in this matter may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

## IV.

IT IS FURTHER ORDERED that within thirty (30) Days after the date this Order to Maintain Assets becomes final, and every thirty (30) Days thereafter until Respondents have fully complied with their obligations to assign, grant, license, divest, transfer, deliver or otherwise convey relevant assets as required by Paragraph II.A., II.B., III.A, IV.A. and V.A. of the related Decision and Order in this matter, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order to Maintain Assets and the related Decision and Order; provided, however, that, after the Decision and Order in this matter becomes final, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondents pursuant to Paragraph VIII of the Decision and Order.

V.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) Days prior to any proposed (1) dissolution of the Respondents, (2) acquisition, merger or

consolidation of Respondents, or (3) any other change in the Respondents that may affect compliance obligations arising out of the order, including, but not limited to, assignment, the creation or dissolution of subsidiaries, or any other change in Respondents.

## VI.

- IT IS FURTHER ORDERED that, for the purposes of determining or securing compliance with this Order to Maintain Assets, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents made to their principal United States Office, Respondents shall permit any duly authorized representatives of the Commission:
  - A. Access, during office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents relating to compliance with this Order to Maintain Assets; and
  - B. Upon five (5) Days notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

## VII.

**IT IS FURTHER ORDERED** that this Order to Maintain Assets shall terminate on the earlier of:

A. Three (3) Days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or

# Order to Maintain Assets

B. The day after the divestiture of all of the Divestiture Assets, as required by and described in the Decision and Order, has been completed and each Interim Monitor, in consultation with Commission staff and the Commission-approved Acquirer(s), notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers and other transitions related to such divestitures are complete, or the Commission otherwise directs that this Order to Maintain Assets is terminated.

By the Commission.

Order to Maintain Assets

# APPENDIX A TO THE ORDER TO MAINTAIN ASSETS PUBLIC

# AGREEMENT CONTAINING CONSENT ORDER AND PROPOSED DECISION AND ORDER

# Analysis of Agreement Containing Consent Orders to Aid Public Comment

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Teva Pharmaceutical Industries Ltd. ("Teva") and IVAX Corporation ("IVAX"), which is designed to remedy the anticompetitive effects of the acquisition of IVAX by Teva. Under the terms of the proposed Consent Agreement, the companies would be required to: (1) assign the IVAX rights and assets necessary to market generic amoxicillin clavulanate potassium ("amox/clav") to Par Pharmaceutical Companies, Inc. ("Par"); (2) divest the IVAX rights and assets necessary to manufacture and market generic long-acting cefaclor ("cefaclor LA") tablets to Par; (3) divest the Teva rights and assets necessary to manufacture and market generic pergolide mesylate tablets to Par; (4) divest the IVAX rights and assets necessary to manufacture and market generic estazolam tablets to Par; (5) assign the IVAX rights and assets necessary to market generic leuprolide acetate injection kits to Par; (6) divest the IVAX rights and assets necessary to manufacture and market generic nabumetone tablets to Par; (7) assign the IVAX rights and assets necessary to market generic amoxicillin to Par; (8) divest the IVAX rights and assets necessary to manufacture and market generic propoxyphene hydrochloride capsules to Par; (9) divest the IVAX rights and assets necessary to manufacture and market generic nicardipine hydrochloride capsules to Barr Pharmaceuticals, Inc. ("Barr"); (10) divest the Teva rights and assets necessary to manufacture and market generic flutamide capsules to Par; (11) divest the Teva rights and assets necessary to manufacture and market generic clozapine tablets to Par; (12) divest the Teva assets necessary to manufacture and market generic tramadol/acetaminophen ("tramadol/apap") tablets to Barr; (13) divest the IVAX rights and assets necessary to manufacture and market generic glipizide and metformin hydrochloride tablets to Barr; (14) assign the IVAX rights and assets necessary to market generic calcitriol injectables to Par; and (15) divest the Teva rights and assets necessary to manufacture and market generic cabergoline tablets to Barr.

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order ("Order").

Pursuant to an Agreement and Plan of Merger dated July 25, 2005, Teva proposes to acquire all of the issued and outstanding shares of IVAX in a transaction valued at approximately \$7.4 billion. The Commission's Complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by lessening competition in the U.S. markets for the manufacture and sale of the following generic pharmaceutical products: (1) amox/clay; (2) cefaclor LA tablets; (3) pergolide mesylate tablets; (4) estazolam tablets; (5) leuprolide acetate injection kits; (6) nabumetone tablets; (7) amoxicillin; (8) propoxyphene hydrochloride capsules; (9) nicardipine hydrochloride capsules; (10) flutamide capsules; (11) clozapine tablets; (12) tramadol/apap tablets; (13) glipizide and metformin hydrochloride tablets; (14) calcitriol injectables; and (15) cabergoline tablets (the "Products"). The proposed Consent Agreement will remedy the alleged violations by replacing the lost competition that would result from the acquisition in each of these markets.

# The Products and Structure of the Markets

The proposed acquisition of IVAX by Teva would make Teva the world's largest generic pharmaceutical supplier. The companies overlap in a number of generic pharmaceutical markets, and if consummated, the transaction likely would lead to anticompetitive effects in fifteen of these markets.

The transaction would reduce the number of competing generic suppliers in the overlap markets. The number of generic suppliers has a direct and substantial effect on generic pricing as each additional generic supplier can have a competitive impact on the market. Because there are multiple generic equivalents for each of the products at issue here, the branded versions no longer significantly constrain the generics' pricing.

In markets for generic pharmaceuticals, a customer often can prevent a price increase either by forcing the incumbent supplier to meet the lower bid of a competitor or by switching to the competitor's product. Therefore, competitors with sufficient capacity, notwithstanding a relatively small current market share, can constrain the price for the generic product and can have a significant competitive impact.

For eleven generic products, Teva and IVAX currently are two of a small number of suppliers offering the product. In each of these markets, there are a limited number of competitors, and in several, Teva and IVAX are the only generic suppliers.

- Amox/clav is a penicillin antibiotic used to treat infections. Annual sales of generic amox/clav are approximately \$676 million. Currently, Teva, IVAX, Sandoz Inc. ("Sandoz"), and Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy") are the only suppliers of various formulations of generic amox/clav in the United States. Teva has approximately 40 percent of the market, while IVAX has 17 percent. Teva and IVAX, however, are the only suppliers of the 600 mg powder formulation of generic amox/clav. The acquisition would leave only Teva, Sandoz, and Ranbaxy in the generic amox/clav market, and increase Teva's market share in all formulations to over 50 percent.
- In the cefaclor LA tablet and pergolide mesylate tablet markets, Teva and IVAX are the only generic suppliers of these products in the United States. The acquisition would eliminate IVAX as a competitor, create a monopoly in each

of these markets, and almost certainly result in higher prices for consumers. Cefaclor LA tablets are cephalosporin antibiotics. Annual sales of generic cefaclor LA tablets are approximately \$2.4 million. Pergolide mesylate tablets are used to treat Parkinson's disease. Annual sales of generic pergolide mesylate tablets are \$19.3 million.

- Estazolam tablets are used to treat seizure disorders. Annual sales of generic estazolam tablets are approximately \$2.7 million. Teva, IVAX, and Watson Pharmaceuticals, Inc. are the only suppliers of generic estazolam tablets in the United States. Teva and IVAX have 52 percent and 13 percent of the market, respectively.
- Leuprolide acetate is an injectable drug used to treat prostate cancer. Annual sales of generic leuprolide acetate are \$6.2 million. Teva is the leading supplier in this market, accounting for 50 percent of the market. IVAX and Sandoz are the only other suppliers of this product.
- Nabumetone tablets are used to treat inflammation. In 2004, total sales of generic nabumetone tablets were \$100 million. Teva is the leading supplier of generic nabumetone tablets in the United States, accounting for over 60 percent of the market. IVAX and Sandoz are the only other suppliers of this product.
- Amoxicillin is a penicillin antibiotic used to treat infections. Teva is the leading supplier in the \$143 million market for generic amoxicillin in the United States, with a share of 55 percent. Teva, IVAX, Ranbaxy, Stada Pharmaceuticals, Inc. ("Stada"), and Sandoz are the only suppliers of various formulations of generic amoxicillin. Teva, IVAX, and Ranbaxy, however, are the only suppliers of the 200 mg and 400 mg oral suspensions, and the 875 mg tablet formulations of the drug.

- Propoxyphene hydrochloride capsules are analgesics used to relieve severe pain. Annual sales of generic propoxyphene hydrochloride capsules are approximately \$8.3 million. Currently, Teva, IVAX, Mylan Pharmaceuticals ("Mylan"), and Qualitest Pharmaceuticals, Inc. are the only suppliers in this market in the United States.
- Nicardipine hydrochloride capsules are used to treat heart conditions. In 2004, total U.S. sales of generic nicardipine hydrochloride capsules were approximately \$674,000. Teva, IVAX, Mylan, and Par are the only generic suppliers in this market.
- Flutamide capsules are used to treat cancer. In 2004, total sales for generic flutamide capsules were approximately \$11 million. Teva and IVAX are the leading suppliers in this market, with 26 percent and 36 percent of the market, respectively. Sandoz and Barr are the only other suppliers of this product in the United States.
- Clozapine tablets are used to treat psychotic and maniac disorders. IVAX, Mylan, and Caraco Pharmaceuticals Ltd. ("Caraco") are the only suppliers in the \$89.6 million U.S. market for generic clozapine tablets. Teva has FDA approval to sell this drug, and has recently begun offering it to some customers. In the absence of its pending acquisition of IVAX, Teva would have offered lower prices to attract customers and ultimately caused the market price of generic clozapine tablets to decrease. The acquisition would leave only the combined Teva/IVAX entity, Mylan, and Caraco as suppliers in this market.

In four product markets, both Teva and IVAX have generic products either on the market or in development. Furthermore, there are few firms that are capable of, and interested in, entering these markets. As a result, the proposed acquisition would eliminate important future competition in these markets.

- Tramadol/apap tablets are analgesics used to treat severe pain. Annual sales of generic tramadol/apap tablets are approximately \$38 million. Currently, Par, IVAX, and Caraco are the only suppliers in this market. Caraco only recently received FDA approval to sell this drug, and has begun offering it to customers. Teva is the only other supplier capable of entering this market in a timely manner. The acquisition would eliminate Teva's planned independent entry into the generic tramadol/apap tablet market.
- Teva and Sandoz currently are the only suppliers of generic glipizide and metformin hydrochloride tablets, blood glucose regulators used to treat type II diabetes. IVAX is one of a limited number of suppliers capable of entering this market in a timely manner. The acquisition would eliminate IVAX's entry into the generic glipizide and metformin hydrochloride tablet market.
- Calcitriol is an injectable form of vitamin D that is used in dialysis patients. Annual U.S. sales of generic calcitriol total approximately \$8.3 million. Teva and American Pharmaceutical Partners, Inc., are the only suppliers in the U.S. market for the manufacture and sale of generic calcitriol. IVAX (through a distribution agreement with Genix Therapeutics, Inc.) is the only supplier capable of entering this market in a timely manner. The acquisition would eliminate IVAX's entry into the generic calcitriol market.
- Cabergoline tablets are used to treat Parkinson's disease.
  The branded product, Dostinex, is manufactured and sold by
  Pfizer, Inc. The patent for Dostinex expired in December
  2005. Teva and IVAX are two of a limited number of
  suppliers who are capable of entering the future market for
  generic cabergoline tablets.

# **Entry**

Entry into the markets for the manufacture and sale of the Products would not be timely, likely or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. Developing and obtaining FDA approval for the manufacture and sale of the Products takes at least two (2) years due to substantial regulatory, technological, and intellectual property barriers. Furthermore, several of the markets at issue are small and declining, making it unlikely that new entry would occur even if prices were to increase by a small but significant amount.

# **Effects**

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for the manufacture and sale of generic amox/clav, cefaclor LA tablets, pergolide mesylate tablets, estazolam tablets, leuprolide acetate injection kits, nabumetone tablets, amoxicillin, propoxyphene hydrochloride capsules, nicardipine hydrochloride capsules, flutamide capsules, and clozapine tablets by eliminating actual, direct, and substantial competition between Teva and IVAX, by increasing the likelihood that Teva will be able unilaterally to exercise market power, by increasing the likelihood and degree of coordinated interaction between or among competitors, and increasing the likelihood that customers will pay higher prices. In these markets, the evidence shows that consumers have obtained lower prices due to the competitive rivalry that exists between market participants. The evidence also shows that as new rivals have entered the markets, consumers have obtained lower prices. The acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for generic tramadol/apap tablets, glipizide and metformin hydrochloride tablets, calcitriol injectables, and cabergoline tablets by eliminating future competition between Teva and IVAX.

# **The Consent Agreement**

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in the relevant product markets. Pursuant to the Consent Agreement, Teva and IVAX are required to divest rights and assets related to the relevant products to a Commission-approved acquirer no later than ten (10) days after the acquisition. Specifically, Teva is required to divest all of the rights and assets related to its pergolide mesylate tablet, flutamide capsule, and clozapine tablet products to Par, and all of the rights and assets related to its cabergoline tablet and tramadol/apap tablet products to Barr. Teva is required to divest all of the rights and assets related to IVAX's cefaclor LA tablet, estazolam tablet, nabumetone tablet, and propoxyphene hydrochloride capsule products to Par, and all of the rights and assets related to IVAX's nicardipine hydrochloride capsule and glipizide and metformin hydrochloride tablet products to Barr. Furthermore, pursuant to the Consent Agreement, Teva is required to assign the rights to IVAX's third party distribution agreements covering amoxicillin, amox/clav, leuprolide acetate injection kit, and calcitriol injectable products to Par.

The acquirers of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the acquisition. A proposed acquirer of divested assets must not itself present competitive problems.

Par, a reputable generic manufacturer, is particularly well-positioned to manufacture and market its acquired products and compete effectively in those markets. Par is the fifth largest generic pharmaceutical company in the United States, with substantial experience in manufacturing, distributing, and marketing generic pharmaceutical products. Par has approximately 187 separate products representing various dosage strengths for over 90 drugs. Moreover, Par will not present competitive problems in any of the

markets in which it will acquire a divested asset because it currently does not compete in those markets. With its resources, capabilities, good reputation, and experience marketing generic products, Par is well-positioned to replicate the competition that would be lost with the proposed acquisition.

Barr, a reputable generic manufacturer, is also particularly well-positioned to manufacture and market its acquired products and compete effectively in those markets. Barr is an established U.S. pharmaceutical company that manufactures and markets over 100 different dosage forms and strengths of over 70 different generic pharmaceutical products. Barr has extensive manufacturing, marketing, and sales expertise in U.S. generic pharmaceutical markets, and significant experience transferring assets from other pharmaceutical companies. Barr will not present competitive problems in any of the markets in which it will acquire a divested asset because it currently does not compete in those markets. With its resources, capabilities, good reputation, and experience marketing generic products, Barr should be successful in restoring the competition that would be lost if the proposed Teva/IVAX transaction were to proceed unremedied.

If the Commission determines that either Par or Barr is not an acceptable purchaser, or that the manner of the divestiture is not acceptable, the parties must unwind the sale and divest the Products within six (6) months of the date the Order becomes final to another Commission-approved acquirer. If the parties fail to divest within six (6) months, the Commission may appoint a trustee to divest the Product assets.

The proposed remedy contains several provisions to ensure that the divestitures are successful. The Order requires Teva and IVAX to provide transitional services to enable the Commission-approved acquirers to obtain all of the necessary approvals from the FDA until the acquirers are able to manufacture and sell all formulations and dosages of the Products independently. These transitional services include technology transfer assistance to manufacture the Products in substantially the same manner and quality employed or achieved

by Teva and IVAX. Furthermore, Teva and IVAX are required to supply the acquirers until they receive approval to manufacture the Products on their own

The Commission has appointed R. Owen Richards of Quantic Regulatory Services, LLC ("Quantic") to oversee the asset transfer and to ensure Teva and IVAX's compliance with all of the provisions of the proposed Consent Agreement. Mr. Richards is President of Quantic and has several years of experience in the pharmaceutical industry. He is a highly-qualified expert on FDA regulatory matters and currently advises Quantic clients on achieving satisfactory regulatory compliance and interfacing with the FDA. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Agreement requires Teva and IVAX to file reports with the Commission periodically until the divestitures and transfers are accomplished.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

Complaint

# IN THE MATTER OF

# **DSW INC.**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4157; File No. 0523096 Complaint, March 7, 2006--Decision, March 7, 2006

This consent order relates to personal information collected from consumers by respondent DSW, Inc., which sells footwear for men and women at approximately 190 stores in 32 states. DSW stored consumers' personal information on computer networks and failed to employ reasonable and appropriate security measures to protect the information, leading to some fraudulent charges on accounts that consumers had used at DSW's stores. The order requires DSW to establish and maintain a comprehensive information security program in writing that is reasonably designed to protect the security, confidentiality, and integrity of personal information it collects from or about consumers. The order also requires DSW to obtain periodic assessments and reports from a qualified, objective, independent third-party professional, certifying, among other things, that DSW has in place a security program that provides protections that meet or exceed the protections required by this order, and DSW's security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of consumers' personal information have been protected. Additional provisions relate to reporting and compliance.

# **Participants**

For the Commission: *Molly Crawford, Laura Kaufmann, Laura Mazzarella, Jessica Rich,* and *Joel Winston*.

For the Respondent: William C. MacLeod, Collier Shannon Scott PLLC; and Benita Kahn and James E. Phillips, Vorys, Sater, Seymour & Pease LLP.

# **COMPLAINT**

The Federal Trade Commission, having reason to believe that DSW Inc. ("respondent") has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

- 1. Respondent DSW Inc. is an Ohio corporation with its principal office or place of business at 4150 East 5th Avenue, Columbus, Ohio 43219.
- 2. The acts and practices of respondent as alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.
- 3. Respondent sells footwear for men and women at approximately 190 stores in 32 states. Consumers pay for their purchases with cash, credit cards, debit cards, and personal checks.
- 4. For credit card, debit card, and check purchases at its stores, respondent uses computer networks to request and obtain authorization for the purchase. To obtain card authorization, respondent collects information from consumers, including name, card number and expiration date, and certain other information. To obtain approval for payments by check, respondent collects the routing number, account number, check number, and the consumer's driver's license number and state (collectively, "personal information").
- 5. For a credit or debit card purchase, respondent typically collects the information from the magnetic stripe of the credit or debit card. The information collected from the magnetic stripe includes, among other things, a security code used to verify electronically that the card is genuine. This code is particularly sensitive because it can be used to create counterfeit credit and debit cards that appear genuine in the authorization process. For purchases using a check, respondent typically collects information from the check using Magnetic Ink Character Recognition ("MICR") technology. In each case, respondent collects the information at the cash register and wirelessly transmits the information, formatted as an authorization request, to a computer network

# Complaint

located in the store ("in-store computer network"). The authorization request is then transmitted to the appropriate bank or check processor, which sends a response back to respondent through the same networks. Until at least March 2005, respondent stored personal information used to obtain credit card, debit card, and check authorizations, including magnetic stripe data, on in-store and corporate computer networks.

- 6. Respondent operates wireless access points through which the cash registers connect to the in-store computer networks. Other wireless access points are used to transmit information about respondent's inventory from in-store scanners to the in-store computer networks.
- 7. Until at least March 2005, respondent engaged in a number of practices that, taken together, failed to provide reasonable and appropriate security for personal information collected at its stores. Among other things, respondent (1) created unnecessary risks to the information by storing it in multiple files when it no longer had a business need to keep the information; (2) did not use readily available security measures to limit access to its computer networks through wireless access points on the networks; (3) stored the information in unencrypted files that could be accessed easily by using a commonly known user ID and password; (4) did not limit sufficiently the ability of computers on one in-store network to connect to computers on other in-store and corporate networks; and (5) failed to employ sufficient measures to detect unauthorized access. As a result, a hacker could use the wireless access points on one in-store computer network to connect to, and access personal information on, the other in-store and corporate networks.
- 8. In March 2005, respondent issued a press release stating that credit card and other purchase information stored on its computer networks had been stolen. In April 2005, respondent issued another press release listing the locations

of 108 stores that were affected by the breach, and stating that checking account and driver's license numbers also had been subject to the breach. In April 2005, respondent also began sending notification letters to customers for whom it had or obtained addresses.

- 9. The breach compromised a total of approximately 1,438,281 credit and debit cards (but not the personal identification numbers associated with the debit cards), along with 96,385 checking accounts and driver's license numbers. To date, there have been fraudulent charges on some of these accounts. Further, some customers whose checking account information was compromised were advised to close their accounts, thereby losing access to those accounts, and have incurred out-of-pocket expenses such as the cost of ordering new checks. Some of these checking account customers have contacted DSW requesting reimbursement for their out-of-pocket expenses, and DSW has provided some amount of reimbursement to these customers.
- 10. As described in Paragraph 7 above, respondent's failure to employ reasonable and appropriate security measures to protect personal information and files caused or is likely to cause substantial injury to consumers that is not offset by countervailing benefits to consumers or competition and is not reasonably avoidable by consumers. This practice was and is an unfair act or practice.
- 11. The acts and practices of respondent as alleged in this complaint constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a).

THEREFORE, the Federal Trade Commission this seventh day of March, 2006, has issued this complaint against respondent.

By the Commission.

#### Decision and Order

#### **DECISION AND ORDER**

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and respondent having been furnished thereafter with a copy of a draft Complaint that the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violation of the Federal Trade Commission Act, 15 U.S.C. § 45 *et seq.*; and

Respondent, its attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order ("Consent Agreement"), an admission by respondent of all the jurisdictional facts set forth in the aforesaid draft Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe respondent has violated the said Act, and that a Complaint should issue stating its charges in that respect, and having thereupon accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days, and having duly considered the comments filed thereafter by interested persons pursuant to Section 2.34 of its Rules, now in further conformity with the procedure described in Section 2.34 of its Rules, the Commission hereby issues its Complaint, makes the following jurisdictional findings and enters the following Order:

1. Respondent DSW Inc. is an Ohio corporation with its principal office or place of business at 4150 East 5<sup>th</sup> Avenue, Columbus, Ohio 43219.

#### Decision and Order

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

# **ORDER**

# **DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- 1. "Personal information" shall mean individually identifiable information from or about an individual consumer including, but not limited to: (a) a first and last name; (b) a home or other physical address, including street name and name of city or town; (c) an email address or other online contact information, such as an instant messaging user identifier or a screen name that reveals an individual's email address; (d) a telephone number; (e) a Social Security number; (f) credit and/or debit card information, including credit and/or debit card number, expiration date, and data stored on the magnetic strip of a credit or debit card; (g) checking account information, including the ABA routing number, account number, and check number; (h) a driver's license number; or (i) any other information from or about an individual consumer that is combined with (a) through (h) above.
- 2. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- 3. Unless otherwise specified, "respondent" shall mean DSW Inc., its successors and assigns and its officers, agents, representatives, and employees.

#### Decision and Order

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, marketing, promotion, offering for sale, or sale of any product or service, in or affecting commerce, shall, no later than the date of service of this order, establish and implement, and thereafter maintain, a comprehensive information security program that is reasonably designed to protect the security, confidentiality, and integrity of personal information collected from or about consumers. Such program, the content and implementation of which must be fully documented in writing, shall contain administrative, technical, and physical safeguards appropriate to respondent's size and complexity, the nature and scope of respondent's activities, and the sensitivity of the personal information collected from or about consumers, including:

- A. the designation of an employee or employees to coordinate and be accountable for the information security program.
- B. the identification of material internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of such information, and assessment of the sufficiency of any safeguards in place to control these risks. At a minimum, this risk assessment should include consideration of risks in each area of relevant operation, including, but not limited to: (1) employee training and management; (2) information systems, including network and software design, information processing, storage, transmission, and disposal; and (3) prevention, detection, and response to attacks, intrusions, or other system failures.
- C. the design and implementation of reasonable safeguards to control the risks identified through risk assessment,

#### Decision and Order

and regular testing or monitoring of the effectiveness of the safeguards' key controls, systems, and procedures.

D. the evaluation and adjustment of respondent's information security program in light of the results of the testing and monitoring required by subparagraph C, any material changes to respondent's operations or business arrangements, or any other circumstances that respondent knows or has reason to know may have a material impact on the effectiveness of its information security program.

II.

IT IS FURTHER ORDERED that, in connection with its compliance with Paragraph I of this order, respondent shall obtain initial and biennial assessments and reports ("Assessments") from a qualified, objective, independent third-party professional, using procedures and standards generally accepted in the profession. The reporting period for the Assessments shall cover: (1) the first one hundred and eighty (180) days after service of the order for the initial Assessment, and (2) each two (2) year period thereafter for twenty (20) years after service of the order for the biennial Assessments. Each Assessment shall:

- A. set forth the specific administrative, technical, and physical safeguards that respondent has implemented and maintained during the reporting period;
- B. explain how such safeguards are appropriate to respondent's size and complexity, the nature and scope of respondent's activities, and the sensitivity of the nonpublic personal information collected from or about consumers;

#### Decision and Order

- C. explain how the safeguards that have been implemented meet or exceed the protections required by Paragraph I of this order; and
- D. certify that respondent's security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of nonpublic personal information is protected and has so operated throughout the reporting period.

Each Assessment shall be prepared and completed within sixty (60) days after the end of the reporting period to which the Assessment applies by a person qualified as a Certified Information System Security Professional (CISSP); a person qualified as a Certified Information Systems Auditor (CISA); a person holding Global Information Assurance Certification (GIAC) from the SysAdmin, Audit, Network, Security (SANS) Institute; or a similarly qualified person or organization approved by the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

Respondent shall provide the initial Assessment, as well as all: plans, reports, studies, reviews, audits, audit trails, policies, training materials, and assessments, whether prepared by or on behalf of respondent, relied upon to prepare such Assessment to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580, within ten (10) days after the Assessment has been prepared. All subsequent biennial Assessments shall be retained by respondent until the order is terminated and provided to the Associate Director of Enforcement within ten (10) days of request.

#### III.

IT IS FURTHER ORDERED that respondent shall maintain, and upon request make available to the Federal Trade Commission for inspection and copying, a print or electronic copy of each

#### Decision and Order

document relating to compliance with the terms and provision of this order, including but not limited to:

- A. for a period of five (5) years: any documents, whether prepared by or on behalf of respondent, that contradict, qualify, or call into question respondent's compliance with this order; and
- B. for a period of three (3) years after the date of preparation of each biennial Assessment required under Paragraph II of this order: all plans, reports, studies, reviews, audits, audit trails, policies, training materials, and assessments, whether prepared by or on behalf of respondent, relating to respondent's compliance with Paragraphs I and II of this order for the reporting period covered by such biennial Assessment.

# IV.

IT IS FURTHER ORDERED that, for a period of ten (10) years after the date of service of this order, respondent shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having supervisory responsibilities with respect to the subject matter of this order. Respondent shall deliver this order to such current personnel within thirty (30) days after the date of service of this order, and to such future personnel within thirty (30) days after the person assumes such position or responsibilities.

V.

IT IS FURTHER ORDERED that respondent shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary,

#### Decision and Order

parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address; *provided, however*, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

# VI.

IT IS FURTHER ORDERED that respondent shall, within one hundred eighty (180) days after service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission an initial report, in writing, setting forth in detail the manner and form in which it has complied with this order.

#### VII.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Paragraph in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. this order if such complaint is filed after the order has terminated pursuant to this Paragraph.

# Decision and Order

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Paragraph as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Analysis to Aid Public Comment

# Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted a consent agreement, subject to final approval, from DSW Inc. ("DSW").

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

As described in the Commission's proposed complaint, DSW sells footwear for men and women at approximately 190 stores in 32 states. Consumers pay for their purchases with cash, credit cards, debit cards, and personal checks. In the course of seeking approval for credit and debit card purchases, DSW collects consumers' personal information, including name, card number and expiration date, and other information, from magnetic stripes on the cards. The information collected from the magnetic stripe is particularly sensitive because it contains a security code which can be used to create counterfeit cards that appear genuine in the authorization process. In the course of seeking approval for personal check purchases, DSW also collects consumers' personal information, including routing number, account number, check number, and the consumer's driver's license number and state, from the check using Magnetic Ink Character Recognition ("MICR") technology.

The Commission's proposed complaint alleges that DSW stored consumers' personal information on computers on networks located at both the store and corporate levels and failed to employ reasonable and appropriate security measures to protect the information. The complaint alleges that this failure was an unfair practice because it caused or was likely to cause substantial consumer injury that was not reasonably avoidable and was not outweighed by countervailing benefits to consumers or competition.

In particular, the complaint alleges that until at least March 2005, DSW engaged in a number of practices which, taken together, failed to provide reasonable security for sensitive personal information, including: (1) creating unnecessary risks to personal information collected at its stores by storing it in multiple files when it no longer had a business need to keep the information; (2) failing to use readily available security measures to limit access to its computer networks through wireless access points on the networks; (3) storing the information in unencrypted files that could be accessed easily by using a commonly known user ID and password; (4) failing to sufficiently limit the ability of computers on one in-store computer network to connect to computers on other in-store and corporate networks; and (5) failing to employ sufficient measures to detect unauthorized access. The complaint further alleges that there have been fraudulent charges on accounts that consumers had used at DSW's stores. Additionally, some consumers whose checking account information was compromised were advised to close their accounts, thereby losing access to those accounts, and incurred outof-pocket expenses such as the cost of ordering new checks.

The proposed order applies to personal information from or about consumers that DSW collects in connection with its business. It contains provisions designed to prevent DSW from engaging in the future in practices similar to those alleged in the complaint.

Specifically, Part I of the proposed order requires DSW to establish and maintain a comprehensive information security program in writing that is reasonably designed to protect the security, confidentiality, and integrity of personal information it collects from or about consumers. The security program must contain administrative, technical, and physical safeguards appropriate to DSW's size and complexity, the nature and scope of its activities, and the sensitivity of the personal information collected. Specifically, the order requires DSW to:

• Designate an employee or employees to coordinate and be accountable for the information security program.

#### Analysis to Aid Public Comment

- Identify material internal and external risks to the security, confidentiality, and integrity of consumer information that could result in unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of such information, and assess the sufficiency of any safeguards in place to control these risks.
- Design and implement reasonable safeguards to control the risks identified through risk assessment, and regularly test or monitor the effectiveness of the safeguards' key controls, systems, and procedures.
- Evaluate and adjust its information security program in light of the results of testing and monitoring, any material changes to its operation or business arrangements, or any other circumstances that DSW knows or has reason to know may have a material impact on the effectiveness of its information security program.

Part II of the proposed order requires that DSW obtain within 180 days, and on a biennial basis thereafter, an assessment and report from a qualified, objective, independent third-party professional, certifying, among other things, that: (1) DSW has in place a security program that provides protections that meet or exceed the protections required by Part I of the proposed order, and (2) DSW's security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of consumers' personal information has been protected. This provision is substantially similar to comparable provisions obtained in prior Commission orders under Section 5 of the FTC Act. *See*, *e.g.*, *BJ's Wholesale Club*, *Inc.*, FTC Docket No. C-4148 (Sept. 20, 2005).

Parts III through VII of the proposed order are reporting and compliance provisions. Part III requires DSW to retain documents relating to compliance. For the assessments and supporting documents, DSW must retain the documents for three (3) years after

the date that each assessment is prepared. Part IV requires dissemination of the order now and for the next ten (10) years to persons with supervisory responsibilities. Part V ensures notification to the FTC of changes in corporate status. Part VI mandates that DSW submit compliance reports to the FTC. Part VII is a provision "sunsetting" the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed order or to modify its terms in any way.

# IN THE MATTER OF

# HEALTH CARE ALLIANCE OF LAREDO, L.C.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4158; File No. 0410097 Complaint, March 23, 2006-Decision, March 23, 2006

This consent order addresses actions of Health Care Alliance of Laredo, L.C., in orchestrating and implementing agreements among its physician members to fix prices and other terms on which they would deal with health plans, and to refuse to deal with such purchasers except on collectively determined terms. Health Care Alliance forced numerous health plans to raise the fees paid to its physician members, and thereby raised the cost of medical care in the Laredo, Texas, area. The order requires the respondent to cease and desist from entering into or facilitating any agreement between or among any physicians (1) to negotiate on behalf of any physician with any payor; (2) to deal, refuse to deal, or threaten to refuse to deal with any payor; (3) regarding any term, condition, or requirement upon which any physician deals, or is willing to deal, with any payor, or (4) not to deal individually with any payor, or not to deal with any payor through any arrangement other than Health Care Alliance. The order requires the respondent, for three years, to notify the Commission before entering into any arrangement to act as a messenger, or as an agent on behalf of any physicians, with payors regarding contracts. The respondent is not precluded from engaging in conduct that is reasonably necessary to form or participate in legitimate joint contracting arrangements among competing physicians. The order also requires the respondent to distribute the complaint and order to all physicians who have participated in Health Care Alliance, and to payors that negotiated contracts with it or indicated an interest in doing so. In addition, the respondent is required, at any payor's request and without penalty, to terminate its current contracts with respect to providing physician services.

# **Participants**

For the Commission: John DeGeeter, Daniel P. Ducore, Tom Iosso, David R. Pender, Connie Salemi, Anne Schenof, and Louis Silvia.

For the Respondent: Gary Hall, Esq.

# **COMPLAINT**

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C.§ 41 *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that Health Care Alliance of Laredo, L.C. ("HAL"), hereinafter sometimes referred to as "Respondent," has violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges in that respect as follows:

# NATURE OF THE CASE

1. This matter concerns agreements among competing physicians, acting through the Respondent, to fix the prices they charge to health plans and other third-party payors ("payors"), and to refuse to deal with payors except on collectively agreed upon terms. The Respondent had no legitimate justification for these agreements, which increased consumer health care costs in the Laredo, Texas, area.

# RESPONDENT

- 2. HAL, an independent practice association ("IPA"), is a forprofit limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its principal address at 230 Calle Del Norte, Laredo, Texas 78041.
- 3. HAL contracts with payors on behalf of its member physicians and establishes uniform prices and other contract terms applicable to its members.
- 4. HAL members include approximately 80 physicians licensed to practice allopathic or osteopathic medicine in Texas.

5. HAL's nine-member Board of Managers consists of physicians who are elected by the HAL members to represent the members' interests in HAL's affairs.

# **JURISDICTION**

- 6. At all times relevant to this Complaint, HAL has been engaged in the business of contracting with payors, on behalf of HAL's physician members, for the provision of physician services.
- 7. Except to the extent that competition has been restrained as alleged herein, a substantial majority of HAL physician members have been, and are now, in competition with each other for the provision of physician services in the Laredo, Texas, area.
- 8. HAL, a for-profit entity, is a corporation within the meaning of Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.
- 9. The general business practices of HAL, and of its physician members, including the acts and practices herein alleged, are in or affect "commerce" as defined in the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

# OVERVIEW OF PHYSICIAN CONTRACTING WITH PAYORS

- 10. Physicians contract with payors to establish the terms and conditions, including price terms, under which they render physician services to the subscribers ("insureds") to the payors' health plans. Physicians entering into such contracts often agree to lower compensation to obtain access to additional patients made available by the payors' relationship with insureds. These contracts may reduce payors' costs and enable them to lower the price of insurance, and thereby result in lower medical care costs for insureds.
  - 11. Absent agreements among them, otherwise competing

physicians unilaterally decide whether to enter into payor contracts to provide services to insureds, and what prices they will accept pursuant to such contracts.

12. The Medicare Resource Based Relative Value Scale ("RBRVS") is a system used by the Centers for Medicare and Medicaid Services to determine the amount to pay physicians for the services they render to Medicare patients. Generally, payors in Texas make contract offers to individual physicians or groups at price levels specified by some percentage of the RBRVS fee for a particular year (e.g., "110% of 2004 RBRVS").

# ANTICOMPETITIVE CONDUCT

- 13. HAL, acting as a combination of its physician members, and in conspiracy with its members, has acted to restrain competition by, among other things, facilitating, entering into, and implementing agreements, express or implied, to fix the prices and other terms at which they would contract with payors; to engage in collective negotiations over terms and conditions of dealing with payors; and to have HAL members refrain from negotiating individually with payors or contracting on terms other than those approved by HAL.
- 14. HAL refers to its contracting system as a "messenger model." Competing physicians sometimes use a "messenger" to facilitate their contracting with payors, in ways that do not constitute an unlawful agreement on prices and other competitively significant terms. Messenger arrangements can reduce contracting costs between payors and physicians. A messenger can be an efficient conduit to which a payor submits a contract offer, with the understanding that the messenger will transmit that offer to a group of physicians and inform the payor how many physicians across specialties accept the offer or have a counteroffer. A messenger may not negotiate prices or other competitively significant terms, however, and may not facilitate coordination among physicians on their responses to contract offers.

- 15. Although purporting to employ a messenger model, from 1998 to 2005, HAL attempted to and did negotiate higher reimbursement rates for its member physicians, sent payor offers to members only after HAL negotiated and approved the rates, and urged its members not to deal individually with payors.
- 16. HAL's Board of Managers authorized and directed each step of the contracting process with payors. The Board initiated negotiations with payors by directing HAL personnel to contact a payor or by authorizing HAL personnel to respond to a payor inquiry. The Board required HAL personnel to report to the Board on the progress of negotiations and to seek authorization from the Board before making counterproposals. Ultimately, the Board either accepted or rejected contracts which HAL personnel presented to it. If the Board accepted the contract, HAL would then, and only then, "messenger" the contract to HAL's members for their individual acceptance or rejection. HAL did not messenger any rates proposed by the payors during negotiations, and messengered only the rates that the Board approved.
- 17. HAL members were fully aware of the payor negotiations HAL was conducting on their behalf. HAL's staff provided updates on the status of contract negotiations to members via telephone, monthly newsletters, and monthly meetings, at which contracts were frequently an important agenda item.
- 18. HAL members often had direct input in payor negotiations, aside from their representation on the Board. For example, in 1999, HAL's Executive Director sent out a survey to members asking them for "the 20 most common codes used in the office and the maximum discount that you are willing to accept." The Executive Director explained that "[t]his will help me when I negotiate contracts on behalf of the organization, since I would present these codes as those for which I will seek the advantageous rates." He also surveyed Board members and spoke to individual members in order to obtain information on fees for their respective specialties, which he used in negotiations with payors. Further, Board members were generally representative of the physician specialties within

HAL, and Board members discussed the rate proposals with other members in their specialty when the rates affected their specialty.

# NEGOTIATIONS WITH UNITED HEALTHCARE OF TEXAS, INC. ("UNITED")

- 19. In the summer of 2003, United was attempting to form a physician network in the Laredo area by contracting individually with area physicians, including HAL's physicians. When HAL learned of this, it informed United that HAL represented a number of Laredo physicians and that any rates would have to be first approved by HAL's Board. Despite being warned by United of the antitrust ramifications of such joint negotiations, HAL negotiated the rates with United's local representative and sent United's offer to HAL members, many of whom accepted it, only after HAL's Board approved United's offer.
- 20. HAL's President later sent a memo to members urging them not to sign individual contracts with Aetna, noting that members should let HAL work on Aetna "similar to what we did with UNITED HEALTHCARE where they were offering . . . individual contracts, but we worked out [a] group contract" at rates that were 30% higher than United's individual contract offers.

# NEGOTIATIONS WITH AETNA HEALTH, INC. ("AETNA")

21. In July of 2003, Aetna began soliciting physicians to join a network it was attempting to establish in Laredo. After learning of this, HAL contacted Aetna and informed Aetna that HAL would negotiate and contract for the HAL physicians. At the same time, HAL began to urge its members not to deal individually with Aetna. HAL's then-President sent a memo addressed to "All HAL Members" and captioned with "UPDATE - PLEASE READ" and "IMPORTANT":

Regarding AETNA we know many are receiving

individual contracts. We have contacted AETNA and will try to negotiate a group contract for the benefit of all of us.

PLEASE DO NOT sign individual contract[s] with very low reimbursement rates. Let us work on this similar to what we did with UNITED HEALTHCARE where they were offering . . . individual contracts, but we worked out [a] group contract [at rates that were 30% higher than United's individual contract offers].

- 22. Aetna warned HAL that its conduct potentially violated the antitrust laws, noting that "you may also be aware that the Federal Trade Commission has been interested in cases involving price fixing by physicians."
- 23. Nonetheless, HAL proceeded to negotiate a contract with Aetna. Aetna initially provided HAL with its standard market fee schedule, known as the Aetna Market Fee Schedule ("AMFS"). HAL rejected Aetna's offer because the rates in the AMFS were "no where close" to HAL's demanded RBRVS rate.
- 24. Aetna ultimately succumbed and offered the RBRVS-based rate demanded by HAL, which was, depending on the particular billing code, between 20% and 90% higher than Aetna's initial offer. HAL then, for the first time, sent out Aetna's offer to its members, many of whom accepted the group-negotiated rates.

# **BOYCOTT OF PACIFICARE OF TEXAS ("PACIFICARE")**

25. HAL sought to negotiate with PacifiCare in 2003, and boycotted PacifiCare after PacifiCare declined to do so. In the spring of 2003, PacifiCare was attempting to form its own network of providers by offering contracts to individual physicians in Laredo. Up until that time, PacifiCare was renting the provider network of Private Healthcare Systems, Inc. ("PHCS"), a third-party administrator, to service its customers. PHCS, in turn, had a contract with HAL, which set the prices HAL members received for seeing

PacifiCare patients.

- 26. PacifiCare's individual contracting efforts were a significant threat to HAL physicians, because HAL's rates through PHCS were significantly higher than PacifiCare's individual contract rate.
- 27. In May 2003, HAL's Board authorized HAL personnel to negotiate a group contract with PacifiCare. After PacifiCare refused to negotiate with HAL, HAL urged its physician members not to sign up with PacifiCare. HAL reminded them that they already had access to PacifiCare patients through PHCS, and that they would continue to have access to PacifiCare patients, even if they did not sign the lower-paying PacifiCare contracts. When PacifiCare contacted individual HAL members to offer them contracts, PacifiCare was repeatedly told by HAL members that HAL had instructed them not to contract with PacifiCare, that HAL told them it was attempting to negotiate a group contract with PacifiCare, and that PacifiCare would have to deal with HAL. A year after starting efforts to obtain contracts with individual physicians, PacifiCare had signed individual contracts with only ten HAL members, though PacifiCare's individual contract rates were sufficient to gain acceptance by many non-HAL members in Laredo.

# **CONTRACTING WITH OTHER PAYORS**

28. HAL, on behalf of its physician members, has also orchestrated collective negotiations with other payors who do business, or have attempted to do business, in the Laredo, Texas, area, including Preferred Health Arrangement, Inc.; TML Intergovernmental Employee Benefits Pool; Humana; HealthSmart Preferred Care, Inc.; Advantage Care Network, Inc.; COASTALCOMP HEALTHNETWORKS®; MultiPlan, Inc.; National Healthcare Alliance, Inc.; Texas True Choice, Inc.; Texas Employers Associated Medical Services, Inc.; and Private Healthcare Systems, Inc. HAL negotiated with these payors on price, making proposals and counter-proposals, as well as accepting or rejecting offers, without transmitting the payors' offers to HAL

members until HAL's Board of Managers approved the negotiated prices.

29. These coercive tactics were successful in raising the prices paid to HAL's physician members.

## RESPONDENT'S PRICE-FIXING IS NOT JUSTIFIED

30. The physician members of HAL have not integrated their practices in any economically significant way, nor have they created efficiencies sufficient to justify their acts or practices described in the foregoing paragraphs 13 through 29.

# RESPONDENT'S ACTIONS HAVE HAD SUBSTANTIAL ANTICOMPETITIVE EFFECTS

- 31. Respondent's actions described in Paragraphs 13 through 29 of this Complaint have had, or tend to have had, the effect of restraining trade unreasonably and hindering competition in the provision of physician services in the Laredo area in the following ways, among others:
  - a. price and other forms of competition among physician members of HAL were unreasonably restrained;
  - b. prices for physician services were increased; and
  - c. health plans, employers, and individual consumers were deprived of the benefits of competition among physicians.

# VIOLATION OF THE FEDERAL TRADE COMMISSION ACT

32. The combination, conspiracy, acts, and practices described above constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. Such combination, conspiracy, acts, and practices, or the effects

thereof, are continuing and will continue or recur in the absence of the relief herein requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirtieth day of March 2006, issues its Complaint against Respondent HAL.

By the Commission.

#### **DECISION AND ORDER**

The Federal Trade Commission ("Commission"), having initiated an investigation of certain acts and practices of the Health Care Alliance of Laredo, L.C. ("HAL"), hereinafter sometimes referred to as "Respondent," and HAL having been furnished with a copy of the draft Complaint that Counsel for the Commission proposed to present to the Commission for its consideration and which, if issued, would charge Respondent with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order to Cease and Desist ("Consent Agreement"), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered this matter and having determined that it had reason to believe that Respondent has violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues the following Order:

1. Respondent HAL is a for-profit limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its

principal address located at 230 Calle Del Norte, Laredo, Texas 78041.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

## **ORDER**

I.

**IT IS ORDERED** that, as used in this Order, the following definitions shall apply:

- A. "Respondent HAL" means Health Care Alliance of Laredo, L.C., its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- B. "Hospital" means a health care facility licensed by any state as a hospital.
- C. "Medical Group Practice" means a bona fide, integrated firm in which physicians practice together as partners, shareholders, owners, or employees, or in which only one physician practices.
- D. "Participate" in an entity means (1) to be a partner, shareholder, owner, member, or employee of such entity, or (2) to provide services, agree to provide services, or offer to provide services, to a payor through such entity. This definition applies to all tenses and forms of the word "participate," including, but not limited to, "participating," "participated," and "participation."

- E. "Payor" means any person that pays, or arranges for payment, for all or any part of any physician services for itself or for any other person. Payor includes any person that develops, leases, or sells access to networks of physicians.
- F. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- G. "Physician" means a doctor of allopathic medicine ("M.D.") or a doctor of osteopathic medicine ("D.O.").
- H. "Preexisting contract" means a contract for the provision of physician services that was in effect on the date of the receipt by a payor that is a party to such contract of notice sent by Respondent HAL, pursuant to Paragraph V.A.3 of this Order, of such payor's right to terminate such contract.
- I. "Principal address" means either (1) primary business address, if there is a business address, or (2) primary residential address, if there is no business address.
- J. "Qualified clinically-integrated joint arrangement" means an arrangement to provide physician services in which:
  - 1. all physicians that participate in the arrangement participate in active and ongoing programs of the arrangement to evaluate and modify the practice patterns of, and create a high degree of interdependence and cooperation among, the physicians that participate in the arrangement, in order to control costs and ensure the quality of services provided through the arrangement; and

- 2. any agreement concerning price or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the arrangement.
- K. "Qualified risk-sharing joint arrangement" means an arrangement to provide physician services in which:
  - 1. all physicians that participate in the arrangement share substantial financial risk through their participation in the arrangement and thereby create incentives for the physicians that participate jointly to control costs and improve quality by managing the provision of physician services, such as risk-sharing involving:
    - a. the provision of physician services to payors at a capitated rate,
    - b. the provision of physician services for a predetermined percentage of premium or revenue from payors,
    - c. the use of significant financial incentives (*e.g.*, substantial withholds) for physicians that participate to achieve, as a group, specified cost-containment goals, or
    - d. the provision of a complex or extended course of treatment that requires the substantial coordination of care by physicians in different specialties offering a complementary mix of services, for a fixed, predetermined price, where the costs of that course of treatment for any individual patient can vary greatly due to the individual patient's condition, the choice,

complexity, or length of treatment, or other factors; and

2. any agreement concerning price or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the arrangement.

II.

IT IS FURTHER ORDERED that Respondent HAL, directly or indirectly, or through any corporate or other device, in connection with the provision of physician services in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any physicians:
  - 1. to negotiate on behalf of any physician with any payor;
  - 2. to deal, refuse to deal, or threaten to refuse to deal with any payor;
  - 3. regarding any term, condition, or requirement upon which any physician deals, or is willing to deal, with any payor, including, but not limited to, price terms; or
  - 4. not to deal individually with any payor, or not to deal with any payor through any arrangement other than Respondent HAL;
- B. Exchanging or facilitating in any manner the exchange or transfer of information between or among physicians

concerning any physician's willingness to deal with a payor, or the terms or conditions, including any price terms, on which the physician is willing to deal with a payor;

- C. Attempting to engage in any action prohibited by Paragraphs II.A or II.B above; and
- D. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A through II.C above.

Provided, however, that, subject to the requirements of Paragraph IV of this Order, nothing in this Paragraph II shall prohibit any agreement involving, or any conduct that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or a qualified clinically-integrated joint arrangement that does not restrict the ability, or facilitate the refusal, of physicians who participate in it to deal with payors on an individual basis or through any other arrangement, or that solely involves physicians in the same medical group practice.

## III.

IT IS FURTHER ORDERED that, for three (3) years after the date this Order becomes final, Respondent HAL shall notify the Secretary of the Commission in writing ("Paragraph III Notification") at least sixty (60) days prior to entering into any arrangement with any physicians or any medical group practices under which Respondent HAL would act as a messenger, or as an agent on behalf of those physicians or those medical group practices, with payors regarding contracts. The Paragraph III Notification shall include the identity of each proposed physician participant; the proposed geographic area in which the proposed arrangement will operate; a copy of any proposed physician participation agreement;

a description of the proposed arrangement's purpose and function; a description of any resulting efficiencies expected to be obtained through the arrangement; and a description of procedures to be implemented to limit possible anticompetitive effects, such as those prohibited by this Order. If, within fifteen (15) days from the Commission's receipt of the Paragraph III Notification, a representative of the Commission makes a written request for additional information to Respondent HAL, then Respondent HAL shall not engage in any conduct described in Paragraph III of this Order prior to the expiration of sixty (60) days after substantially complying with such request for additional information.

*Provided, however*, that written confirmation reducing the applicable waiting period may be granted, upon request to the Bureau of Competition. The expiration of any waiting period described herein without a request for additional information or without the initiation of an enforcement proceeding shall not be construed as a determination by the Commission, or its staff, that a violation of the law, or of this Order, may not have occurred.

Provided further that Paragraph III Notification is not required for Respondent HAL to inform any physicians that a payor has exercised its right, pursuant to the first proviso of Paragraph V.D of the Order, to extend the term of its contract, nor is Paragraph III Notification required for Respondent HAL's subsequent acts as a messenger pursuant to an arrangement for which this Paragraph III Notification has been given.

Receipt by the Commission of any Paragraph III Notification is not to be construed as a determination by the Commission that any action described in such Paragraph III Notification does or does not violate this Order or any law enforced by the Commission.

## IV.

**IT IS FURTHER ORDERED** that, for three (3) years from the date this Order becomes final, pursuant to each qualified clinically-integrated joint arrangement or qualified risk-sharing joint

arrangement ("Arrangement") in which Respondent HAL is a participant, Respondent HAL shall notify the Secretary of the Commission in writing ("Paragraph IV Notification") at least sixty (60) days prior to:

- A. Participating in, organizing, or facilitating any discussion or understanding with or among any physicians or medical group practices in such Arrangement relating to price or other terms or conditions of dealing with any payor; or
- B. Contacting a payor, pursuant to an Arrangement, to negotiate or enter into any agreement relating to price or other terms or conditions of dealing with any payor, on behalf of any physician in such Arrangement.

*Provided, however*, that Paragraph IV Notification shall not be required for an Arrangement whenever such Notification has been previously given for that Arrangement.

# Provided further:

- 1. that with respect to any Paragraph IV Notification, Respondent HAL shall include the following information:
  - a. the identity of each physician participant, the medical or other physician specialty, group practice, if applicable, and the name of each hospital where the physician has privileges;
  - b. a description of the Arrangement and its purpose, function, and geographic area of operation;
  - c. a description of the nature and extent of the integration and the efficiencies resulting from the Arrangement;

- d. an explanation of how any agreement on prices, or on contract terms related to price, furthers the integration and achievement of the efficiencies resulting from the Arrangement;
- e. a description of any procedures proposed to be implemented to limit possible anticompetitive effects resulting from the Arrangement or its activities; and
- f. all studies, analyses, and reports that were prepared for the purpose of evaluating or analyzing competition for physician services in the Laredo, Texas area, including, but not limited to, the market share of physician services in such market; and
- 2. if, within sixty (60) days from the Commission's receipt of the Paragraph IV Notification, a representative of the Commission makes a written request for additional information to Respondent HAL, then Respondent HAL shall not engage in any conduct described in Paragraph IV.A or Paragraph IV.B of this Order prior to the expiration of thirty (30) days after substantially complying with such request for additional information, or such shorter waiting period as may be granted in writing from the Bureau of Competition. The expiration of any waiting period described herein without a request for additional information or without the initiation of an enforcement proceeding shall not be construed as a determination by the Commission, or its staff, that a violation of the law, or of this Order, may not have occurred. Further, receipt by the Commission from Respondent HAL of any Paragraph IV Notification is not to be construed as a determination by the Commission that any such Arrangement does or does

not violate this Order or any law enforced by the Commission.

V.

# **IT IS FURTHER ORDERED** that Respondent HAL shall:

- A. Within thirty (30) days after the date on which this Order becomes final, send a copy of this Order and the Complaint by:
  - first-class mail, with return receipt requested or delivery confirmation, or electronic mail, with return confirmation, to each physician that participates in Respondent HAL;
  - 2. first-class mail, with return receipt requested or delivery confirmation, or electronic mail, with return confirmation, to each present officer, director, manager, and employee of Respondent HAL; and
  - 3. first-class mail, return receipt requested, and with the letter attached as Appendix A to this Order, to the chief executive officer of each payor with whom Respondent HAL has a record of being in contact since January 1, 2001, regarding contracting for the provision of physician services; *provided, however*, that a copy of Exhibit A need not be included in the mailings to those payors with whom Respondent HAL has not entered into or renewed (including any automatic renewal of) a contract since January 1, 2001.
- B. For a period of three (3) years after the date this Order becomes final:

- 1. Distribute a copy of this Order and the Complaint by:
- a. first-class mail, with return receipt requested or delivery confirmation, or electronic mail, with return confirmation, to each physician that begins participating in Respondent HAL, and that did not previously receive a copy of this Order and the Complaint from Respondent HAL, within thirty (30) days of the day that such participation begins;
- b. first-class mail, return receipt requested, to each payor that contracts with Respondent HAL for the provision of physician services, and that did not previously receive a copy of this Order and the Complaint from Respondent HAL, within thirty (30) days of the day that such payor enters into such contract;
- c. first-class mail, with return receipt requested or delivery confirmation, or electronic mail, with return confirmation, to each person who becomes an officer, director, manager, or employee of Respondent HAL, and who did not previously receive a copy of this Order and the Complaint from Respondent HAL, within thirty (30) days of the day that he or she assumes such responsibility with Respondent HAL; and
- 2. Annually publish a copy of this Order and the Complaint in an official annual report or newsletter sent to all physicians who participate in Respondent HAL, with such prominence as is given to regularly featured articles.
- C. File a verified written report within sixty (60) days after the date on which this Order becomes final, annually thereafter for three (3) years on the anniversary of the

date this Order becomes final, and at such other times as the Commission may by written notice require. Each such report shall include:

- 1. A detailed description of the manner and form in which Respondent HAL has complied and is complying with this Order;
- 2. The name, address, and telephone number of each payor with which Respondent HAL has had any contact; and
- 3. Copies of the delivery confirmations or electronic mail confirmations required by Paragraphs V.A.1, V.A.2, V.B.1.a and V.B.1.c of this Order, and copies of the signed return receipts required by Paragraphs V.A.3, V.B.1.b, and V.E of this Order.
- D. Terminate, without penalty or charge, and in compliance with any applicable laws, any preexisting contract with any payor for the provision of physician services, at the earliest of:
  - the termination date specified in a written request from a payor to Respondent HAL to terminate such contract;
  - 2. the earliest termination or renewal date (including any automatic renewal date) of such contract; or
  - 3. one year from the date this Order becomes final.

Provided, however, a preexisting contract may extend beyond any such termination or renewal date no later than one (1) year from the date that the Order becomes final if, prior to such termination or renewal date, (a) the payor submits to Respondent HAL a written request to extend such contract to a specific date

no later than one (1) year from the date that this Order becomes final, and (b) Respondent HAL has determined not to exercise any right to terminate;

*Provided further*, that any payor making such request to extend a contract retains the right, pursuant to part (1) of Paragraph V.D of this Order, to terminate the contract at any time.

E. Within ten (10) days of receiving a written request from a payor, pursuant to Paragraph V.D (1) of this Order, distribute, by first-class mail, return receipt requested, a copy of that request to each physician participating in Respondent HAL as of the date Respondent HAL receives such request.

## VI.

IT IS FURTHER ORDERED that Respondent HAL shall notify the Commission at least thirty (30) days prior to any proposed (1) dissolution of Respondent HAL, (2) acquisition, merger or consolidation of Respondent HAL, or (3) other change in Respondent HAL that may affect compliance obligations arising out of this Order, including but not limited to assignment, the creation or dissolution of subsidiaries, or any other change in Respondent HAL.

#### VII.

IT IS FURTHER ORDERED that Respondent HAL shall notify the Commission of any change in its principal address within twenty (20) days of such change in address.

#### VIII.

**IT IS FURTHER ORDERED** that, for the purpose of determining or securing compliance with this Order, Respondent HAL shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in its possession, or under its control, relating to any matter contained in this Order; and
- B. Upon five (5) days' notice, and in the presence of counsel, and without restraint or interference from it, to interview officers, directors, or employees of the Respondent.

IX.

**IT IS FURTHER ORDERED** that this Order shall terminate twenty (20) years from the date it is issued.

By the Commission.

#### APPENDIX A

[Letterhead of Respondent HAL]

[date]

[name and address of payor's CEO]

Dear [CEO]:

Enclosed is a copy of a complaint and a decision and order ("Order") issued by the Federal Trade Commission against Health Care Alliance of Laredo, L.C. ("HAL").

Pursuant to Paragraph V.D of the Order, HAL must allow you to terminate, upon your written request, without any penalty or charge, any contracts with HAL for the provision of physician services that are in effect as of the date you receive this letter.

If you do not make a written request to terminate the contract, Paragraph V.D further provides that the contract will terminate on the earlier of:

- 1. [date], the contract's termination or renewal date; or
- 2. [date], one year from the date the Order becomes final.

You may, however, ask HAL to extend the contract beyond [date], the termination or renewal date, to any date no later than [date], one (1) year after the date the Order becomes final.

If you choose to extend the term of the contract, you may later terminate the contract at any time.

Any request either to terminate or to extend the contract should be made in writing, and sent to me at the following address: [address].

Sincerely,

[signatory]

[HAL to fill in applicable dates]

# **Analysis of Agreement Containing Consent Order** to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a proposed consent order with Health Care Alliance of Laredo, L.C. ("HAL"). The agreement settles charges that HAL violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by orchestrating and implementing agreements among physician members of HAL to fix prices and other terms on which they would deal with health plans, and to refuse to deal with such purchasers except on collectively-determined terms. The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order, or to modify their terms in any way. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by HAL that it violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

# The Complaint

The allegations of the complaint are summarized below.

HAL is a multi-specialty independent practice association ("IPA") in the Laredo, Texas, area with approximately 80 member physicians, a substantial majority of whom are competitors of one another. HAL contracts with payors on behalf of its member physicians and thereby establishes uniform prices and other contract terms applicable to its members.

Although purporting to employ a "messenger model," from 1998 to 2005, HAL attempted to and did negotiate higher reimbursement rates for its member physicians, sent payor offers to its members only after HAL negotiated and approved the rates, and urged its members not to deal individually with payors.

HAL's Board of Managers, nine physicians who are elected by and represent HAL's physician members, authorized and directed each step of the contracting process. The Board initiated negotiations by directing HAL personnel to contact a payor. On several occasions, HAL personnel contacted payors after learning that the payors were soliciting contracts with individual physicians. HAL personnel told the payors that HAL would represent and contract on behalf of HAL's physician members. As negotiations between payors and HAL personnel proceeded, HAL personnel were required to report to the Board on the progress of negotiations, and to seek authorization from the Board before making counterproposals. Ultimately, the Board either accepted or rejected contracts which HAL personnel presented to itIf the Board accepted the contract, HAL would then, and only then, "messenger" the contract to HAL's members for their individual acceptance or rejection. HAL did not messenger any rates proposed by the payors during negotiations, and messengered only the rates that the Board approved.

HAL members were fully aware of the payor negotiations HAL conducted on their behalf. HAL's staff provided updates to members on the status of contract negotiations via telephone, monthly

Some arrangements can facilitate contracting between health care providers and payors without fostering an illegal agreement among competing physicians on fees or feerelated terms. One such approach, sometimes referred to as a "messenger model" arrangement, is described in the 1996 Statements of Antitrust Enforcement Policy in Health Care jointly issued by the Federal Trade Commission and U.S. Department of Justice, at 125. *See* http://www.ftc.gov/reports/hlth3s.htm#9.

newsletters, and monthly meetings. On several occasions, as HAL personnel were attempting to negotiate a group contract, HAL urged its members not to negotiate individually with the health plans, and significant numbers of HAL members refused to deal individually with those payors.

HAL members also had direct input in payor negotiations, aside from their representation on the Board. In 1999, HAL surveyed its members, asking them for "the 20 most common codes used in the office and the maximum discount that you are willing to accept." HAL's Executive Director explained that "[t]his will help me when I negotiate contracts on behalf of the organization, since I would present these codes as those for which I will seek the advantageous rates." In addition to the 1999 survey, HAL personnel and Board members regularly solicited input on acceptable rates from HAL's members, which were then used in negotiations with payors

HAL has orchestrated collective agreements on fees and other terms of dealing with health plans, carried out collective negotiations with health plans, and fostered refusals to deal. HAL succeeded in forcing numerous health plans to raise the fees paid to HAL physician members, and thereby raised the cost of medical care in the Laredo, Texas, area. HAL engaged in no efficiency-enhancing integration sufficient to justify joint negotiation of feesBy the acts set forth in the Complaint, HAL violated Section 5 of the FTC Act.

## **The Proposed Consent Order**

The proposed order is designed to remedy the illegal conduct charged in the complaint and prevent its recurrence. It is similar to recent consent orders that the Commission has issued to settle charges that physician groups engaged in unlawful agreements to raise fees they receive from health plans. The proposed order's specific provisions are as follows:

Paragraph II.A prohibits HAL from entering into or facilitating any agreement between or among any physicians: (1) to negotiate with payors on any physician's behalf; (2) to deal, not to deal, or

threaten not to deal with payors; (3) on what terms to deal with any payor; or (4) not to deal individually with any payor, or to deal with any payor only through an arrangement involving HAL.

Other parts of Paragraph II reinforce these general prohibitions. Paragraph II.B prohibits HAL from facilitating exchanges of information between physicians concerning whether, or on what terms, to contract with a payorParagraph II.C bars attempts to engage in any action prohibited by Paragraph II.A or II.B, and Paragraph II.D proscribes HAL from inducing anyone to engage in any action prohibited by Paragraphs II.A through II.C.

As in other Commission orders addressing providers' collective bargaining with health care purchasers, certain kinds of agreements are excluded from the general bar on joint negotiations. HAL would not be precluded from engaging in conduct that is reasonably necessary to form or participate in legitimate joint contracting arrangements among competing physicians in a "qualified risk-sharing joint arrangement" or a "qualified clinically-integrated joint arrangement." The arrangement, however, must not facilitate the refusal of, or restrict, physicians in contracting with payors outside of the arrangement.

As defined in the proposed order, a "qualified risk-sharing joint arrangement" possesses two key characteristics. First, all physician participants must share substantial financial risk through the arrangement, such that the arrangement creates incentives for the physician participants jointly to control costs and improve quality by managing the provision of services. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement.

A "qualified clinically-integrated joint arrangement," on the other hand, need not involve any sharing of financial risk. Instead, as defined in the proposed order, physician participants must participate in active and ongoing programs to evaluate and modify

their clinical practice patterns in order to control costs and ensure the quality of services provided, and the arrangement must create a high degree of interdependence and cooperation among physicians. As with qualified risk-sharing arrangements, any agreement concerning price or other terms of dealing must be reasonably necessary to achieve the efficiency goals of the joint arrangement

Paragraph III, for three years, requires HAL to notify the Commission before entering into any arrangement to act as a messenger, or as an agent on behalf of any physicians, with payors regarding contracts. Paragraph III also sets out the information necessary to make the notification complete. Paragraph IV, for three years, requires HAL to notify the Commission before participating in contracting with health plans on behalf of a qualified risk-sharing joint arrangement, or a qualified clinically-integrated joint arrangement. The contracting discussions that trigger the notice provision may be either among physicians, or between HAL and health plans. Paragraph IV also sets out the information necessary to satisfy the notification requirement.

Paragraph V requires HAL to distribute the complaint and order to all physicians who have participated in HAL, and to payors that negotiated contracts with HAL or indicated an interest in contracting with HAL. Paragraph V.D requires HAL, at any payor's request and without penalty, or, at the latest, within one year after the order is made final, to terminate its current contracts with respect to providing physician services. Paragraph V.D. also allows any contract currently in effect to be extended, upon mutual consent of HAL and the contracted payor, to any date no later than one year from when the order became final. This extension allows both parties to negotiate a termination date that would equitably enable them to prepare for the impending contract termination. Paragraph V.E requires HAL to distribute payor requests for contract termination to all physicians who participate in HAL.

Paragraphs VI, VII, and VIII of the proposed order impose various obligations on HAL to report or provide access to

information to the Commission to facilitate monitoring HAL's compliance with the order.

The proposed order will expire in 20 years.

## IN THE MATTER OF

# ALLERGAN, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4156; File No. 0610031 Complaint, March 7, 2006--Decision, April 17, 2006

This consent order addresses the acquisition of Inamed Corporation by Allergan, Inc. Both companies are engaged in the research, development, manufacture, and sale of facial aesthetic products. Allergan's Botox® is the only botulinum toxin type A approved by the U.S. Food and Drug Administration for the treatment of facial wrinkles. The acquisition would eliminate the next most likely entrant in the market, Inamed's cosmetic botulinum, tentatively branded Reloxin®. The order requires the respondents to divest the Reloxin® development and distribution rights, including the ongoing clinical trials and certain intellectual property, back to Ipsen Ltd., its manufacturer, which had originally granted Inamed the exclusive rights to develop and distribute a botulinum toxin type A product. Respondents are required to provide personnel, assistance, advice, and training, at the request of Ipsen, until the Reloxin® assets are fully transferred. The order requires the respondents to ensure that confidential business information relating to Reloxin® will not be obtained or used by Allergan, and that Ipsen and/or its future marketing partner have the opportunity to enter into employment contracts with certain key individuals who have experience relating to Reloxin®. The Commission appointed an Interim Monitor to oversee the transfer of confidential business information to Ipsen and to ensure compliance with all of the provisions of this order.

# **Participants**

For the Commission: Roberta S. Baruch, Brendan J. McNamara, Michael R. Moiseyev, Robert R. Pickett, James E. Southworth, and David A. Von Nirschl.

For the Respondents: M. Sean Royall, Gibson, Dunn & Crutcher L.L.P.; and W. Stephen Smith and John Gowdy, Morrison & Foerster LLP.

## **COMPLAINT**

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Respondent Allergan, Inc. ("Allergan"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Inamed Corporation ("Inamed"), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act ("FTC Act"), as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

#### I. DEFINITIONS

- 1. "Commission" means the Federal Trade Commission.
- 2. "FDA" means the United States Food and Drug Administration.
- 3. "Ipsen" means Ipsen Ltd., a company organized, existing, and doing business under the laws of England, with its registered offices located at 190 Bath Road, Slough, Berkshire SL1 3XE, United Kingdom.
- 4. "Respondents" means Allergan and Inamed, individually and collectively.

## II. RESPONDENTS

5. Respondent Allergan is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 2525 Dupont Drive, Irvine, California 92612. Allergan, among other

things, is engaged in the research, development, manufacture, and sale of facial aesthetic products.

- 6. Respondent Inamed is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 5540 Ekwill Street, Suite D, Santa Barbara, California 93111. Inamed, among other things, is engaged in the research, development, manufacture, and sale of facial aesthetic products.
- 7. Respondents are, and at all times relevant herein have been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and are corporations whose business is in or affects commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

# III. THE PROPOSED ACQUISITION

8. On December 20, 2005, Allergan and Inamed entered into an Agreement and Plan of Merger (the "Merger Agreement") whereby Allergan agreed to acquire all of the outstanding common shares of Inamed in a transaction valued at approximately \$3.2 billion (the "Acquisition").

## IV. THE RELEVANT MARKET

- 9. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the Acquisition is the research, development, manufacture, and sale of cosmetic botulinum toxin.
- 10. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant line of commerce.

# V. THE STRUCTURE OF THE MARKETS

11. Allergan dominates the market for the research, development, manufacture, and sale of cosmetic botulinum toxins with its product Botox. Botox is currently the only botulinum toxin product approved by the FDA for cosmetic indications. Inamed plans to enter the market with its cosmetic botulinum toxin product Reloxin, which is licensed to Inamed from Ipsen. Inamed is in Phase III of clinical development with Reloxin, and is the firm best positioned next to enter the market. Other firms that are undertaking efforts to develop cosmetic botulinum toxin products lag well behind Inamed.

## VI. ENTRY CONDITIONS

12. Entry into the relevant line of commerce described in Paragraph 9 would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Developing and obtaining FDA approval for manufacture and sale of this product takes at least two years due to substantial regulatory and technological barriers.

## VII. EFFECTS OF THE ACQUISITION

13. The effects of the Acquisition, if consummated, may be substantially to lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others: (a) by eliminating potential competition between Allergan and Inamed in the market for the research, development, manufacture, and sale of cosmetic botulinum toxin, thereby increasing the ability of the combined firm unilaterally to raise prices of cosmetic botulinum toxin products; and (b) by increasing the likelihood that the combined entity would delay or forego the launch of Inamed's Reloxin, thereby delaying or eliminating the price competition that

would have resulted from Inamed's entry into the market for cosmetic botulinum toxin.

# VIII. VIOLATIONS CHARGED

- 14. The Merger Agreement described in Paragraph 8 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.
- 15. The Acquisition described in Paragraph 8, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this seventh day of March, 2006, issues its Complaint against said Respondents.

By the Commission, Commissioner Rosch recused.

## **DECISION AND ORDER**

The Federal Trade Commission ("Commission") having initiated an investigation of the proposed acquisition by Respondent Allergan, Inc. ("Allergan") of Respondent Inamed Corporation ("Inamed"), hereinafter referred to as "Respondents," and Respondents having been furnished thereafter with a copy of a draft of a Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

- 1. Respondent Allergan is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 2525 Dupont Drive, Irvine, California 92612.
- 2. Respondent Inamed is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 5540 Ekwill Street, Suite D, Santa Barbara, California 93111.
- 3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

## **ORDER**

I.

**IT IS ORDERED** that, as used in this Order, the following definitions shall apply:

- A. "Allergan" means Allergan, Inc., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups, and affiliates (in each case controlled by Allergan), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Allergan shall include Inamed.
- B. "Inamed" means Inamed Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups, and affiliates (in each case controlled by Inamed), and the respective directors,

- officers, employees, agents, representatives, successors, and assigns of each.
- C. "Respondents" means Allergan and Inamed, individually and collectively.
- D. "Commission" means the Federal Trade Commission.
- E. "Acquisition" means the acquisition contemplated by the "Agreement and Plan of Merger" dated December 20, 2005, by and among Allergan, Inc., Banner Acquisition, Inc., and Inamed Corporation.
- F. "Agency(ies)" means any governmental regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term "Agency" includes, but is not limited to, the United States Food and Drug Administration ("FDA").
- G. "BLA" means the Biologic License Application filed or to be filed with the FDA for the Joint Development Botulinum Products pursuant to 21 C.F.R. 601.2, et seq., and Section 351 of the Public Health Service Act, and all supplements, amendments, revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between the Respondents and the FDA or other Agency relative thereto.
- H. "Closing Date" means the date on which Respondent(s) (or a Divestiture Trustee) and Ipsen consummate a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Joint Development Botulinum Products Assets pursuant to this Order.

- I. "Confidential Business Information" means all information that is not in the public domain related to the research, Development, manufacture, marketing, commercialization, distribution, importation, exportation, cost, pricing, supply, sales, sales support, or use of the Joint Development Botulinum Product(s) and/or any other information proprietary to Ipsen; provided however, that the restrictions contained in this Order regarding the use, conveyance, provision to employees, or disclosure of "Confidential Business Information" shall not apply to the following:
  - 1. information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by Respondents;
  - 2. information related to the Joint Development Botulinum Product(s) that is not proprietary to Ipsen that Respondent Allergan can demonstrate it obtained without the assistance of Respondent Inamed prior to the Acquisition; or
  - 3. information that is required by Law to be publicly disclosed.
- J. "Development" means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining any and all approvals (including, but not limited to, formulating clinical study protocols, generating clinical study reports, and accumulating raw data from clinical studies from physician investigators that track the case

history and observations for each patient), licenses, registrations, or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any governmental price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. "Develop" means to engage in Development.

- K. "Divestiture Trustee" means a trustee appointed by the Commission pursuant to Paragraph IV of this Order.
- L. "Direct Cost" means a cost not to exceed the cost of labor, material, travel, and other expenditures to the extent they are directly incurred to provide the relevant assistance or service. "Direct Cost" to Ipsen for its use of any of the Respondents' employees' labor shall not exceed the average hourly wage rate for such employee.
- M. "Domain Name" means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any entity or authority that issues and maintains the domain name registration. "Domain Name" shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- N. "Effective Date" means the earlier of the following dates:
  - 1. the date the Respondents close on the Acquisition pursuant to the Acquisition Agreement, or
  - 2. the date the merger contemplated by the Acquisition Agreement becomes effective by filing the certificate of merger with the Secretary of State of the State of Delaware.

- O. "Final FDA Approval" means approval of a Product by the FDA pursuant the Federal Food, Drug, and Cosmetic Act § 505(b), 21 U.S.C. 355(b).
- P. "Governmental Entity" means any Federal, state, local, or non-U.S. government, or any court, legislature, governmental agency, or governmental commission, or any judicial or regulatory authority of any government.
- Q. "Interim Monitor" means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- R. "Investigational New Drug Application" ("IND") means an application filed with the FDA pursuant to 21 C.F.R. § 312.1, et seq. (as defined in 21 C.F.R. § 312.3), or its foreign Agency equivalent, and all supplements, amendments, and revisions thereto, any preparatory work, drafts, and data necessary for the preparation thereof, and all correspondence between Respondent(s) and the FDA or other Agency relative thereto.
- S. "Ipsen" means Ipsen Ltd., a company organized, existing, and doing business under the laws of England, with registered offices located at 190 Bath Road, Slough, Berkshire SL1 3XE, United Kingdom.
- T. "Joint Development and Distribution Agreement" means the "Development and Distribution Agreement" by and between Ipsen Ltd. and Inamed Corporation dated July 30, 2002, and all amendments, exhibits, attachments, agreements, and schedules thereto. The Joint Development and Distribution Agreement is attached to this Order and contained in Non-Public Appendix III.
- U. "Joint Development Botulinum Product(s)" means all Product(s) that contain botulinum toxin(s) and that are

the subject of the Joint Development and Distribution Agreement.

- V. "Joint Development Botulinum Products Assets" means all rights, title, and interest in and to (except as is otherwise provided below) all Product Intellectual Property and all assets related to the research, Development, manufacture, distribution, marketing, and sale of the Joint Development Botulinum Products for the United States market that are owned or controlled by, or licensed to Respondent Inamed on or before the Effective Date, to the extent legally transferable, including, without limitation, the following:
  - 1. all Product Intellectual Property related to the Joint Development Botulinum Products;
  - 2. all rights to all INDs or BLAs related to the Joint Development Botulinum Products;
  - 3. all rights to all Joint Development Botulinum Products Key Clinical Trials;
  - 4. all Product Scientific and Regulatory Material related to the Joint Development Botulinum Products;
  - 5. all Product Marketing Materials related to the Joint Development Botulinum Products;
  - 6. all other Confidential Business Information;
  - 7. at Ipsen's option, all Product Assumed Contracts related to the Joint Development Botulinum Product(s);

provided, however, that where any such contract or agreement also relates to Product(s) of the Respondent(s) other than the Joint Development Botulinum Product(s), Respondent(s) shall assign Ipsen all such rights under the contract or agreement as are related to the Joint Development Botulinum Product(s), but concurrently may retain similar rights for the purposes of the Retained Product(s); and

8. all Respondent Inamed's books, records, and files related to the foregoing, owned by, or in the possession or control of, Respondent Inamed, or to which Respondent Inamed has a right of access, in each case such as is in existence as of the Closing Date;

provided, however, that in cases in which documents or other materials included in the Joint Development Botulinum Products Assets contain information: (1) that relates both to the Joint Development Botulinum Products and to other Products or businesses of Respondent Inamed and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Joint Development Botulinum Products; or (2) for which Respondent Inamed has a legal obligation to retain the original copies, Respondent Inamed shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to Ipsen, Respondent Inamed shall provide Ipsen access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that Respondent Inamed provides Ipsen with the above-described information without requiring Respondent Inamed completely to divest itself of information that, in content, also relates to Retained Products.

- W. "Joint Development Botulinum Products Key Clinical Trials" means the following clinical trials related to the Development of the Joint Development Botulinum Products that are assigned the following study numbers: (1) Y-97-52120-717, (2) Y-97-52120-718, (3) Y-97-52120-085, (4) Y-97-52120-720, (5) Y-97-52120-096, (6) Y-97-52120-719, and (7) Y-97-52120-732.
- X. "Joint Development Botulinum Products Releasee(s)" means any entity controlled by or under common control with Ipsen, any licensees, sublicensees, joint venture partners, manufacturers, suppliers, distributors, and customers of Ipsen, or of Ipsen's affiliated entities. "Joint Development Botulinum Products Releasee(s)" excludes the Respondents.
- Y. "Joint Development Botulinum Products Termination Agreement" means the "Termination Agreement" by and between Ipsen Ltd. and Inamed Corporation dated December 20, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto. The Joint Development Botulinum Products Termination Agreement is attached to this Order and contained in Non-Public Appendix III.
- Z. "Law" means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Governmental Entity having the effect of law.
- AA. "New Joint Development Partner" means the entity designated by Ipsen as its joint venture partner to provide any aspect of the research, Development, manufacture, use, import, export, distribution, marketing, or sale related to the Joint Development Botulinum Products.

- BB. "Ownership Interest" means any and all rights, present or contingent, of Respondents to hold any voting or nonvoting stock, share capital, equity or other interests, or beneficial ownership in an entity.
- CC. "Patents" means all patents, patent applications, including provisional patent applications, and statutory invention registrations, in each case existing as of the Closing Date (*except* where this Order specifies a different time), and includes all reissues, divisions, continuations, continuations-in-part, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any Product or device owned or controlled by Respondent(s) as of the Closing Date (*except* where this Order specifies a different time).
- DD. "Product" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient.
- EE. "Product Access Personnel" means the employees of Inamed and Third Party Consultant(s) identified as such in Non-Public Appendix V of this Order.
- FF. "Product Assumed Contracts" means all of the contracts or agreements (copies of each such contract to be provided to Ipsen on or before the Closing Date and segregated in a manner that clearly identifies the Third Party to each such contract):
  - that make specific reference to the Joint Development Botulinum Product(s) and pursuant to which any Third Party is obligated to purchase the Joint Development Botulinum Product(s) from Respondent Inamed;

- 2. relating to any clinical study and/or trial involving the Joint Development Botulinum Product(s);
- 3. with universities or other research institutions for the use of the Joint Development Botulinum Product(s) in scientific research;
- relating to the particularized marketing of the Joint Development Botulinum Product(s) or educational matters relating to the Joint Development Botulinum Product(s);
- 5. constituting agreements to maintain information related to the Joint Development Botulinum Product(s) confidential;
- involving any royalty, licensing, or similar arrangement involving the Joint Development Botulinum Product(s);
- 7. pursuant to which a Third Party provides any specialized services for the purposes of the research, Development, or manufacture of the Joint Development Botulinum Product(s) to Respondent Inamed, including consultation arrangements; and/or
- 8. pursuant to which any Third Party collaborates with Respondent Inamed in the performance of research, Development, marketing, or selling of the Joint Development Botulinum Product(s) or the business associated with the Joint Development Botulinum Product(s).
- GG. "Product Copyrights" means rights to all original works of authorship of any kind related to the Joint Development Botulinum Product(s) and any registrations and applications for registrations thereof, including, but

not limited to, the following: all promotional materials for healthcare providers; all promotional materials for patients; educational materials for the sales force; copyrights in all pre-clinical, clinical, and process development data and reports relating to the research and Development of the Joint Development Botulinum Product(s) or of any materials used in the research, Development, manufacture, marketing, or sale of the Joint Development Botulinum Product(s), including all raw data relating to clinical trials of the Joint Development Botulinum Product(s), all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports, and statistical programs (if any) used for marketing and sales research; customer information, promotional and marketing materials, the Joint Development Botulinum Product(s) sales forecasting models, medical education materials, sales training materials, Website content, and advertising and display materials; all records relating to employees who accept employment with Ipsen (excluding any personnel records the transfer of which is prohibited by applicable Law); all records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all data contained in laboratory notebooks relating to the Joint Development Botulinum Product(s) or relating to its biology; all adverse experience reports and files related thereto (including source documentation) and all periodic adverse experience reports and all data contained in electronic data bases relating to adverse experience reports and periodic adverse experience reports; all analytical and quality control data; and all correspondence with the FDA or other Agency.

- HH. "Product Core Personnel (Group 1)" means the employees of Inamed identified as such in Non-Public Appendix V of this Order.
- II. "Product Core Personnel (Group 2)" means the employees of Inamed identified as such in Non-Public Appendix V of this Order.
- JJ. "Product Firewalled Employee(s)" means the following persons, individually and collectively:
  - 1. Product Access Personnel,
  - 2. Product Core Personnel (Group 1),
  - 3. Product Core Personnel (Group 2),
  - 4. Product Marketing Employees,
  - 5. Product Research and Development Employees, and
  - 6. any employee of Inamed not falling into the other aforementioned categories of "Product Firewalled Employees" determined by the Interim Monitor (if applicable) to have received any documents or other communications that disclose with particularity Confidential Business Information.
- KK. "Product Intellectual Property" means all of the following related to the Joint Development Botulinum Product(s):
  - 1. Patents;
  - 2. Product Copyrights;
  - 3. Product Trademarks;

- 4. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in any jurisdiction to limit the use or disclosure thereof;
- 5. rights to obtain and file for Patents and registrations thereof; and
- 6. rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation, or breach of any of the foregoing;

provided, however, that "Product Intellectual Property" does not include the names "Allergan," "Inamed," or the names of any other corporations or companies owned by Respondent Allergan or Respondent Inamed or related logos to the extent used on other of Respondents' Products.

- LL. "Product Key Personnel" means the employee(s) of Inamed identified as such in Non-Public Appendix V of this Order.
- MM. "Product Marketing Employee(s)" means management level employees of Respondent Inamed who have participated (irrespective of the portion of working time involved unless such participation consisted solely of oversight of accounting, tax or financial compliance) in the market research, marketing, contracting, or promotion of the Joint Development Botulinum Product(s) since the date of the Joint Development and Distribution Agreement. "Product Marketing Employees" shall include all such employees of Respondent Inamed that have received any documents or other communications that disclose with particularity Confidential Business Information.

- "Product Marketing Materials" means all marketing NN. materials used anywhere in the world related to the Joint Development Botulinum Product(s) as of the Closing Date, including, without limitation, all advertising materials, public relations materials, training materials, product data, price lists, pricing plans, pricing strategy materials, mailing lists, sales materials (e.g., detailing reports, vendor lists, sales data, financial projections, forecasts of sales, and sales forecasting models), marketing information (e.g., competitor information; consumer research data; market intelligence reports; promotional and marketing materials; brand name research information, including such information related to all brands considered for the Product; branding studies; branding strategy information; marketing plans, including pre-launch, short term, or long-term plans); statistical programs (if any) used for marketing and sales research, customer information (including physician and patient information), medical educational materials, Website content and advertising and display materials, speaker lists, artwork for the production of packaging components, television masters, and other similar materials related to the Product(s).
- OO. "Product Personnel Information" means the following, as and to the extent permitted by the Law within the jurisdiction in which the individual resides or works:
  - 1. with respect to each Product Access Personnel, Product Core Personnel (Group 1), and Product Core Personnel (Group 2), the following information:
    - a. the date of hire and effective service date;
    - b. job title or position held;

- c. a specific description of the individual's responsibilities related to the Joint Development Botulinum Products; provided, however, in lieu of this description, Respondent(s) may provide the individual's most recent performance appraisal;
- d. the base salary or current wages;
- e. the most recent bonus paid, aggregate annual compensation for the Respondent's last fiscal year and current target or guaranteed bonus, if any;
- f. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and
- g. any other material terms and conditions of employment in regard to such individual that are not otherwise generally available to similarly situated individuals; and
- 2. at Ipsen's option, copies of all current employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.
- PP. "Product Research and Development Employees" means all employees of Respondent Inamed who have participated (irrespective of the portion of working time involved unless such participation consisted solely of oversight of accounting, tax, or financial compliance) in the research or Development of the Joint Development Botulinum Products since the date of the Joint Development and Distribution Agreement. "Product Research and Development Employees" shall include all such employees of Respondent Inamed that have received any documents or other communications that

disclose with particularity Confidential Business Information.

- QQ. "Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and clinical trial materials and information related to the Joint Development Botulinum Product(s), and all rights thereto, in any and all jurisdictions.
- RR. "Product Trade Dress" means the current or planned trade dress of the Joint Development Botulinum Product(s), including, but not limited to, product packaging associated with the sale of the Joint Development Botulinum Product(s) in the United States and the lettering of the Product(s)' trade name or brand name.
- SS. "Product Trademark(s)" means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration thereof (and all renewals, modifications, and extensions thereof), and all common law rights, and the goodwill symbolized thereby and associated therewith, for the Joint Development Botulinum Product(s).
- TT. "Remedial Agreement" means the following: (1) any agreement between Respondent(s) and Ipsen that is specifically referenced in and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Joint Development Botulinum Products Assets, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final; and/or (2) any agreement between the Respondent(s) and

Ipsen (or between a Divestiture Trustee and Ipsen) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Joint Development Botulinum Products Assets and that has been approved by the Commission to accomplish the requirements of this Order.

- UU. "Retained Product" means any Product(s) other than a Joint Development Botulinum Product.
- VV. "Third Party(ies)" means any private entity other than the following: (1) the Respondents, or (2) Ipsen.
- WW. "Third Party Consultant(s)" means any Third Party (including, but not limited to, any clinical study and/or trial consultants, marketing consultants, or any individual (including, but not limited to, physician investigators involved in clinical studies)) who is performing or has performed work on behalf of Respondent Inamed or Ipsen related to the research, Development, manufacture, marketing, commercialization, distribution, importation, exportation, cost, pricing, supply, sales, sales support, or use of the Joint Development Botulinum Product(s) since the date of the Joint Development and Distribution Agreement. "Third Party Consultants" include, but are not limited to, the persons and entities listed in Appendix IV of this Order.
- XX. "Website" means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by Respondents; provided, however, "Website" shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by Respondent(s) that are incorporated in such Website(s), such as stock photographs used in the

Website(s), *except* to the extent that Respondent(s) can convey its rights, if any, therein; or (2) content unrelated to the Product(s).

II.

# **IT IS FURTHER ORDERED** that:

Α. Not later than twenty (20) days after the Effective Date, Respondents shall divest the Joint Development Botulinum Products Assets (to the extent that such assets are not already owned, controlled, or in the possession of Ipsen), absolutely and in good faith, to Ipsen pursuant to and in accordance with the Joint Development Botulinum Products Termination Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Ipsen or to reduce any obligations of the Respondents under such agreement), and such agreement, if it becomes the Remedial Agreement for the Joint Development Botulinum Products Assets, is incorporated by reference into this Order and made a part hereof;

provided, however, that if the Respondents have divested the Joint Development Botulinum Products Assets to Ipsen prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies the Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct the Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Joint Development Botulinum Products Assets to Ipsen (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Any Remedial Agreement related to the Joint Development Botulinum Products Assets shall be deemed incorporated into this Order, and any failure by Respondents to comply with the terms of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondents shall include in each Remedial Agreement for the Joint Development Botulinum Products Assets a specific reference to this Order and the remedial purpose thereof.
- D. Upon reasonable notice and request from Ipsen to the Respondents, Respondents shall provide, in a timely manner at no greater than Direct Cost, assistance and advice of knowledgeable employees of Respondent Inamed as Ipsen might reasonably need to transfer the Joint Development Botulinum Products Assets, and shall continue providing such personnel, assistance and training, at the request of Ipsen, until such assets are fully transferred to Ipsen.

# E. Respondents shall:

- 1. submit and deliver to Ipsen, at Respondents' expense, all Confidential Business Information within Respondents' possession or control as follows:
  - a. in good faith;
  - b. as soon as practicable, avoiding any delays in transmission of the respective information; and
  - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;

- 2. pending complete delivery of all such Confidential Business Information to Ipsen, provide Ipsen and the Interim Monitor (if any has been appointed) with access to the following:
  - a. all Confidential Business Information within Respondents' possession and control;
  - all Respondents' employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Joint Development Botulinum Products that contain Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
  - c. all Third Party Consultants who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Joint Development Botulinum Products that contain Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
- 3. not use, directly or indirectly, any Confidential Business Information other than as necessary to comply with the following:
  - a. the requirements of this Order or the related Order to Maintain Assets;
  - b. the Respondents' obligations to Ipsen under the terms of any Remedial Agreement related to the Joint Development Botulinum Product(s); or
  - c. applicable Law;

- 4. not use, directly or indirectly, any Confidential Business Information in connection with any suit, in law or equity, against Ipsen or the Joint Development Product Releasee(s) under United States Patents;
- 5. not disclose or convey any Confidential Business Information, directly or indirectly, to any person except Ipsen and such Joint Development Botulinum Products Releasee(s) or such Third Party Consultants as are authorized by Ipsen to receive such information; and
- 6. not provide, disclose, or otherwise make available, directly or indirectly, any Confidential Business Information to Respondent Allergan or any of Respondents' employees associated with business related to those Retained Products that contain botulinum toxin.
- F. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary for the divestiture of the Joint Development Botulinum Products Assets to Ipsen, or for the continued research, Development, manufacture, sale, marketing, or distribution of the Joint Development Botulinum Products in the United States of America by Ipsen;

provided, however, Respondents may satisfy this requirement by certifying that Ipsen has executed any such agreements directly with each of the relevant Third Parties or agreed that such consent or waiver is not required.

G. Respondents shall not enforce any agreement against a Third Party or Ipsen to the extent that such agreement may limit or otherwise impair the ability of Ipsen to acquire all Confidential Business Information. Not later than ten (10) days after the Closing Date, Respondents

shall grant a release to each such Third Party that allows the Third Party to provide all Confidential Business Information within the Third Party's possession or control to Ipsen. This includes, but is not limited to, such releases as may be necessary to permit the transfer to Ipsen of any attorney work-product related to the Product Intellectual Property in the possession of Respondent Inamed's outside counsel. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to Ipsen.

H. Until all of Respondent Inamed's rights to enforce restrictions on the use, disclosure, conveyance or provision of Confidential Business Information are fully assigned or conveyed to Ipsen, Respondents shall enforce any agreement against a Third Party to the extent that such agreement prevents or limits the ability of the Third Party to provide any Confidential Business Information to any person or entity other than: (1) Ipsen or (2) any Joint Development Botulinum Products Releasee(s) or Third Party Consultant authorized by Ipsen to receive such information.

# I. Respondents shall:

- 1. for a period of at least one (1) year after the Closing Date, provide Ipsen and/or the New Joint Development Partner (as designated by Ipsen to employ or contract with the relevant person or entity) with the opportunity to enter into employment contracts with any of the Product Access Personnel, Product Core Personnel (Group 1) or to contract with any Third Party Consultant;
- 2. for a period of at least six (6) months after the Closing Date, provide Ipsen with the opportunity to

enter into employment contracts with any of the Product Core Personnel (Group 2);

These periods are hereinafter referred to as the "Access Period(s)"; and

- 3. not later than ten (10) days after the Closing Date, provide Ipsen with the Product Personnel Information related to the Product Access Personnel, Product Core Personnel (Group 1) and Product Core Personnel (Group 2). Failure by Respondents to provide the Product Personnel Information for any relevant individual within the time provided herein shall extend the Access Period with respect to that individual in an amount equal to the delay.
- J. During the respective Access Periods, Respondents shall:
  - 1. not interfere with the hiring, employing, or contracting with the Product Access Personnel, Product Core Personnel (Group 1) or the Third Party Consultants by Ipsen or the New Joint Development Partner;
  - 2. not interfere with the hiring, employing, or contracting with the Product Core Personnel (Group 2) by Ipsen;
  - 3. remove any impediments within the control of Respondents that may deter the Product Access Personnel, Product Core Personnel (Group 1), Product Core Personnel (Group 2), and/or the Third Party Consultants from accepting such a relationship with Ipsen;
  - 4. remove any impediments within the control of Respondents that may deter the Product Access

Personnel, Product Core Personnel (Group 1), and/or the Third Party Consultants from accepting such a relationship with the New Joint Development Partner;

- 5. eliminate any provisions of any Product Access Personnel's, Product Core Personnel (Group 1)'s, Product Core Personnel (Group 2)'s and/or Third Party's Consultant's contract with the Respondent(s) that has the potential to interfere with such employee's or Third Party's Consultant's ability to perform work related to the Joint Development Botulinum Products, including, but not limited to, those provisions that would prohibit such employee or Third Party Consultant from:
  - a. being employed by or contracting with Ipsen;
  - b. for those subject to Paragraph II.J.1, being employed by or contracting with the New Joint Development Partner as authorized by Ipsen to hire or contract with such employee or Third Party Consultant; or
  - c. disclosing information related to the Joint Development Botulinum Products to Ipsen or the New Joint Development Partner;
- 6. facilitate Ipsen in notifying any Product Key Personnel, Product Access Personnel, Product Core Personnel (Group 1), Product Core Personnel (Group 2), and Third Party Consultant that such person or entity is specifically identified as such in this Order;
- 7. facilitate Ipsen in providing an explanation to each of the above-described persons or entities of the provisions of this Order related to such person or

entity's potential employment or use by Ipsen or Ipsen's New Joint Development Partner;

- 8. not make any counteroffer to a Product Access Personnel or an individual who is a Third Party Consultant who receives a written offer of employment or contract from Ipsen or the New Joint Development Partner; and
- 9. in addition to the foregoing, provide to each Product Key Personnel who accepts employment with either Ipsen or Ipsen's New Joint Development Partner during the Access Period, an incentive equal to at least six (6) months of such employee's annual base salary to be paid within six (6) months of such employee's commencement of employment with Ipsen or Ipsen's New Joint Development Partner.

provided, however, that Paragraph II.J. shall not prohibit the Respondents from making offers of continued employment to, continuing to employ, or continuing to use the services of, any Product Access Personnel, Product Core Personnel (Group 1), Product Core Personnel (Group 2), or Third Party Consultant, during the Access Period (subject to the conditions of employment or contract prescribed in this Order regarding the prohibitions on use and disclosure of Confidential Business Information);

provided, further however, that Paragraph II.J. shall not prohibit the Respondents from maintaining any reasonable restrictions on the disclosure of proprietary non-public information related solely to the Respondents' Retained Products by an employee who accepts an offer of employment with Ipsen or the New Joint Development Partner where such restrictions were a part of the relevant employee's contract of employment with Respondent Inamed prior to December 20, 2005.

K. For a period beginning on the Effective Date and continuing until either the date of Final FDA Approval of the first of the Joint Development Botulinum Product(s) to receive such approval, or three (3) years after the Effective Date, whichever is earlier, Respondents shall not use any Product Access Personnel or any Product Core Personnel (Group 1) for any purpose related to the research, Development, manufacturing, marketing, or sales of any of Respondents' Retained Products that contain botulinum toxins. For a period beginning on the Effective Date and continuing until six (6) months after the Effective Date, Respondents shall not use any Product Core Personnel (Group 2) for any purpose related to the research, Development, manufacturing, marketing, or sales of any of Respondents' Retained Products that contain botulinum toxins;

provided, however, the periods of restriction may be reduced as to a particular individual identified as a Product Access Personnel, Product Core Personnel (Group 1) or Product Core Personnel (Group 2) provided that the Respondents have received the express written approval of Ipsen to the reduction of the period as it pertains to the particular individual.

L. For a period beginning on the Effective Date and continuing until one year after the Effective Date, Respondents shall not, directly or indirectly, use the services of any employee or contractor of a Third Party Consultant who was directly involved in the research, Development, manufacture, marketing, or sales of the Joint Development Botulinum Products for any purpose related to the research, Development, manufacturing, marketing, or sales of any of Respondents' Retained Products that contain botulinum toxins;

provided, however, this period of restriction may be reduced as to a particular employee or contractor, provided that the Respondents have received the express written approval of Ipsen to the reduction of the period as it pertains to the particular employee(s), contractor(s), or general groups of employees or contractors of the relevant Third Party Consultant.

- M. Respondents shall require, as a condition of employment post-divestiture or as a condition of work to be performed on behalf of Respondents post-divestiture, that each Product Firewalled Employee or Third Party Consultant sign a confidentiality agreement pursuant to which such Product Firewalled Employee or Third Party Consultant shall be required strictly to maintain all Confidential Business Information as confidential to anyone except Ipsen and such Joint Development Botulinum Products Releasee(s) or Third Party Consultants as are authorized by Ipsen to receive such information and not to disclose any such information to any employees, executives, or other personnel of Respondents (other than as necessary to comply with the requirements of this Order, the Remedial Agreement(s), or the Order to Maintain Assets). Respondents shall keep a file of such agreements until one (1) year after the Final FDA approval of the first of the Joint Development Botulinum Product(s) to receive such approval. Respondents shall provide a copy of such agreements to Ipsen. Respondents shall maintain complete records of all such agreements at Respondents' corporate headquarters and shall provide an officer's certification to the Commission stating that each of the relevant Product Firewalled Employees or Third Party Consultants has signed such agreement and has and is complying with the respective agreement. Respondents shall provide Ipsen with copies of such certifications.
- N. Respondents shall provide written notification of the restrictions on the use and disclosure of the Confidential

Business Information related to the Joint Development Botulinum Product(s) to all of Respondents' employees and any Third Party Consultant who:

- 1. had access to any Confidential Business Information;
- are involved in the research, Development, manufacturing, distribution, sale, or marketing of any of Retained Products that contain botulinum toxins and/or are approved by the FDA for use in the cosmetic treatment of the facial area; and/or
- 3. may have Confidential Business Information related to the Joint Development Botulinum Products.

Such notification shall be in substantially the form set forth in the "Notice of Antitrust Remedy and Requirement for Confidentiality" attached to this Order as Public Appendix I, and to the Order to Maintain Assets as Public Appendix A. Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts until one (1) year after the Final FDA approval of the first of the Joint Development Botulinum Product(s) to receive such approval. Respondents shall provide a copy of such notification to Ipsen. Respondents shall maintain complete records of all such notifications Respondents' corporate headquarters and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondents shall provide Ipsen with copies of all certifications, notifications, and reminders sent to Respondents' personnel.

O. Until the Closing Date for the divestiture of the Joint Development Botulinum Products Assets has occurred, the Respondents shall provide all Third Party Consultants with reasonable financial incentives to

continue performing their work related to the Joint Development Botulinum Products until the Closing Date. Such incentives shall include a continuation of all contractual benefits provided by Respondent Inamed as were provided to such Third Party Consultant prior to the decision to terminate the Joint Development Botulinum Products Agreement.

- P. Counsel for Respondents (including in-house counsel under appropriate confidentiality arrangements) may retain unredacted copies of all documents or other materials provided to Ipsen and may have access to original documents (under circumstances where copies of documents are insufficient or otherwise unavailable) provided to Ipsen only in order to:
  - 1. comply with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals), any data retention requirement of any applicable Governmental Entity, or any taxation requirements; or
  - 2. defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of the Joint Development Botulinum Products Assets; provided, however, that Respondents may disclose such information as necessary for the purposes set forth in this Paragraph only pursuant to an appropriate confidentiality order, agreement, or arrangement;

provided, however, that pursuant to Paragraph II.P. Respondents shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with Ipsen (but shall not be deemed to have violated this requirement if Ipsen withholds such agreement unreasonably); and (2) use

their best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

- Q. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against Ipsen or the Joint Development Botulinum Products Releasee(s) under any United States Patent that is owned or licensed by Respondent Inamed prior to the Effective Date that claims a method of making, using, or administering, or a composition of matter, relating to botulinum toxin(s) or that claims a device relating to the use thereof, if such suit would have the potential to interfere with Ipsen's freedom to practice the research, Development, manufacture, use, import, export, distribution, or sale of the Joint Development Botulinum Products. Respondents shall also covenant to Ipsen that as a condition of any assignment, transfer, or license to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue Ipsen or the Joint Development Botulinum Products Releasee(s) under such Patents, if the suit would have the potential to interfere with Ipsen's freedom to practice in the research, Development, manufacture, use, import, export, distribution, or sale of the Joint Development Botulinum Products. Respondents shall include the above-described covenants in the Remedial Agreement(s) with Ipsen.
- R. Respondents shall not, in the United States of America:
  - 1. use the Product Trademarks related to the Joint Development Botulinum Products or any mark confusingly similar to such Product Trademarks, as a trademark, trade name, or service mark;
  - 2. attempt to register such Product Trademarks;

- 3. attempt to register any mark confusingly similar to or resulting in dilution of such Product Trademarks;
- 4. challenge or interfere with Ipsen's use and registration of such Product Trademarks; or
- 5. challenge or interfere with Ipsen's efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties;

provided however, this Paragraph shall only apply to those Product Trademarks conceived, registered, or developed prior to the Effective Date. Respondents shall include the above-described covenant in the Remedial Agreement(s) with Ipsen.

S. For a period commencing on the date this Order becomes final and continuing for ten (10) years, Respondents shall not, without providing advance written notification to the Commission, acquire, directly or indirectly, through subsidiaries or otherwise, any additional or greater Ownership Interest in Ipsen or any entity that: (1) that engages in scientific research, Development, manufacture, distribution, marketing, or selling of the Joint Development Botulinum Product(s) and (2) has a financial interest in the Joint Development Botulinum Product(s), greater than that which exists as of the Closing Date. Said notification shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (hereinafter referred to as "the Notification"), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such Notification, Notification shall be filed with the Secretary of the Commission, Notification need not be made to the United States Department of Justice, and Notification is required only of the Respondents and not of any other party to the transaction. Respondents shall

provide two (2) complete copies (with all attachments and exhibits) of the Notification to the Commission at least thirty (30) days prior to consummating any such transaction (hereinafter referred to as the "first waiting period"). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondents shall not consummate the transaction until thirty (30) days after substantially complying with such request. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition; provided, however, that prior notification shall not be required by this Paragraph for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

T. Pending divestiture of the Joint Development Botulinum Products Assets, Respondents shall take such actions as are necessary to maintain the full economic viability, marketability, and competitiveness of the business related to the research, Development, manufacture, distribution, marketing, and sale of the Joint Development Botulinum Products, to minimize any risk of loss of competitive potential for such business, and to prevent the destruction, removal, wasting, deterioration, or impairment of the Joint Development Botulinum Products Assets until after their respective transfer to Ipsen in a manner that ensures that there is no disruption, delay, or impairment of the Joint Development Botulinum Products Key Clinical Trials and regulatory approval process. Respondents shall not sell, transfer, encumber or otherwise impair the Joint Development Botulinum Products Assets (other than in the manner prescribed in this Order) nor take any action that lessens

the full economic viability, marketability, or competitiveness of the above-described business.

U. The purpose of Paragraph II of this Order is to ensure the continued research, Development, manufacture, marketing, and sale of the Joint Development Botulinum Products independently of Respondents and for the same purposes for which the Joint Development Botulinum Products were researched, Developed, manufactured, marketed and/or sold by Inamed and Ipsen at the time of the announcement of the Acquisition, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

### III.

# **IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint an Interim Monitor to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order and the Order to Maintain Assets (collectively "the Orders") and the Remedial Agreements. The Commission may appoint one or more Interim Monitors to assure Respondents' compliance with the requirements of the Orders and the related Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If neither Respondent has opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Interim Monitor, Respondents shall be deemed

to have consented to the selection of the proposed Interim Monitor.

- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. If one or more Interim Monitors are appointed pursuant to this Paragraph or pursuant to the relevant provisions of the Order to Maintain Assets in this matter, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of each Interim Monitor:
  - 1. The Interim Monitor shall have the power and authority to monitor Respondents' compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission;
  - 2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission;
  - 3. The Interim Monitor shall serve until the latest of:
    - a. the completion by Respondents of the divestiture of the Joint Development Botulinum Products Assets (including, but not limited to, the delivery of all Confidential Business Information in

Respondents' possession or control to Ipsen) required to be divested pursuant to the Decision and Order in a manner that fully satisfies the requirements of the Orders and notification by Ipsen to the Interim Monitor that Ipsen is fully capable of completing the Joint Development Botulinum Products Key Clinical Trials;

- b. the implementation of appropriate firewalls and other measures within the Respondents' business operations to prevent the misuse or improper disclosure of Confidential Business Information; and
- c. the completion by Respondents of the last obligation under the Orders pertaining to the Interim Monitor's service;

*provided, however,* that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders;

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with their obligations under the Orders, including, but not limited to, their obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Orders;

- 5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of the Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities;
- 6. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor;
- 7. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by Ipsen with respect to the performance of Respondents' obligations under the Orders or the Remedial Agreement. Within one (1) month from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Orders; and

- 8. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph or the relevant provisions of the Order to Maintain Assets in this matter.
- G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- H. The Interim Monitor appointed pursuant to this Order or the relevant provisions of the Order to Maintain Assets in this matter may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

# IV.

# **IT IS FURTHER ORDERED** that:

- If Respondents have not fully complied with the A. obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey relevant assets as required by this Order, the Commission may appoint a Divestiture Trustee(s) to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets required to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed pursuant to each of the relevant Paragraphs in a manner that satisfies the requirements of each such Paragraph. In the event that the Commission or the Attorney General brings an action pursuant to  $\S 5(l)$  of the Federal Trade Commission Act, 15 U.S.C. § 45(*l*), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey the relevant assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to  $\S 5(l)$  of the Federal Trade Commission Act or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within

ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by the Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
  - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed;
  - 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve-month period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed Divestiture Trustee, by the court; provided, however,

the Commission may extend the divestiture period only two (2) times;

- 3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court;
- 4. The Divestiture Trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. Each divestiture shall be made in the manner and to an acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondents from among those approved by the Commission; *provided further* that Respondents

shall select such entity within five (5) days after receiving notification of the Commission's approval;

- 5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed Divestiture Trustee, by the court, of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order;
- 6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, *except* to the extent that such losses, claims, damages, liabilities, or expenses result from

misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee;

- 7. In the event that the Divestiture Trustee determines that he or she is unable to assign, grant, license, divest, transfer, deliver or otherwise convey the relevant assets required to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed in a manner that preserves their marketability, viability and competitiveness and ensures their continued use in the research, Development, manufacture, distribution, marketing, promotion, sale, or after-sales support of the relevant Product, the Divestiture Trustee may assign, grant, license, divest, transfer, deliver, or otherwise convey such additional assets of Respondents and effect such arrangements as are necessary to satisfy the requirements of this Order;
- 8. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed by this Order;
- 9. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture; and
- 10. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.
- G. The Divestiture Trustee appointed pursuant to this Paragraph may be the same person appointed as Interim Monitor pursuant to the relevant provisions of this Order or the relevant provisions of the Order to Maintain Assets in this matter.

V.

#### IT IS FURTHER ORDERED that:

- A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the date this Order becomes final, and every sixty (60) days thereafter until Respondents have fully complied with Paragraphs II.A., II.D., II.E.1, II.E.2., II.F., II.H., II.O., and II.T., Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order. Respondents shall submit at the same time a copy of their report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondents shall

include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant Paragraphs of the Order, including a description of all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all parties contacted. Respondents shall include in their reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning completing the obligations.

C. One (1) year after the date this Order becomes final, annually for the next nine (9) years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which they have complied and are complying with this Order.

#### VI.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed (1) dissolution of the Respondents, (2) acquisition, merger, or consolidation of Respondents, or (3) other change in the Respondents that may affect compliance obligations arising out of the Order, including, but not limited to, assignment, the creation or dissolution of subsidiaries, or any other change in Respondents.

#### VII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents made to their principal United

States offices, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents related to compliance with this Order; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

**IT IS FURTHER ORDERED** that this Order shall terminate on April 17, 2016.

By the Commission, Commissioner Rosch recused.

#### APPENDIX I TO THE DECISION AND ORDER PUBLIC

### NOTICE OF ANTITRUST REMEDY AND REQUIREMENT FOR CONFIDENTIALITY

On [INSERT], Allergan Inc. ("Allergan") and Inamed ("Inamed") hereinafter referred to as "Respondents," entered into an Agreement Containing Consent Orders ("Consent Agreement") with the Federal Trade Commission ("FTC") relating to the divestiture of certain assets. That Consent Agreement includes two orders: the Decision and Order and the Order to Maintain Assets.

The Decision and Order requires the divestiture of assets relating to Reloxin<sup>®</sup>. These assets are hereinafter referred to as the "Reloxin<sup>®</sup> Divested Assets." Both the Decision and Order and the Order to Maintain Assets require Respondents to commit that no Confidential Business Information relating to the Reloxin® Divested Assets will be disclosed to or used by any employee of the combined entity formed by the acquisition of a controlling interest in Inamed by Allergan ("Combined Entity"). In particular, this is to prevent Confidential Business Information from being used in any way for the research, development, sale, or manufacture of any product that competes or may compete with the Reloxin<sup>®</sup> Divested Assets after the proposed acquisition. The Decision and Order also requires the complete divestiture of ALL documents (including electronically stored material) that contain Confidential Business Information related to the Reloxin<sup>®</sup> Divested Assets. Accordingly, no employee of the Combined Entity may maintain copies of documents containing such information, except as otherwise permitted by the Consent Order, required by law, or to comply with Inamed's obligations to terminate the Joint Development and Distribution Agreement with Ipsen.

Under the Decision and Order, the Respondents are required to divest the Reloxin<sup>®</sup> Divested Assets to Ipsen. Until a complete

divestiture of all of the Reloxin® Divested Assets occurs, the requirements of the second order – the Order to Maintain Assets – are in place to ensure the continued marketability, viability, and competitive vigor of the Reloxin® Divested Assets and to ensure that no Confidential Business Information related to Reloxin® is communicated to the employees of Allergan.

You are receiving this notice because you are one or more of the following: (i) an employee with work responsibilities related to Reloxin®; (ii) a Third Party Consultant to Inamed with work responsibilities related to Reloxin®; (iii) an employee of Allergan or the Combined Entity who has work responsibilities in some way related to products that compete or may compete with Reloxin®; or (iv) an employee, former employee, contractor, or former contractor of Inamed who might have Confidential Business Information in your possession related to Reloxin®.

All Confidential Business Information related to the Reloxin® Divested Assets must be retained and maintained by the persons involved in the operation of that business on a confidential basis, and such persons must not provide, discuss, exchange, circulate, or otherwise disclose any such information to or with any other person whose employment involves responsibilities unrelated to the Reloxin® Divested Assets (such as persons with job responsibilities related to Allergan's BOTOX® products or other products that compete or may compete with Reloxin®). In addition, any person who possesses such Confidential Business Information related to the Reloxin® Divested Assets and who becomes involved in the Combined Entity's business related to any product that competes or may compete with Reloxin<sup>®</sup> must not provide, discuss, exchange, circulate, or otherwise disclose any such information to or with any other person whose employment relates to such businesses. Finally, any Inamed employee, former employee, contractor, or former contractor with documents that contain information that he or she believes might be considered Confidential Business Information related to Reloxin® and who has not received specific instructions as to how the documents in his or her possession should be disposed of should contact the contact person identified at the end of this notice. Furthermore, the Decision and Order places restrictions upon the functions that certain management level employees of Inamed, or certain contractors to Inamed, can perform for the Combined Entity until [insert description of length of these restrictions].

Any violation of the Decision and Order or the Order to Maintain Assets may subject Allergan, Inamed, or the Combined Entity to civil penalties and other relief as provided by law. If you have any questions regarding the contents of this notice, the confidentiality of information, the Decision and Order or the Order to Maintain Assets, you should contact [insert name and title].

# I, \_\_\_\_\_\_ (print name), hereby acknowledge that I have read the above notification and agree to abide by its provisions.

#### APPENDIX II TO THE DECISION AND ORDER PUBLIC

ORDER TO MAINTAIN ASSETS

## APPENDIX III TO THE DECISION AND ORDER NON-PUBLIC

AGREEMENTS RELATED TO THE JOINT DEVELOPMENT BOTULINUM PRODUCTS

[Redacted From the Public Record Version But Incorporated By Reference]

## APPENDIX IV TO THE DECISION AND ORDER NON-PUBLIC

#### THIRD PARTY CONSULTANTS

[Redacted From the Public Record Version But Incorporated By Reference]

APPENDIX V
TO THE DECISION AND ORDER
NON-PUBLIC

PRODUCT KEY PERSONNEL,
PRODUCT ACCESS PERSONNEL,
PRODUCT CORE PERSONNEL (GROUP 1),
AND
PRODUCT CORE PERSONNEL (GROUP 2)

[Redacted From the Public Record Version But Incorporated By Reference]

#### ORDER TO MAINTAIN ASSETS

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Allergan, Inc. ("Allergan") of Respondent Inamed Corporation ("Inamed"), hereinafter referred to as "Respondents," and Respondents having been furnished thereafter with a copy of a draft Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and that, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

1. Respondent Allergan is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its offices and

principal place of business located at 2525 Dupont Drive, Irvine, California 92612.

- 2. Respondent Inamed is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 5540 Ekwill Street, Suite D, Santa Barbara, California 93111.
- 3. The Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

#### **ORDER**

I.

IT IS ORDERED that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final, the Decision and Order), which are attached hereto as Appendix B and incorporated herein by reference and made a part hereof, shall apply:

- A. "Allergan" means Allergan, Inc., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups, and affiliates (in each case controlled by Allergan), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Allergan shall include Inamed.
- B. "Inamed" means Inamed Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups, and affiliates (in each case controlled by Inamed), and the respective directors,

### FEDERAL TRADE COMMISSION DECISIONS VOLUME 141

#### Order to Maintain Assets

- officers, employees, agents, representatives, successors, and assigns of each.
- C. "Respondents" means Allergan and Inamed, individually and collectively.
- D. "Commission" means the Federal Trade Commission.
- E. "Acquisition" means the acquisition contemplated by the "Agreement and Plan of Merger" dated December 20, 2005, by and among Allergan, Inc., Banner Acquisition, Inc., and Inamed Corporation.
- F. Closing Date" means the date on which Respondent(s) (or a Divestiture Trustee) and Ipsen consummate a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Joint Development Botulinum Products Assets pursuant to the Decision and Order.
- G. "Confidential Business Information" means all information that is not in the public domain related to the research, Development, manufacture, marketing, commercialization, distribution, importation, exportation, cost, pricing, supply, sales, sales support, or use of the Joint Development Botulinum Product(s) and/or any other information proprietary to Ipsen; provided however, that the restrictions contained in this Order to Maintain Assets regarding the use, conveyance, provision to employees, or disclosure of "Confidential Business Information" shall not apply to the following:
  - 1. information that subsequently falls within the public domain through no violation of this Order to Maintain Assets or breach of confidentiality or non-disclosure agreement with respect to such information by Respondents;

- 2. information related to the Joint Development Botulinum Product(s) that is not proprietary to Ipsen that Respondent Allergan can demonstrate it obtained without the assistance of Respondent Inamed prior to the Acquisition; or
- 3. information that is required by Law to be publicly disclosed.
- H. "Effective Date" means the earlier of the following dates:
  - 1. the date the Respondents close on the Acquisition pursuant to the Acquisition Agreement; or
  - 2. the date the merger contemplated by the Acquisition Agreement becomes effective by filing the certificate of merger with the Secretary of State of the State of Delaware.
- I. "Interim Monitor" means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- J. "Ipsen" means Ipsen Ltd., a company organized, existing, and doing business under the laws of England, with registered offices located at 190 Bath Road, Slough, Berkshire SL1 3XE, United Kingdom.
- K. "Joint Development Botulinum Product Business(es)" means Respondent Inamed's business within the United States of America related to the Joint Development Botulinum Products, including the research, Development, manufacture, distribution, marketing, and sale of the Joint Development Botulinum Products and the assets related to such business, including, but not

limited to, the Joint Development Botulinum Product Assets.

- L. "Orders" means the Decision and Order and this Order to Maintain Assets.
- M. "Pre-Acquisition Plan" means any plan related to the research, Development, manufacture, distribution, marketing, or sale of the Joint Development Botulinum Products that was planned or implemented within the period immediately prior to the Acquisition and without consideration of the influence of the pending Acquisition for the Joint Development Botulinum Products Business.
- N. "Remedial Agreement" means the following: (1) any agreement between Respondent(s) and Ipsen that is specifically referenced in and attached to the Decision and Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Joint Development Botulinum Assets, and that has been approved by the Commission to accomplish the requirements of the Decision and Order in connection with the Commission's determination to make the Decision and Order final; and/or (2) any agreement between the Respondent(s) and Ipsen (or between a Divestiture Trustee and Ipsen) that has been approved by the Commission to accomplish the requirements of the Decision and Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Joint Development Botulinum Assets, and that has been approved by the Commission to accomplish the requirements of the Decision and Order.

II.

**IT IS FURTHER ORDERED** that from the date this Order to Maintain Assets becomes final:

- Respondents shall take such actions as are necessary to Α. maintain the full economic viability, marketability, and competitiveness of the Joint Development Botulinum Products Business, to minimize any risk of loss of competitive potential for the Joint Development Botulinum Products Business, to ensure that there is no disruption, delay, or impairment of the Joint Development Products Key Clinical Trials and the regulatory approval process, and to prevent the destruction, removal, wasting, deterioration, or impairment of the Joint Development Botulinum Products Assets until after their respective transfer to Ipsen. Respondents shall not sell, transfer, encumber, or otherwise impair the Joint Development Botulinum Product Assets (other than in the manner prescribed in the Decision and Order and that is consistent with the remedial purposes of the Decision and Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the Joint Development Botulinum Products Business.
- B. Respondents shall maintain the operations of the Joint Development Botulinum Products Business in the regular and ordinary course of business and in accordance with past practice (other than as necessary to comply with provisions of this Order to Maintain Assets and the Decision and Order to maintain Confidential Business Information as confidential) and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Joint Development Botulinum Products Business and shall use their best efforts to preserve the existing relationships with the following:

Third Party Consultants, physicians participating in clinical studies and/or trials, suppliers, vendors and distributors, customers, Agencies, employees, and others having business relations with the Joint Development Botulinum Products Business. Respondents' responsibilities shall include, but are not limited to, the following:

- 1. providing the Joint Development Botulinum Products Business with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for the Joint Development Botulinum Products Business;
- 2. continuing, at least at their scheduled pace, any additional expenditures for the Joint Development Botulinum Products Business authorized prior to the date the Consent Agreement was signed by Respondents including, but not limited to, all research, Development, manufacture, distribution, marketing, and sales expenditures;
- 3. provide such resources as may be necessary to ensure that there is no disruption, delay, or impairment of the Joint Development Botulinum Products Key Clinical Trials and regulatory approval process;
- 4. providing the Joint Development Botulinum Products Business with such funds as are necessary to maintain the full economic viability, marketability, and competitiveness of the Joint Development Botulinum Products Business; and

- 5. providing such support services to the Joint Development Botulinum Products Business as were being provided to this business by Respondent Inamed as of the date the Consent Agreement was signed by Respondents.
- C. Respondents shall maintain a work force at least as equivalent in size, training, and expertise to what has been associated with the Joint Development Botulinum Products (including the work force associated with the Third Party Consultants) for the Joint Development Botulinum Product's most recent Pre-Acquisition Plan.
- D. Until the Closing Date, Respondents shall provide the Product Access Personnel, Product Core Personnel (Group 1), and Third Party Consultants with reasonable financial incentives to continue in their positions relating to the research, Development, marketing, or sale of the Joint Development Botulinum Products consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Joint Development Botulinum Products pending divestiture, to ensure successful execution of the Pre-Acquisition Plan, and to ensure that no disruption, delay, or impairment results to the Joint Development Botulinum Products Key Clinical Trials and regulatory approval process. Such incentives shall include a continuation of all contractual benefits provided by Respondent Inamed as were provided to each such Third Party Consultant prior to the decision to terminate the Joint Development Botulinum Products Agreement.

#### E. Respondents shall:

1. for a period of at least one (1) year after the Closing Date, provide Ipsen and/or the New Joint Development Partner (as designated by Ipsen to employ or contract with the relevant person or entity)

with the opportunity to enter into employment contracts with any of the Product Access Personnel, Product Core Personnel (Group 1) or to contract with any Third Party Consultant;

2. for a period of at least six (6) months after the Closing Date, provide Ipsen with the opportunity to enter into employment contracts with any of the Product Core Personnel (Group 2);

These periods are hereinafter referred to as the "Access Period(s)"; and

- 3. not later than ten (10) days after the Closing Date, provide Ipsen with the Product Personnel Information related to the Product Access Personnel, Product Core Personnel (Group 1), and Product Core Personnel (Group 2). Failure by Respondents to provide the Product Personnel Information for any relevant individual within the time provided herein shall extend the Access Period with respect to that individual in an amount equal to the delay.
- F. During the respective Access Periods, Respondents shall:
  - 1. not interfere with the hiring, employing, or contracting with the Product Access Personnel, Product Core Personnel (Group 1), or the Third Party Consultants by Ipsen or the New Joint Development Partner;
  - 2. not interfere with the hiring, employing, or contracting with the Product Core Personnel (Group 2) by Ipsen;

- 3. remove any impediments within the control of Respondents that may deter the Product Access Personnel, Product Core Personnel (Group 1), Product Core Personnel (Group 2), and/or the Third Party Consultants from accepting such a relationship with Ipsen;
- 4. remove any impediments within the control of Respondents that may deter the Product Access Personnel, Product Core Personnel (Group 1), and/or the Third Party Consultants from accepting such a relationship with the New Joint Development Partner;
- 5. eliminate any provisions of any Product Access Personnel's, Product Core Personnel (Group 1)'s, Product Core Personnel (Group 2)'s, and/or Third Party Consultant's contract with the Respondent(s) that has the potential to interfere with such employee's or Third Party Consultant's ability to perform work related to the Joint Development Botulinum Products, including, but not limited to, those provisions that would prohibit such employee or Third Party Consultant from:
  - a. being employed by or contracting with Ipsen;
  - b. for those subject to Paragraph II.F.1, being employed by or contracting with the New Joint Development Partner as authorized by Ipsen to hire or contract with such employee or Third Party Consultant; or
  - c. disclosing information related to the Joint Development Botulinum Products to Ipsen or the New Joint Development Partner;

- facilitate Ipsen in notifying any Product Key Personnel, Product Access Personnel, Product Core Personnel (Group 1), Product Core Personnel (Group 2), and Third Party Consultant that such person or entity is specifically identified as such in the Decision and Order;
- 7. facilitate Ipsen in providing an explanation to each of the above-described persons or entities of the provisions of this Order to Maintain Assets and the Decision and Order related to such person or entity's potential employment or use by Ipsen or Ipsen's New Joint Development Partner; and
- 8. not make any counteroffer to a Product Access Personnel or an individual who is a Third Party Consultant who receives a written offer of employment or contract from Ipsen or the New Joint Development Partner;

provided, however, that Paragraph II.F. shall not prohibit the Respondents from making offers of continued employment to, continuing to employ, or continuing to use the services of, any Product Access Personnel, Product Core Personnel (Group 1), Product Core Personnel (Group 2), or Third Party Consultant, during the Access Period (subject to the conditions of employment or contract prescribed in this Order to Maintain Assets or the Decision and Order regarding the prohibitions on use and disclosure of Confidential Business Information);

provided, further however, that Paragraph II.F. shall not prohibit the Respondents from maintaining any reasonable restrictions on the disclosure of proprietary non-public information related solely to the Respondents' Retained Products by an employee who

accepts an offer of employment with Ipsen or the New Joint Development Partner where such restrictions were a part of the relevant employee's contract of employment with Respondent Inamed prior to December 20, 2005.

- G. Pending divestiture of the Joint Development Botulinum Product Assets, Respondents shall:
  - 1. provide Ipsen and the Interim Monitor (if any has been appointed) with access to the following:
    - a. all Confidential Business Information within Respondents' possession and control;
    - all Respondents' employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Joint Development Botulinum Products that contain Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
    - c. all Third Party Consultants who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Joint Development Botulinum Products that contain Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
  - 2. not use, directly or indirectly, any Confidential Business Information other than as necessary to comply with the following:
    - a. the requirements of this Order to Maintain Assets or the related Decision and Order;

- b. the Respondents' obligations to Ipsen under the terms of any Remedial Agreement related to the Joint Development Botulinum Product(s); or
- c. applicable Law;
- 3. not disclose or convey any Confidential Business Information, directly or indirectly, to any person except Ipsen and such Joint Development Botulinum Products Releasee(s) or Third Party Consultants as are authorized by Ipsen to receive such information; and
- 4. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information to Respondent Allergan or any of Respondents' employees associated with business related to those Retained Products that contain botulinum toxin.
- H. For a period beginning on the Effective Date and continuing until either the date of Final FDA Approval of the first of the Joint Development Botulinum Product(s) to receive such approval, or three (3) years after the Effective Date, whichever is earlier, Respondents shall not use any Product Access Personnel or any Product Core Personnel (Group 1) for any purpose related to the research, Development, manufacturing, marketing, or sales of any of Respondents' Retained Products that contain botulinum toxins. For a period beginning on the Effective Date and continuing until six (6) months after the Effective Date, Respondents shall not use any Product Core Personnel (Group 2) for any purpose related to the research, Development, manufacturing, marketing, or sales of any of Respondents' Retained Products that contain botulinum toxins:

provided, however, the periods of restriction may be reduced as to a particular individual identified as a Product Access Personnel, Product Core Personnel (Group 1) or Product Core Personnel (Group 2) provided that the Respondents have received the express written approval of Ipsen to the reduction of the period as it pertains to the particular individual.

I. For a period beginning on the Effective Date and continuing until one year after the Effective Date, Respondents shall not, directly or indirectly, use the services of any employee or contractor of a Third Party Consultant who was directly involved in the research, Development, manufacture, marketing, or sales of the Joint Development Botulinum Products for any purpose related to the research, Development, manufacturing, marketing, or sales of any of Respondents' Retained Products that contain botulinum toxins;

provided, however, this period of restriction may be reduced as to a particular employee or contractor, provided that the Respondents have received the express written approval of Ipsen to the reduction of the period as it pertains to the particular employee(s), contractor(s), or general groups of employees or contractors of the relevant Third Party Consultant.

J. Not later than thirty (30) days from the Effective Date, Respondents shall secure a confidentiality agreement from each Product Firewalled Employee or Third Party Consultant as of such date. Such agreement shall require, as a condition of employment post-divestiture or as a condition of work to be performed on behalf of Respondents post-divestiture, that each Product Firewalled Employee or Third Party Consultant shall maintain all Confidential Business Information as confidential to anyone except Ipsen and such Joint Development Botulinum Products Releasee(s) or Third Party Consultants as are authorized by Ipsen to receive

such information and not to disclose any such information to any employees, executives, or other personnel of Respondents (other than as necessary to comply with the requirements of this Order to Maintain Assets, the Remedial Agreement(s), or the Decision and Respondents shall keep a file of such agreements until one (1) year after the Final FDA approval of the first of the Joint Development Botulinum Product(s) to receive such approval. Respondents shall provide a copy of such agreements to Ipsen. Respondents shall maintain complete records of all such agreements at Respondents' corporate headquarters and shall provide an officer's certification to the Commission stating that each of the relevant Product Firewalled Employees or Third Party Consultants has signed such agreement and has and is complying with the respective agreement. Respondents shall provide Ipsen with copies of such certifications.

- K. Not later than thirty (30) days from the Effective Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Joint Development Botulinum Product(s) to all of Respondents' employees and any Third Party Consultant who:
  - 1. had access to any Confidential Business Information;
  - 2. are involved in the research, Development, manufacturing, distribution, sale, or marketing of any of Retained Products that contain botulinum toxins and/or are approved by the FDA for use in the cosmetic treatment of the facial area; and/or
  - 3. may have Confidential Business Information related to the Joint Development Botulinum Products.

Such notification shall be in substantially the form set forth in the "Notice of Antitrust Remedy and Requirement for Confidentiality" attached to this Order to Maintain Assets as Public Appendix A, and to the Decision and Order as Public Appendix I. Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts until one (1) year after the Final FDA approval of the first of the Joint Development Botulinum Product(s) to receive such approval. Respondents shall provide a copy of such notification to Ipsen. Respondents shall maintain complete records of all such notifications at Respondents' corporate headquarters and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondents shall provide Ipsen with copies of all certifications, notifications and reminders sent to Respondents' personnel.

- L. Respondents shall adhere to and abide by the Remedial Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of the Orders, it being understood that nothing in the Orders shall be construed to reduce any obligations of Respondents under such agreement(s)), which are incorporated by reference into this Order to Maintain Assets and made a part hereof.
- M. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability, and competitiveness of the Joint Development Botulinum Products Business, to minimize any risk of loss of competitive potential for the Joint Development Botulinum Products Business, to ensure that there is no disruption, delay, or impairment of the Joint Development Products Key Clinical Trials and regulatory approval process, and to prevent the

destruction, removal, wasting, deterioration, or impairment of any of the Joint Development Botulinum Product Assets until after their respective transfer to Ipsen.

#### III.

#### **IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint an Interim Monitor to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by the Orders and the Remedial Agreements. The Commission may appoint one or more Interim Monitors to assure Respondents' compliance with the requirements of the Orders, and the related Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent Allergan, which consent shall not be unreasonably withheld. If Respondent Allergan has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent Allergan of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the

relevant requirements of the Orders in a manner consistent with the purposes of the Orders.

- D. If one or more Interim Monitors are appointed pursuant to this Paragraph or pursuant to the relevant provisions of the Decision and Order in this matter, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of each Interim Monitor:
  - 1. The Interim Monitor shall have the power and authority to monitor Respondents' compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission;
  - 2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission;
  - 3. The Interim Monitor shall serve until the latest of:
    - a. the completion by Respondents of the divestiture of the Joint Development Botulinum Products Assets (including, but not limited to, the delivery of all Confidential Business Information in Respondents' possession or control to Ipsen) required to be divested pursuant to the Decision and Order in a manner that fully satisfies the requirements of the Orders and notification by Ipsen to the Interim Monitor that Ipsen is fully capable of completing the Joint Development Botulinum Products Key Clinical Trials;
    - b. the implementation of appropriate firewalls and other measures within the Respondents' business

operations to prevent the misuse or improper disclosure of Confidential Business Information; and

c. the completion by Respondents of the last obligation under the Orders pertaining to the Interim Monitor's service;

provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of this Order to Maintain Assets.

- E. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with their obligations under the Orders, including, but not limited to, their obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Orders.
- F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of the Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.

- G. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
- H. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order to Maintain Assets and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by Ipsen with respect to the performance of Respondents' obligations under the Orders or the Remedial Agreement. Within one (1) month from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Orders.
- I. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement;

provided, however, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.

J. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's

consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.

- K. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph or the relevant provisions of the Decision and Order in this matter.
- L. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- M. The Interim Monitor appointed pursuant to this Order to Maintain Assets or the relevant provisions of the Decision and Order in this matter may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets becomes final, and every thirty (30) days thereafter until Respondents have fully complied with their obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey relevant assets as required by Paragraphs II.A. and II.E.1. of the related Decision and Order in this matter, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order to Maintain Assets and the related Decision and Order; *provided*,

however, that, after the Decision and Order in this matter becomes final, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondents pursuant to Paragraph V of the Decision and Order.

V.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed (1) dissolution of the Respondents, (2) acquisition, merger or consolidation of Respondents, or (3) any other change in the Respondents that may affect compliance obligations arising out of this Order to Maintain Assets, including, but not limited to, assignment, the creation or dissolution of subsidiaries, or any other change in Respondents.

#### VI.

IT IS FURTHER ORDERED that, for the purposes of determining or securing compliance with this Order to Maintain Assets, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents made to their principal United States Office, Respondents shall permit any duly authorized representatives of the Commission:

- A. Access, during office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents relating to compliance with this Order to Maintain Assets; and
- B. Upon five (5) days notice to Respondents and without restraint or interference from Respondents, to interview

officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

#### VII.

**IT IS FURTHER ORDERED** that this Order to Maintain Assets shall terminate either:

- A. Three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. The latter of:
  - 1. the day after the divestiture of all of the Joint Development Botulinum Product Assets, as required by and described in the Decision and Order, has been completed and the Interim Monitor, in consultation with Commission staff and Ipsen, notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers and other transitions related to such divestitures are complete; or
  - 2. the day the related Decision and Order becomes final.

By the Commission, Commissioner Rosch recused.

### APPENDIX A TO THE ASSET MAINTENANCE ORDER

### NOTICE OF ANTITRUST REMEDY AND REQUIREMENT FOR CONFIDENTIALITY

On **[INSERT]**, Allergan Inc. ("Allergan") and Inamed ("Inamed") hereinafter referred to as "Respondents," entered into an Agreement Containing Consent Orders ("Consent Agreement") with the Federal Trade Commission ("FTC") relating to the divestiture of certain assets. That Consent Agreement includes two orders: the Decision and Order and the Order to Maintain Assets.

The Decision and Order requires the divestiture of assets relating to Reloxin®. These assets are hereinafter referred to as the "Reloxin® Divested Assets." Both the Decision and Order and the Order to Maintain Assets require Respondents to commit that no Confidential Business Information relating to the Reloxin® Divested Assets will be disclosed to or used by any employee of the combined entity formed by the acquisition of a controlling interest in Inamed by Allergan ("Combined Entity"). In particular, this is to prevent Confidential Business Information from being used in any way for the research, development, sale, or manufacture of any product that competes or may compete with the Reloxin® Divested Assets after the proposed acquisition. The Decision and Order also requires the complete divestiture of ALL documents (including electronically stored material) that contain Confidential Business Information related to the Reloxin® Divested Assets. Accordingly, no employee of the Combined Entity may maintain copies of documents containing such information, except as otherwise permitted by the Consent Order, required by law, or to comply with Inamed's obligations to terminate the Joint Development and Distribution Agreement with Ipsen.

Under the Decision and Order, the Respondents are required to divest the Reloxin® Divested Assets to Ipsen. Until a complete divestiture of all of the Reloxin® Divested Assets occurs, the requirements of the second order – the Order to Maintain Assets –

are in place to ensure the continued marketability, viability, and competitive vigor of the Reloxin® Divested Assets and to ensure that no Confidential Business Information related to Reloxin® is communicated to the employees of Allergan.

You are receiving this notice because you are one or more of the following: (i) an employee with work responsibilities related to Reloxin<sup>®</sup>; (ii) a Third Party Consultant to Inamed with work responsibilities related to Reloxin<sup>®</sup>; (iii) an employee of Allergan or the Combined Entity who has work responsibilities in some way related to products that compete or may compete with Reloxin<sup>®</sup>; or (iv) an employee, former employee, contractor, or former contractor of Inamed who might have Confidential Business Information in your possession related to Reloxin<sup>®</sup>.

All Confidential Business Information related to the Reloxin® Divested Assets must be retained and maintained by the persons involved in the operation of that business on a confidential basis, and such persons must not provide, discuss, exchange, circulate, or otherwise disclose any such information to or with any other person whose employment involves responsibilities unrelated to the Reloxin<sup>®</sup> Divested Assets (such as persons with job responsibilities related to Allergan's BOTOX® products or other products that compete or may compete with Reloxin®). In addition, any person who possesses such Confidential Business Information related to the Reloxin® Divested Assets and who becomes involved in the Combined Entity's business related to any product that competes or may compete with Reloxin<sup>®</sup> must not provide, discuss, exchange, circulate, or otherwise disclose any such information to or with any other person whose employment relates to such businesses. Finally, any Inamed employee, former employee, contractor, or former contractor with documents that contain information that he or she believes might be considered Confidential Business Information related to Reloxin® and who has not received specific instructions as to how the documents in his or her possession should be disposed of should contact the contact person identified at the end of this notice.

Furthermore, the Decision and Order places restrictions upon the functions that certain management level employees of Inamed, or certain contractors to Inamed, can perform for the Combined Entity until [insert description of length of these restrictions].

Any violation of the Decision and Order or the Order to Maintain Assets may subject Allergan, Inamed, or the Combined Entity to civil penalties and other relief as provided by law. If you have any questions regarding the contents of this notice, the confidentiality of information, the Decision and Order or the Order to Maintain Assets, you should contact [insert name and title].

#### **ACKNOWLEDGMENT**

I,	(print name),
hereby acknowledge that I have read the abo	ve notification and
agree to abide by its provisions.	

## PUBLIC APPENDIX B TO THE ORDER TO MAINTAIN ASSETS

## AGREEMENT CONTAINING CONSENT ORDER AND PROPOSED DECISION AND ORDER

#### Complaint

#### IN THE MATTER OF

#### VALASSIS COMMUNICATIONS, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4160; File No. 0510008 Complaint, April 19, 2006--Decision, April 19, 2006

This consent order relates to allegations that Valassis Communications, Inc., a publisher of co-operative free-standing inserts commonly found in Sunday newspapers, invited its only competitor to collude in ceasing to compete for customers, which would enable the firms to raise prices within their respective uncontested domains and to end the price war between them. The order prohibits Valassis from inviting collusion and from actually entering into or implementing a collusive scheme to divide markets, to allocate customers, or to fix prices. The order does not interfere with Valassis' efforts to negotiate prices with prospective customers, and it would permit Valassis to provide investors with considerable information about company strategy. The order also includes a safe harbor provision permitting Valassis to communicate publicly any information the public disclosure of which is required by the federal securities laws.

#### **Participants**

For the Commission: *David Conn, Sean Gates, Geoffrey M. Green,* and *Geoffrey Oliver*.

For the Respondent: Robert Pitofsky, Arnold & Porter LLP; Raymond A. Jacobsen, Nicholas R. Koberstein, and Mark Thoman, McDermott, Will & Emery LLP; and Brian L. Sullivan, Winston & Strawn LLP.

#### **COMPLAINT**

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that Valassis Communications, Inc., a corporation, has violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and it appearing to

#### Complaint

the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges in that respect as follows:

#### PRELIMINARY ALLEGATIONS

- 1. Respondent Valassis Communications, Inc. ("Valassis" or "respondent") is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 19975 Victor Parkway, Livonia, Michigan 48152.
- 2. The line of commerce relevant to assessing respondent's anticompetitive conduct is the production and distribution in the United States of cooperative free-standing inserts ("FSI's"). FSI's are multi-page booklets containing discount coupons for the products of various firms; these booklets are inserted into newspapers for distribution to consumers. For manufacturers of consumer packaged goods and others, FSI's are a uniquely efficient means of distributing coupons on a mass scale. Entry into the relevant market is difficult and is not likely to deter or counteract the competitive harm described below.
- 3. For over a decade, there have been only two U.S. publishers of FSI's: Valassis and News America Marketing ("News America"). On a typical Sunday, both the Valassis FSI and the News America FSI are distributed by hundreds of newspapers to over 50 million households.
- 4. Valassis is a publicly traded corporation, and holds a conference call with securities analysts on a quarterly basis. Any person may listen to the call live over the internet, or obtain a transcript of the call from the Valassis website. During these "earnings conference calls," Valassis executives provide information and answer questions about recent business developments.

5. As detailed below, during the course of an earnings conference call in July 2004, Valassis invited its competitor, News America, to join with Valassis in a scheme to allocate FSI customers and to fix FSI prices. Valassis intended thereby to bring an end to the price war being waged in the FSI industry.

### THE FSI PRICE WAR

- 6. Between 1998 and 2001, Valassis and News America each published approximately fifty percent of FSI industry pages. Valassis' minimum price or "floor price" during this period was \$6 per full page per thousand booklets.
- 7. In June 2001, Valassis notified its clients of a five percent price increase. On all future contracts, Valassis' FSI floor price would be \$6.30 for a full page. Valassis anticipated that News America would follow its FSI price increase.
- 8. News America did not follow the Valassis price move. As a result, News America captured additional customers and built up a substantial market share lead.
- 9. Valassis largely adhered to its \$6.30 floor price for eight months. In February 2002, Valassis determined that the company had waited as long as it could for a favorable signal from News America, and rolled back the price increase.
- 10. Over a three year period (2001-2004), FSI prices fell by nearly 20 percent due to competition between Valassis and News America. By 2004, FSI prices were below \$5 per full page. Valassis' strategic objective, announced publicly on numerous occasions, was to regain a 50 percent share of the FSI market.

# VALASSIS INVITES ITS COMPETITOR TO COLLUDE

11. In mid-2004, Valassis determined that its aggressive pursuit of greater market share was no longer serving the company's interests. Company executives developed a new strategy. Valassis

would communicate to News America its readiness to cease challenging for News America customers, provided that News America ceased competing for Valassis customers. This would enable each firm to raise FSI prices within its uncontested domain.

- 12. Valassis held its second quarter 2004 earnings conference call on July 22, 2004. Valassis executives were aware that News America representatives would be monitoring the call. A complete transcript of the earnings conference call is annexed hereto as Exhibit A.
- 13. The President and Chief Executive Officer of Valassis, Alan Schultz, opened the earnings conference call by detailing the company's new strategy for increasing FSI prices. Specifically, the following program was announced:
  - a. Valassis will abandon its 50 percent market share goal. The company will be content to maintain its current share (mid-40s). "[W]e can achieve our 2005 target for pages produced with no further shifts in co-op FSI market share." Exhibit A at 3.
  - b. As necessary, Valassis will aggressively defend its existing customers and its existing market share. "[W]e will defend our customers and market share and use whatever pricing is necessary to protect our share." *Id.* at 4.
  - c. But with regard to customers with expiring contracts with News America, Valassis will submit bids at a level substantially above current prices. Effective July 26, 2004, "we will quote all News America first right of refusal customers at the floor price which was effective in May of 2001; hence our net price after ancillary price discounts, rebates, et cetera, will not go below \$6 [per thousand] for a full page and \$3.90 [per thousand] for a half page." *Id.* at 3-4.

- d. With regard to the small number of customers that divide their FSI business between Valassis and News America, Valassis will seek to retain its current share of each customer's business, but not to encroach upon News America's position. "For Valassis/News America shared accounts we'll price our share at whatever price is necessary to retain our share of the business. If the client wants us to take more than our previous year's share, we will quote the new floor price [\$6 per thousand] on that portion of the business." *Id.* at 4.
- e. For a limited time, Valassis will continue to honor its outstanding bids to News America customers at market prices. "We have proposals currently outstanding to four News America customers where we have previously quoted lower than the 6 and 3.90 floor. We will notify these four clients that the price quotes in these previously delivered proposals will expire on August 1, 2004. Thereafter, after August 1, 2004, all News America customers or market share will be quoted at our new floor price." *Id.* at 4.
- f. Finally, Valassis will monitor News America's response to this overture. If News America competes for Valassis customers, then the price war will resume. "In the recent past News America has been quick to make their intentions known. We don't expect to read the tea leaves. We expect that concrete evidence of News America's intentions will be available in the marketplace in short order. If News continues to pursue our customers and market share then we will go back to our previous strategy." *Id.* at 4.
- 14. Valassis acted with the intent to facilitate collusion and without a legitimate business purpose.

- 15. Valassis' invitation to collude, if accepted by News America, would likely have resulted in higher FSI prices and reduced output.
- 16. The acts and practices of Valassis, including the acts and practices alleged herein, are in commerce or affect commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

# VIOLATION ALLEGED

- 17. As set forth in Paragraphs 11 through 16 above, Valassis invited its competitor to collude with Valassis in violation of Section 5 of the Federal Trade Commission Act, as amended.
- 18. The acts and practices of respondent, as alleged herein, constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices will continue or recur in the absence of appropriate relief.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this nineteenth day of April, 2006, issues its complaint against respondent.

By the Commission.

## **EXHIBIT A**

## VALASSIS COMMUNICATIONS #566835 July 22, 2004, 11:00 a.m., ET Chairperson: Alan Schultz Second Quarter 2004 Earnings

Operator

Good morning, ladies and gentlemen, and welcome to the Valessis Communications Second Quarter 2004 Earnings conference call. At this time all participants are in a listen-only mode. Following today's presentation instructions will be given for the question and answer session. If anyone needs assistance at any time during the conference, please press the star followed by the zero. As a reminder, this conference is being recorded on Thursday, July 22, 2004. Please refer to the Safe Harbor language on the earnings document released this morning. This call will be governed by the language stated thereon.

I would now like to turn the conference over to Mr. Alan Schultz, Chairman, President and Chief Executive Officer of Valassis Communications. Please go ahead, sir.

A. Schultz

Good merning. I'm here with Bob Recchia, our Chief Financial Officer, and Sherry Lauderbach, our Director of Investor Relations.

Today's agenda will include the following: a review of our record quarterly revenue, a discussion of business segments or specific products. I'll elaborate on the opportunity to improve co-op FSI industry pricing mentioned in the press release. I'd like to share some highlights from our continuously improving balance sheet and then of course as always we'll answer any questions that you may have.

Our quarterly revenue of \$257 million is the best in company history. We were pleased with 5.6% revenue growth, particularly when you consider it's on top of 20% revenue growth schieved in the second quarter of 2003, so we had a difficult comp.

As we have expanded our product portfolio it has created additional levers to drive both revenue and profitability. In addition, the broadening of our customer base has created a fertile platform to cultivate this expanded product and services portfolio.

We now do business with 79% of the top 100 advertisers in the United States. In short, I find our diversified product portfolio a tremendous luxury and we are fortunate to have the support of so many outstanding advertisers who participate in a wide variety of industries.

Our one-to-one business performed exceptionally well in the second quarter

### **EXHIBIT A**

with a 17% increase in revenue. Most importantly this segment crossed the bridge to profitability in the second quarter and the quarterly profit was significant enough to make the one-to-one segment profitable through the first six menths of 2004.

I'm really proud of what this team has accomplished and there are a number of people and teams worthy of recognition. Sue Griffin, Ron Goulsby and Todd Wisely have done an outstanding job of getting our three previously autonomous one-to-one business units to work together to meet customer needs. The level of collaboration has been exemplary.

Drew Bennes and his team have played a critical role in using our best of breed frequent shopper management technology to drive other parts of our one-to-one business and to forge stronger relationships with our retail partners.

Lou Zanko and his retail sales team have done an outstanding job of presenting creative concepts to our retail partners in order to help them accomplish their goals and objectives.

Robin Marcot and the Direct Mail Operations Group have worked unbelievably hard to support the volume increases associated with our 77% revenue growth.

Gary Youst and the Targeting and Analytics Team have overcome numerous challenges.

Auren Trager and his Anderson Printing Division have stepped up to not only handle the increased volume but to do so with substantial improvements in efficiency levels.

Last but not least, Rex Bostright and our Creative Teams in both Levonia and Boston have produced high quality creative to assure substantial consumer response.

After achieving profitability on a stand-alone basis I'm extremely excited about the future prospects of our one-to-one segment.

Switching to our cluster targeted segment. As I previously indicated, the primary focus of our cluster targeted segment was to improve profitability. I told you we were going to trade out low margin business.

As we drove revenue growth in other product lines that was beyond our expectations we accelerated the divestiture of less profitable cluster targeted business. As a result gross profit dollars were up 3.3% in the second quarter even though revenues were down just over 12%.

### **EXHIBIT A**

Through the first half of 2004 gross profit dollars were up 27% on virtually flat revenue. Since this segment continues to focus primarily on profitability we are revising our revenue growth assumption from the low end of 10% to 15% to less than 10%.

Keep in mind that last year we focused primarily on revenue growth and achieved a 26.3% increase so the revenue comparisons this year are challenging. Also keep in mind that this business by nature does not track consistently on a quarterly basis year against year.

Now switching to the international and services segment, we executed an explan performance. Strong performances in Canada, Spain, Italy and the United Kingdom offset softness in France. We delivered prumotional media tests in Germany and Italy and we are currently selling in a second test in Germany. In addition we are attempting to sell clients into new concepts in Spain and France which we hope to execute this fall.

I recently vished Italy and Spain and was encouraged by the level of customer interest in and receptiveness to new promotional concepts.

Moving onto the math segment. Let's start with our ROP business where we broker space on the pages of the newspapers in our database. We encourage you to focus on gross margin dollars in this business. In 2004 our goal is to increase margin dollars by 10% to 15%. We have exceeded that goal through the first half of 2004 and the reported revenue increases are consistent with our original assumption of over 80%.

Now I'd like to discuss the co-op FSI industry. When we developed our 2004 guidance we assumed the co-op FSI industry unit growth would be low single digits. Unit growth has continued to exceed our expectations and the industry drove its eighth consecutive quarter of year-over-year unit growth. As a result, our co-op FSI revenue was up 1% for the first six months of this year. In essence we have been able to achieve our page volume objectives with less than a 50% market shere due to industry strength.

In addition some clients, who have long term agreements with us, recently indicated they plan to run more FSI pages with us in 2005. When you combine this knowledge with the fact that 80% of all co-op FSI pages for 2005 are now covered by corporate contracts which average 30 months in duration, we believe we can achieve our 2005 target for pages produced with no further shifts in co-op FSI market share.

Based on these conditions we believe that now is the time to create a low risk opportunity to change the long term pricing trends in the co-op FSI industry. Therefore effective Monday, July 26th we will quote all News America first

## **EXHIBIT A**

right of refusal customers at the floor price which was in effect in May of 2001; hence our net price after ancillary product discounts, rebates, etc., will not go below \$6 for a full page and \$3,90 for a half page.

The reason I said this is a low risk opportunity is that we will defend our customers and market share and use whatever pricing is necessary to protect our share. For Valassis/News America shared accounts, we will price our share at whatever price is necessary to retain our share of the business. If the client wants us to take more than our previous year's share, we will quote the new floor price on that portion of the business.

This strategy differs greatly from the price increase we attempted in June of 2001 where we were willing to walk away from business in order to demonstrate our resolve to improve industry pricing and our willingness to reduce our share down to historical levels. In the current situation we will not walk away from our existing customers or market share. We have proposals currently outstanding at four News America customers where we have previously quoted at prices lower than the \$6 and \$3.90 floor. We will notify these four clients that the price quotes in these previously delivered proposals will expire on August 1, 2004. Therefore, after August 1, 2004, all News America customers or market share will be quoted at our new floor price.

In the recent past News America has been quick to make their intentions known. We don't expect the need to read the tea leaves. We expect that concrete evidence of News America's intentions will be available in the marketplace in short order.

If News continues to pursue our customers and market share, then we will go back to our previous strategy. Our objective has always been to give customers a high quality product that provides them with an exceptional return on investment and while doing that, to foster an industry that maximizes our profitability and creates a platform for long term profit enhancement on an annual basis. We believe the pricing approach I just described has the potential to accomplish all those objectives.

At we have mentioned previously, we believe that an exceptionally strong balance sheet is an important attribute to maintain in this highly competitive co-op FSI environment. I want to review major changes in our cash balance during the quarter and a transaction to swap \$50 million in fixed debt for floating debt.

As of March 31, 2004 we had \$214 million in cash. We made two tax payments in the second quarter which totaled \$28 million. On June 6<sup>th</sup> we repurchased \$39 million of our convertible bond due in 2021 and speat an additional \$8 million in the quarter against our authorized share repurchase program. That nets cash down to \$139 million, but as of June 30, 2004 we

## **EXHIBIT A**

had \$164 million in each meaning we generated roughly \$25 million in each from operations during the quarter without going into all the ins and outs.

From a financial perspective we also swapped \$50 million of the \$100 million issue of our 6-5/8th percent fixed rate debt due in 2009 to a floating rate on June 29, 2004.

Now we'd like to eracrtain your questions. Thank you.

Operator

Thank you, sir. Ladies and gentlemen, at this time we will begin the question and answer session. If you have a question, please press the star followed by the one on your pushbutton phone. If you would like to decline from the polling process, please press the star followed by the two. You will hear a three-tone prompt acknowledging your selection. Your questions will be polled in the order they are received. If you are using speaker equipment you will need to lift the handset before pressing the numbers. One moment, please, for our first question.

Our first question comes from Lauren Fine with Merrill Lynch. Please go ahead with your question, ma'arm.

L. Fine

Trank you. I have two questions. The first just to go back to the quarter for a second. On the FSI business I think you had one extra publishing date and I'm wondering if you could then help us because of that making it more difficult to assess, what was the industry unit growth in the quarter and/or what is your page increase year-over-year? Then related to that, where are we on a reported basis in terms of whether your pricing has troughed yet?

Then could you refresh our memory on what your market share goals were for this year and whether that's changed and what they are for next year? Then I'll come back with my next question.

A. Schultz

Lauren, we'll check my memory here now.

L. Fine

Breaking down FSI into the components is what I'm really trying to get at in the second quarter.

A. Schultz

The number of dates, we did have one additional date in the second quarter versus what we had last year. So last year we had 10 dates, this year we have 11 dates. From a custom co-op standpoint, last year we had three and this year we also had three, so it's just really the one date difference.

From a unit growth standpoint we once again saw unit growth north of 6%. Obviously we had anticipated low single digits and we did significantly better than that.

## **EXHIBIT A**

From a page standpoint, particularly on a pages sold basis, full price business, we saw high single digit growth in pages sold and then we had a slight increase in the number of direct response pages. That's how that broke out.

From a pricing standpoint right now as we look through the balance of this year, we had built the model that accounted for some reductions in price as we got into the second half of this year. I don't really think anything has changed in that model. You may remember in the fourth quarter of last year we got into a situation where we had under-estimated the impact of declining prices and we didn't want to repeat that so we built our model this year more in line with what we had experienced last year.

I can't tell you that pricing has bottomed out yet at this point. It's going to be interesting to see obviously what happens with our new pricing approach in terms of the impact that has on the industry in terms of pricing.

From a market share goal standpoint, we're pretty comfortable with where our share stands today and what we have in the way of business locked up out in the future for the back half of this year and what we have secured for 2005.

Where we currently stand we don't really see any need to change market share from what it already looks like today for the balance of 2004 and 2005. The industry looks to be very strong and the supply/demand economics are clearly working in our favor and those supply/demand economics should create some pricing leverage in the industry.

L. Fine

Just to refine that, where is your share now? Then on the pricing improvement that you're trying to put in place, it sounds like that is a goal to stabilize pricing from where you've got some contract bids out right now. Would you care to share what you think Newscorp will do in response?

A. Schultz

I certainly can't speak for *Newscorp* so I certainly don't know what they're going to do in response. The approach we're taking I view as more than stabilization though. I think it is a strategy which is designed to return prices at least to the floor level that was in place back in May of 2001.

Now keep in mind at that particular point in time we were actually selling at prices that were well above that floor price so this is really designed to try to return pricing to the old floor level which would be a step in the right direction and create a longer term trend line of improved pricing and therefore improve the profit picture on a going forward basis.

L. Fine

And your current share?

## **EXHIBIT A**

A. Schultz

Our current share is pretty much on plan for what we had anticipated. The way we measure our shares, we look at all the co-op volume when we measure shares so we include our regular co-op and our custom co-ops in share. We're in the mid-40s right now and look like we're up on plan for increasing share as we had indicated in 2004 for 2004.

L. Fine

Great. Thank you very much.

Operator

Our next question comes from Steven Barlow with Prudential Equity Group. Please go sheed with your question, sir.

S. Barlow

Thank you. Could you break out what was going on in cluster targeted in terms of was it VIP that was up or sampling was down? Just trying to get a handle on the pieces there.

Bob, it looks like you have reclassified the \$13.6 million of debt back to long term, so I guess there's no thought of that being paid out because not everyone went for the offer that you had. I just wanted to clarify what the thoughts are on that.

Then, Al, you made a comment that flat revenue on the international, etc., section was on plan. Is that your plan for the third and fourth quarter for that revenue in that group to be flat? Thanks.

A. Schultz

The cluster targeted business when you break it out in its components in the quarter, we actually saw a mid-single digit decline in preprints which is the biggest component. In the polybag sampling and advertising, we were down a larger percentage of that, a double-digit decline there.

Again, that is very consistent with what I instructed this group to do which was try to filter out some of the lower margin business, as I had mentioned. Last year we grew revenue in that segment by 26%. In doing that we picked up some customers that were at unacceptable margins. And based on what we see going on in the printing industry in general where it looks like volumes are picking up, margins are picking up, we feel as if conditions are right to focus more on profitability.

With all that said, I think it's important to note that this business tends to have some pretty wild swings on a quarterly basis year against year. In fact, if you look back at the last few years you'll see swings from one quarter to the next where revenues were down 12%, 14%, 15% and then come back and increase by over 40%. So this isn't unusual and they're really doing at this point in time what I'm asking them to do.

From a debt perspective on the \$13 million, that debt does not have an opportunity to be put to us for another two years so therefore it would be into

## **EXHIBIT A**

long term classification and at this point in time we have no current desire or no plans I should say to pursue that debt to bring it back in.

Flat revenue for our international and services as far as subsequent quarters go, the answer to that is no. We expect that we're going to have revenue growth in our international and services sector in the second half of this year. In fact, some of the test programs that we're delivering that will generate some test revenue will fall into the third and fourth quarters which should improve the revenue picture there.

If you remember, overall if you discount the extra month and a half of revenue from NCH, we expected low to mid-single digit revenue growth. We think we're still on plan to deliver that. There's really no change in our essumption there.

S. Barlow

Just to clarify on the one-to-one, is that a gross profit that they were in the positive territory?

A. Schultz

No, that is a net pretax profit and that is on a stand-alone basis. As you know in the past we had felt as if our one-to-one unit was in fact profitable because when we looked at other business from other product lines that we were able to secure from customers that we were able to attract because of our one-to-one capability, we thought when we looked at it from that standpoint the business had crossed the line into profitability last year. But now we're looking at it totally on a stand-alone basis, not looking at any of the other ancillary benefits associated with those customers and we are talking about a not profit after all SG&A.

I think it's a very, very important milestone for the business that was achieved in the second quarter. Again, just to reiterate, it was a significant enough profit that it offset the loss from the first quarter so that we're now looking at a net pretax profit through the first six months of the year that's north of a half million dollars.

S. Barlow

Thanks very much.

Operator

Thank you. Our next question comes from Fred Searby with JP Morgan. Please go shead with your question.

F. Searby

Good marning, everybody. One or two questions, Alan. It sounds historically you've said to me and you're strategizing and I think you've said that it really is up to the market share leader to make price moves and you expected *News America* to raise prices and then we had this circ increase which you all were somewhat skeptical of.

What's the reversal here in that thought? You're trying to actually raise prices

### **EXHIBIT A**

now. Obviously News America's not budging. Then on your existing accounts, have there been any major account losses? The market share ... you say you're in line with guidance, and my assumption was in the past that you thought you'd get back to 50% and it sounds like you're going to be still in the 40s next year.

A. Schultz

From an existing account standpoint there really haven't been a lot of changes from a market share standpoint. From a historical standpoint the answer to your question is yes, historically the market share leader has always been the price leader. With that said I think as a management team and as a company it's important that you're always alert to new possibilities. It's always important that you're creative to consider new ideas, new concepts and that you're agile enough not flexible enough to take advantage of opportunities that may present themselves in the marketplace.

We clearly believe that based on what's going on from an overall industry growth standpoint, it has created somewhat of a unique opportunity for us. We feel as if the pricing approach that I laid out is a very creative and unusual strategy that has never been attempted or implemented in the past.

Again, that's our job to take on that responsibility that and we have a duty to look for ways to improve the long term pricing trend in the FSI industry.

As far as our 50% market share goal, I think when you really get to the underlying goal, our goal, has always been to create a long term, more profitable FSI industry to create a long term, more profitable Valassis. We feel that's in the best interest of all the stakeholders involved in the FSI industry, certainly including our customers. We feel the current market conditions have created a better alternative to achieve that goal.

We are merely being alert in recognizing the opportunities that exist and flexible in adjusting our strategy to best accomplish our goal. We believe our goal can best be accomplished with no further changes in market share from where we're at today.

F. Searby

Speaking of creative, on the circ issue when they raised their circ and you said it was somewhat dubious and would fall flat on its face, how has that done for them because it was a de facto price increase, right?

A. Schultz

From the measurements we've done so far, what we tend to look at is what is the average full run circulation for Valassis and what is the average full run circulation for our competitor. What we've seen is that there are really no differences between us and them in terms of what clients are buying in terms of their full run circulation.

F. Searby

Again, congratulations on some results in light of the challenging conditions.

J. Choy

A. Schultz

A. Schultz

### Complaint

# **EXHIBIT A**

A. Schultz Thanks, Fred, appreciate that.

Operator Our next question comes from Alexia Quadrani with Bear Stearns. Please go ahead with your question, ma'arn.

This is Julian Choy. I have some questions on behalf of Alexia. A couple of questions here. Just wondering how your pricing is on contracts today compared on average to pricing on contracts signed last year. And I also wanted to know how paper prices are trending for the full year.

Julia, we haven't really given any guidance in terms of what's going on on a day-to-day standpoint in terms of contract pricing so I can't really comment on that.

As far as paper prices, we had anticipated that paper would increase in terms of pricing during the year and based on what we currently see today paper prices are increasing as we had anticipated that they would increase.

J. Choy Is that the 8% to 9% increase?

There's really nothing here that is surprising us. When you look at paper in terms of what we had built into our models for the year we had assumed that we'd have a mid to high single digit price increase as a result of the contracts that we have in place through 2005 particularly in the FSI business that have caps and powers in them, cap quanerly increases and then cap annual increases.

Right now it's preny much on plan and then because of some of the increased volumes that we've talked about, some of which we had anticipated and some of which we had not anticipated, that increased volume has helped us from a media cost standpoint and helped us from a production cost standpoint.

I also want to make note that from a production cost standpoint or a printing standpoint, clearly our manufacturing teams have done a very nice job, had a very good quarter in the second quarter. Then some of the capital additions we've made on the Man Rolland presses have also been highly efficient presses. As a result of that, the combination of media and printing costs have really offset that price increase in paper to basically give us a flat cost of goods sold in the co-op FSI.

Given your better than expected share repurchase activity this quarter, I think it's about twice the amount that you purchased last quarter, are you comfortable with current levels?

Comfortable with what levels, Julia?

VALASSIS COMMUNICATIONS

J. Choy

A. Schultz

### **EXHIBIT A**

J. Choy

With the current amount of shares that you're repurchasing?

A. Schultz

We've taken the approach that says that we want to be opportunistic from a share repurchase standpoint, we want to try to buy as many shares as we possibly can for the money. We do have the ability per our Board to spend 75% of our free cash flow on share repurchase if we elect to do that. We havent elected to do that but I would describe our strategy as it relates to share repurchase as being very flexible, kind of dependent on market conditions.

J. Choy

Thank you.

Operator

Thank you. Our next question comes from Troy Mastin with William Blair and Company. Please go ahead with your question, sir.

T. Mastin

Good morning. Being this far into the 2004 contracting season and with what I think are now longer contracts at 30 months, correct me if I'm wrong there, when might this attempted price increase begin to have a meaningful impact on prices? When could we start to see your effective prices on the FSI going up in aggregate if this price increase works?

A. Schultz

The way to look at it, Troy, is that there's about 15% of the business that really never gets covered by a corporate contract. That's what we describe as the bid business. In theory that 15% of the business could start to be priced at higher levels in a relatively short period of time. It has the potential, those prices, to gravitate up near the floor.

Then when you assume the length of contracts which you are correct, that is longer than what we've had previously in terms of length of contracts. I think you have to assume that somewhere between 30% to 40% of the business in any given year, the contract is likely to expire and then the prices on those contracts would step up over time as contracts expire. So I think that's the way you have to look at it.

Then probably the one other factor to be considered is that this is a category, exclusive medium, which means that there are times where business cannot be placed with the company that has the contract because of category blockage problems and then that business ultimately goes to the non-contracted company, typically at higher prices. So in this case from our perspective that would be our floor price.

Today that's a selatively small percentage of the business based on current industry practice but if the supply/demand equation continues to work in our favor and we continue to see strong increases in demand with really insignificant increases of supply or days and a change in business practice, a

# **EXHIBIT A**

larger percentage of the business could go to the non-contracted company and I would assume that if this were to all come to fruition that it would be at those floor prices.

If you took all of those factors into consideration, Tray, that would be the way to look at it.

T. Mastin

Can you give an idea in a reasonable or maybe even a best case scenario when you might finally start to enjoy average FSI prices increasing?

A. Schultz

At this point in time we're going to continue to look for some type of concrete evidence in the marketplace. As I had mentioned earlier, we've seen our competitor make their intentions known relatively quickly and we're going to monitor that situation on a daily basis.

T. Mastin

Onto the one-to-one business, is there any temporary benefit at this business as a result of competitors that have de-emphasized or shut down their operations that might not be recurring or would you characterize the growth in one-to-one as purely fundamental or maybe industry organic?

A. Schultz

Troy, you've got a little bit of everything going on here. There is no doubt that there is organic growth taking place in the one-to-one business. That's being driven by a number of factors, one of which is the macro trends that we have talked about.

You've got the do not call registry where you've got a huge amount of dollars that are shifting from telemarketing into other promotional media vehicles. You've got the consumer evasiveness issue, the satellite melio, the TV fragmentation, the TTVO, the desire on clients, to link their marketing spend to revenue generation and ROI. All those things create a very positive picture for our entire product portfolio and certainly the direct mail business.

There's no doubt that we are seeing organic growth taking place there. Clearly we're benefiting as a result of our competitors in the marketplace changing strategies and their future being somewhat in question from a share standpoint. But there's no doubt that we're seeing growth there and from a consumer package goods industry standpoint, consumer package goods companies seem to be very committed to direct mail being part of their overall marketing mix.

Of course our overall strategy as a company is to be the only company that offers mass delivered promotional products, cluster targeted or neighborhood targeted products and one-to-one targeted products and the only company that has the ability to integrate all those into a single solution.

T. Mostin

Then finally one more question. Have you seen any negative impact as a

### **EXHIBIT A**

result of the circulation issues that have come up in a few newspapers? I know they might not be too relevant to your circulation but more specifically do you sense that advertisers are less interested in using the freestanding insert? Have you had any conversations along those lines despite the strong volume trends you've been steing?

A. Schultz

The answer to that is no. We have not heard a lot of clients, in fact we have heard very little if any client discussion on the subject of what's going on at these three newspapers, The Sun Times, Long Island Newsday and Hoy [inaudible] in New York.

I want to assure you also that as I've discussed before we've always believed in a high quality market list. We only provide newspapers with the number of inserts that we're comfortable they can distribute and that will ultimately get into the hands of the consumer.

We also give the newspapers an order of distribution. An example would be we say first we want you to cover the paid home delivered circulation within the MSA, then we want you to cover paid home delivered circulation outside the MSA, then go into the paid box within the MSA, then out of the MSA and then our last choice would be to go into TMC programs. Based on everything we know today, we believe that all of our inserts ultimately have reached consumers in the order that we have specified.

I would also point out that we have a division called Promotion Watch which does promotion security consulting. That group does random audits of our newspapers and they have done over 20 random audits this year and based on what we learn as a result of this situation with the newspapers, they will revise their audit procedures to make sure we're looking for some of the problems that materialize at these three newspapers. These three newspapers will not be audited in the future on a random basis but on a specific basis. So we're pretty comfortable with this issue.

T. Mastin

Thanks a lot.

Operator

Our next question comes from Mark Bacurin with Robert W. Baird. Please go ahead with your question, sir.

M. Bacurin

Good morning. Alan, I'm hoping I can dig in on this new pricing strategy a little bit. First I wanted to follow up on a comment you made in response to Troy's question. You said you have seen your competitor make their indications known on this new pricing strategy and you're going to continue to monitor it. Am I to read into that you've already tried this and you've actually seen News America make some sort of response?

A. Schultz

No. When I said that we expect News America to react relatively quickly

# **EXHIBIT A**

what I mean is from what we've seen over the last two years we've seen News America make their intentions known relatively quickly. We would assume, we don't know for sure but we would assume at this point that their track record of the last two years would continue.

M. Bacurin

I understand. Then as I understand the strategy you will not be pushing forward the new pricing floor on renewals with existing clients but only on business that you currently do not have, is that correct?

A. Schultz

That is correct, yes.

M. Bacurin

What about renewals for more volume? Would you implement the new floor on incremental volume from those same clients?

A. Schultz

If it was a first right of missal customer with Valassis the answer to that is no, not at this point in time. But if it was a client that was shared between Valassis and News America then the answer to that question is yes. If they wanted us to take on incremental market share, incremental volume beyond our share percentage then the answer to that is yes, we would implement the floor.

M. Bacurin

As I understand this strategy then this will not necessarily move pricing up for you; the only place you would see a price increase is if you took a competitive win against *News America* and then vice versa, if they respond with a similar increase to the price floor they theoretically shouldn't be taking any clients from you at a higher price point unless it's at a higher price point?

A. Schultz

Yes, that is correct. I think there's another side of this that you probably need to consider which is if it's a News America renewal and we're quoting the floor price and they currently have a contract which is less than the floor price, then they would cenainly have an opportunity to move their pricing up also. It's hard to say what the impact of that will be.

M. Bacurin

I understand. Assuming that strategy works to your benefit and pricing moves up on these renewals, as you said, I guess most of the contracts are locked in for '05 except for some spot type business that you might achieve. So we would actually expect those benefits to start accruing more in the '06 timeframe?

A. Schultz

Yes. You'd see benefit in the spot business and then as I have mentioned in the conversation, I believe it was with Troy, where there is some business that moves back and forth between the companies if one of the companies is blocked from a category standpoint, that business would also go up. That's currently a relatively small percentage based on practice but the answer to the question is you're correct. The bulk of the opportunity would materialize in '06.

### **EXHIBIT A**

M. Bacurin

Assuming there has been some clasticity of demand with the lower pricing, are you concerned that if prices do move back up that the volumes you're assuming that you might be able to achieve at this lower market share level might actually decline with the higher price point such that you're back in a position where you're not necessarily getting the same kind of profitability out of each book that you would hope?

A. Schultz

As I had mentioned, again I think it was in the conversation with Troy, I think there're some macro trends that are really moving dollars in our favor and that is the desire by clients to link marketing spend to revenue generation.

The FSI has by far the best return on investment bar none, it's an outstanding vehicle for a return on investment standpoint. Even at the floor pricing it's an outstanding return on investment versus where we're pricing at today. Then there's of course these issues with television that we are all well aware of with TIVO and the personal recording devices and the popularity of satellite internet radio which is commercial free.

Consumers these days want to be in charge of when they receive messages and what messages they receive. The bottom line is that consumers invert time these days, they want value for that time and our products typically provide some type of value.

Then we've got a number of clients that have had tremendous success in the industry and in their business by using our products and I think that has a positive impact on other products.

We need to also keep in mind that we experienced strong unit growth in this industry for the last eight quarters and when you go back in time, that's when prices were relatively stable. When prices were higher than what they are today, when you look at the possibility of returning this industry to the floor pricing that existed back in May of 2001, please keep in mind that we were selling at that time at prices that were significantly higher than the floor. That was still providing clients with a great return on investment and at that time we really didn't have clients that were complaining about the price level.

I think that there is some price elasticity in our industry and some of the growth we have seen as a result of price but I clearly don't think that returning to our floor price with all these other macro trends taking place will dampen demand in a significant way.

M. Becurin

Then, Al, in terms of how you see the response from News America, is it a function of whatever contracts are up right now you go out with a new floor price. If it's a News America client and then you learn back from that client

# **EXHIBIT A**

	what the pricing actually was done with News America assuming they keep it, but at a higher price point? Is that how it works or what is the feedback you get?
A. Schultz	We try to monitor the market in a number of different ways. We will use every means at our disposal to try to monitor the situation. What you just described is certainly one way to determine what's taking place in the marketplace but there are a number of different ways that we would monitor the market.
M. Bacurin	Great Thanks a lot.
Operator	Our next question comes from Edward Atorino with Fulcrum. Please go ahead with your question.
E. Atorino	My question's been basically answered about seven times so I won't try to go over it again. One other question, on the refinancing, what does that do to your interest expense going forward? I presume it takes it down a notch or two?
A. Schultz	Ed, the first thing I want to do is correct the name. It's Ed Atorino.
E. Atorino	Close enough.
A. Schultz	I just want to make sure everybody's clear about that. With that said I'm going to let Bob give you the answer in terms of interest expense and the impact that the swap will have on an anticipated basis for the back half of this year.
B. Reochia	Ed, it will take down our overall interest expense obviously depending upon what rates do going forward. But immediately it reduces our interest expense from the 6-5/8ths down by a couple of percentage points plus.
E. Atorino	It should be under 3 then for the balance of the year?
B. Recchia	Percent?
E. Atorino	Dollars, millions. You were \$3 million in the second, \$3.1 was it? \$3 million for the second quarter.
B. Recchia	It should come under \$3 million for the next two quarters, that's correct.
E. Atorino	Thanks. I'll talk to Sherry offline and go through some more stuff. Thanks.
A. Schultz	Thanks, Ed.

### **EXHIBIT A**

Operator Our next question comes from Richard Diamond with Inwood Capital.

Please go ahead with your question, sir.

Hi, Al. What happens if *Newscorp* decides to continue to be irrational in the co-op advertising business? The reason 1 mention this is that the price war has been irrational from the start. What's the downside case and how does that play out?

When you consider the increased client demand for co-op FSI pages and you couple that with really no significant increase in date supply, we think we're at a point where we believe both FSI companies can achieve significant volume with their current market share positions.

Generally this type of supply/demand equation typically leads to increased pricing power and logic would suggest that this condition provides an opportunity to create a positive long term pricing trend. So clearly that pricing trend could lead to increased profitability.

Clearly as we assess the situation we think it makes sense. If it doesn't work, we will continue to look for creative ideas and opportunities to improve our profitability. We'll try to do so sooner as opposed to later.

We believe today's market is very fluid and dynamic and this type of market presents opportunities but you've got to be constantly alert and you've got to quickly identify the opportunities and then of course you need to be agile enough to develop and execute a strategy in the marketplace. I think our objective's clear - how do we create an FSI industry that will improve our profitability. That's our ongoing responsibility not only in the FSI industry but it's our ongoing responsibility in every business we participate in.

R. Diamond Thank you very much, Al.

Our next question comes from Jim Kostell with Cuyahoga Capital. Please go ahead with your question.

Hi. It's Jim Kostell. A couple of questions. First of all I may have this statistically incorrect because it's been a long day and my typing isn't so good but it appears that the accounts receivable relative to days sales have gone up

here a bit. Is that correct and could you address why that is?

A. Schultz I'm going to let Bob handle the accounts receivable question.

It's up at about \$258 million at the end of the quarter and once again it's mostly timing. We had a couple of major programs where monies came in the first week of July and that threw us up higher. When you look at actual days sales and receivables it hasn't moved all that much.

R. Diamond

A. Schultz

Operator

J. Kostell

R. Recchie

## **EXHIBIT A**

The other part of it is some increased volume at NCH that we're seeing drive up the receivables number as well.

Once again it's mainly a timing issue. There's no real major trends or problems with collectability. It has a lot to do with the volume of business we're taking through in the ROP business and the volume we're taking through at NCH as well.

J. Kostell

Is my addition here of 90 days versus 66 correct?

B. Recchia

Well, if you take a simple point in time and measure it you can get that but we measure it on a rolling basis and unfortunately when you just grab the end of the month it can lock really good and really bad. What I would tell you that the numbers are up slightly because of the type of businesses that we've ventured into and the receivable dynamics in getting paid but nowhere near 90 days.

J. Kostell

Secondly, it's been so long since May of '01 I can't even remember where I worked then. Could you tell me, the \$6 and the \$3.90, that's up about 20% from where prices are now?

B. Recchie

I can't get into that with you, Jim.

J. Kostell

Can you make any comment as to the general level of the pricing over that period of time?

A. Schultz

What we can say is that we've been in a declining price environment since basically June of 2001. I guess it was relatively stable at that period and then we went through a period of decline and clearly this is an attempt to change that trend line and create a positive trend line in terms of pricing and reverse that negative trend line.

J. Kostell

I was sitting here trying to think about how a customer would feel about this in a sense that if I've got a contract with you and I come to you and say I'd like to do some more volume with you and you say okay but it's up an awful lot in terms of price ... have you gone and talked to any of your customers about this and felt them out ahead of just implementing this?

A. Schultz

We have talked to customers on an ongoing basis and have told them that we feel like the current pricing environment is not a realistic pricing environment and that prices will need to ultimately at some point return to more historical levels. I don't think there's any clients that I've come across that would disagree with that. Certainly clients appreciate the lower prices, certainly clients want to take advantage of the lower prices as anyone would but we've been trying to do a good job on an ongoing basis to educate our clients that

## **EXHIBIT A**

this is a snapshot in time, an opportunity in time for them to take advantage of lower prices and at some point in the future that window's going to close and that opportunity is no longer going to exist. Certainly every client I've talked to understands that.

J. Kostell

In terms of your comment about you'll see the response pretty quick, is pretty quick generally speaking defined in days, weeks, a month? What does the word pretty quick mean?

A. Schultz

I would think in this situation we're talking about weeks.

J. Kostell

Thank you very much.

Operator

Management, at this time we have no questions. Please continue with any further remarks or closing comments that you would like to make.

A. Schultz

Thank you. Just in closing I'd like to point out the fact that our first half performance was strong and as a result of that strong performance in the first half, it's allowed us to tighten up our annual earnings guidance and we have updated our 2004 carnings per share range which was \$1.65 to \$1.85 to \$1.85.

It is our sense that the strengthening economy has resulted in growing marketing budgets and increased demand for our products. We clearly believe these conditions create an opportunity to improve margins across our entire product portfolio while at the same time encouraging customers to consider our integrated solutions for which we have already sold 25 this year.

We're encouraged by what we've seen through the first six months of this year. Wa're at the halfway point, we clearly have a lot of work to do but we are optimistic about the future.

I'd like to thank you for your time, your questions and your interest and have a great day.

Operator

Ladies and gentlemen, this concludes the Valassis Communications Second Quarier 2004 Earnings conference call. If you would like to listen to a replay of today's conference please dial in to 1-800-405-2236 or 303-590-3000 and use the access code of 566835.

We thank you for your participation. You may now disconnect and thank you for using ACT Teleconferencing.

# **DECISION AND ORDER**

The Federal Trade Commission having initiated an investigation of certain acts and practices of Valassis Communications, Inc. (hereinafter referred to as "Respondent"), and Respondent having been furnished thereafter with a copy of the draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order ("Consent Agreement"), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Order:

1. Proposed Respondent Valassis Communications, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware,

- with its office and principal place of business located at 19975 Victor Parkway, Livonia, Michigan 48152.
- 2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

### ORDER

I.

**IT IS ORDERED** that, as used in this Decision and Order, the following definitions shall apply:

- A. "Valassis" or "Respondent" means Valassis Communications, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled, directly or indirectly, by Valassis Communications, Inc.; and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. "News America" means News America Marketing and The News Corporation Limited, their directors, officers, employees, agents, representatives, successors, and assigns; their subsidiaries, divisions, groups, and affiliates controlled, directly or indirectly, by either News America Marketing or The News Corporation Limited; and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. "Commission" means the Federal Trade Commission.
- D. "Competitor" means News America and any other person engaged in the business of publishing, producing, distributing, or selling FSI's.

- E. "Consultant" means any person retained by Valassis to provide advice or assistance to Valassis relating to its pricing or marketing strategy.
- F. "Designated Employees" means each employee of Valassis with direct or supervisory responsibility for investor relations, sales, or marketing.
- G. "Federal Securities Laws" means the securities laws as that term is defined in § 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. § 78c(a)(47), and any regulation or order of the Securities and Exchange Commission issued under such laws.
- H. "FSI" means free-standing insert, and includes any multi-page booklet or other publication containing coupons or advertisements that is inserted into a newspaper for distribution to consumers.
- I. "Insider" means a Consultant, officer, director, employee, agent, or attorney of Valassis; *provided, however,* that a Competitor shall not be considered to be an "Insider."
- J. Person" means both natural persons and artificial persons, including, but not limited to, corporations, partnerships, and unincorporated entities.

II.

IT IS FURTHER ORDERED that in connection with the publication, production, distribution, offering for sale, or sale of any FSI in or affecting commerce, as "commerce" is defined by the Federal Trade Commission Act, Respondent shall cease and desist from, either directly or indirectly, or through any corporate or other device:

- A. Communicating, publicly or privately, to any Person who is not an Insider, that Respondent is ready or willing:
  - 1. to forbear from competing for any customer, contract, sale, or business opportunity, conditional upon a Competitor also forbearing from competing for any customer, contract, sale, or business opportunity; or
  - 2. to raise, fix, maintain, or stabilize prices or price levels, conditional upon a Competitor also raising, fixing, maintaining, or stabilizing prices or price levels.
- B. Entering into, participating in, implementing, continuing, or otherwise facilitating any combination, agreement, or understanding, either express or implied, with any Competitor:
  - 1. to allocate or divide markets, customers, contracts, lines of commerce, or territories; or
  - 2. to raise, fix, maintain, or stabilize prices or price levels, or to engage in any other pricing action.

Provided, however, that it shall not, of itself, constitute a violation of Paragraph II of this Decision and Order for Respondent: (1) to communicate to any actual or prospective FSI customer Respondent's price for that customer and/or that Respondent is ready or willing to lower its price in response to a Competitor's price; or (2) publicly to disclose any information where and at such time as the public disclosure of this information by Respondent is required by the Federal Securities Laws.

# III.

## **IT IS FURTHER ORDERED** that:

- A. Within sixty (60) days after the date this Decision and Order becomes final, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which that Respondent has complied and is complying with this Order.
- B. One (1) year after the date this Decision and Order becomes final, annually for the next four (4) years on the anniversary of the date this Decision and Order becomes final, and at other times as the Commission may require, Respondent shall file with the Commission a verified written report setting forth in detail the manner and form in which it has complied and is complying with this Decision and Order.

### IV.

**IT IS FURTHER ORDERED** that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondent,
- B. Any proposed acquisition, merger, or consolidation of Respondent, or
- C. Any other change in Respondent that may affect compliance obligations arising out of this Order, including but not limited to assignment, the creation or dissolution of subsidiaries, or any other change in Respondent.

## V.

- **IT IS FURTHER ORDERED** that, for the purpose of determining or securing compliance with this order, upon written request, Respondent shall permit any duly authorized representative of the Commission:
  - A. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Respondent relating to any matters contained in this Decision and Order; and
  - B. Upon five (5) days' notice to Respondent and without restraint or interference from it, to interview officers, directors, or employees of Respondent.

## VI.

# **IT IS FURTHER ORDERED** that Respondent shall:

- A. Within thirty (30) days after the date on which this Decision and Order becomes final, send a copy of this Decision and Order by first class mail to each of its directors, officers, and Designated Employees.
- B. Mail a copy of this Decision and Order by first class mail to each person who becomes a director, officer, or Designated Employee, no later than (30) days after the commencement of such person's employment or affiliation with Respondent.
- C. Require each person to whom a copy of this Decision and Order is furnished pursuant to subparagraphs VI.A and VI.B of this Decision and Order to sign and submit to Respondent within thirty (30) days of the receipt thereof a statement that: (1) acknowledges receipt of the

Decision and Order; (2) represents that the undersigned has read and understands the Decision and Order; and (3) acknowledges that the undersigned had been advised and understands that non-compliance with the Decision and Order may subject Valassis to penalties for violation of the Decision and Order.

# VII.

**IT IS FURTHER ORDERED** that this Decision and Order shall terminate twenty (20) years from the date the Decision and Order is issued.

By the Commission.

# Analysis of Agreement Containing Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a proposed consent order with Valassis Communications, Inc. ("Valassis" or "Respondent"), a publisher of co-operative free-standing inserts ("FSIs") with its principal place of business located at 19975 Victor Parkway, Livonia, Michigan 48152. The agreement settles charges that Valassis violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by inviting its only FSI rival to collude so as to eliminate competition. The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate comment on the proposed order. The analysis does not constitute an official interpretation of the agreement and proposed order, and does not modify their terms in any way. Further, the proposed consent order has been entered into for settlement purposes only, and does not constitute an admission by Respondent that it violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

# I. The Complaint

The allegations of the complaint are summarized below:

FSIs are multi-page coupon booklets commonly found in Sunday newspapers across the country. FSIs are an efficient means for consumer packaged goods manufacturers and other firms to distribute coupons on a mass scale. For more than a decade, there have been only two U.S. publishers of FSIs: Valassis and News America Marketing ("News America"). On a typical Sunday, both

Valassis FSIs and News America FSIs are distributed by hundreds of newspapers to over 50 million households.

## A. The FSI Price War

Between 1998 and 2001, Valassis and News America each published approximately 50 percent of FSI pages. In June 2001, Valassis notified its clients of a five percent price increase, bringing Valassis' floor price from \$6.00 for a full page per thousand inserts to \$6.30. News America did not follow the Valassis price move. As a result, News America captured additional customers and built a substantial market share lead. In February 2002, Valassis abandoned its efforts to increase prices and sought to regain a 50 percent share of FSI pages, leading to FSI prices falling below \$5.00 per page by 2004.

# B. Valassis Invites its Competitor to Collude

In mid-2004, Valassis determined that its aggressive pursuit of greater market share was no longer serving the company's interests. Company executives developed a new strategy. Valassis decided to communicate to News America an offer to cease competing for News America customers, provided that News America ceased competing for Valassis customers. Valassis intended this offer to enable the firms to raise FSI prices within their respective uncontested domains and to end the FSI price war.

As a publicly traded corporation, Valassis holds a conference call with securities analysts on a quarterly basis. Any person may listen to the call live over the Internet or obtain a transcript of the call from the Valassis website. Valassis held its second quarter analyst call on July 22, 2004<sup>1</sup>. Valassis executives were aware that News America representatives would be monitoring the call, and they determined to use this conference call as the vehicle to

A transcript of the earnings conference call is annexed to the complaint as Exhibit A.

communicate Valassis' offer to News America. To ensure that News America clearly understood the terms of the Valassis offer, including what Valassis expected in return from News America, the President and Chief Executive Officer of Valassis, Alan Schultz, opened the earnings conference call by proposing the following:

- 1. Valassis would abandon its 50 percent market share goal. The company would be content to maintain the share (mid-40s percent) that it then held.
- 2. Valassis would aggressively defend its existing customers and price at whatever level was necessary to retain its existing market share.
- 3. With regard to customers with expiring contracts with News America, effective July 26, 2004, Valassis would observe a floor price of \$6.00 per page and \$3.90 per half page. This was the floor price that had been in effect prior to the price war. That meant that for News America's historical customers, Valassis would submit bids at a level substantially above prevailing market prices.
- 4. With regard to the small number of customers that divide their FSI business between Valassis and News America, Valassis would price its share at whatever level was necessary to retain its historical share of that customer's business. If the customer wanted Valassis to take more than its historical share, however, Valassis would price that portion of the business at the new (\$6.00) price floor.
- 5. As to four bids that Valassis already had outstanding to News America customers, Valassis would honor those bids only until August 1, 2004, and thereafter all News America customers would be quoted at the new higher price.
- 6. Finally, Valassis would monitor News America's response to this invitation, looking for "concrete evidence" of reciprocity in "short order." If News America continued to

compete for Valassis customers and market share, then Valassis would return to its previous pricing strategy, and the price war would resume.

According to the allegations of the complaint, Valassis made the foregoing proposal with the intent to facilitate collusion and without a legitimate business purpose. Although the proposal was made in the context of an analyst call, Valassis' statements provided information that would not ordinarily have been disclosed to the securities community, and the company would not have made the statements except in the expectation that its sole competitor would be listening. Far from being normal guidance to its investors or the marketplace with respect to the company's future business plans, Valassis' statements described with precision the terms of its invitation to collude to News America. If the invitation had been accepted by News America, the result likely would have been higher FSI prices and reduced output<sup>2</sup>.

# II. Legal Analysis of Invitations to Collude

Invitations to collude have been judged unlawful under Section 2 of the Sherman Act as acts of attempted monopolization,<sup>3</sup> as well as under the federal wire and mail fraud statutes<sup>4</sup>. In addition, the Commission has entered into consent agreements in several cases

Evidence reviewed in the course of the Commission's investigation did not support a charge that the anticompetitive agreement proposed by Valassis was consummated.

<sup>&</sup>lt;sup>3</sup> United States v. American Airlines, 743 F.2d 1114 (5th Cir. 1984), *cert. dismissed*, 474 U.S. 1001 (1985).

<sup>&</sup>lt;sup>4</sup> United States v. Ames Sintering Co., 927 F.2d 232 (6th Cir. 1990).

alleging that an invitation to collude – though unaccepted by the competitor – violated Section 5 of the FTC Act.<sup>5</sup>

The preceding line of authority rejects the proposition that competition would be adequately protected if antitrust enforcement were directed only at consummated cartel agreements. Several legal and economic justifications support the imposition of liability upon firms that communicate an invitation to collude where acceptance cannot be proven. First, it may be difficult to determine whether a particular solicitation has or has not been accepted. Second, even an unaccepted solicitation may facilitate coordinated interaction by disclosing the solicitor's intentions or preferences. Third, the antisolicitation doctrine serves as a useful deterrent against conduct that is potentially harmful and that serves no legitimate business purpose.<sup>6</sup>

Previous FTC actions challenging invitations to collude generally have addressed private conversations between the respondent and its competitor<sup>7</sup>. The complaint here alleges that Valassis chose to communicate its offer through a public means. The Commission has concluded that the fact of public communication should not, without more, constitute a defense to an invitation to collude, particularly where market conditions suggest that collusion, if attempted, likely would be successful (here, a durable duopoly). Private negotiation – in a proverbial smoke-filled room – may well

<sup>&</sup>lt;sup>5</sup> MacDermid, Inc., \_\_\_ F.T.C. \_\_\_ (C-3911) (1999); Stone Container Corp., 125 F.T.C. 853 (1998); Precision Moulding Co., 122 F.T.C. 104 (1996); YKK (USA) Inc., 116 F.T.C. 628 (1993); A.E. Clevite, Inc., 116 F.T.C. 389 (1993); Quality Trailer Products Corp., 115 F.T.C. 944 (1992).

<sup>&</sup>lt;sup>6</sup> See generally P. Areeda & H. Hovenkamp, VI ANTITRUST LAW ¶1419 (2003).

<sup>&</sup>lt;sup>7</sup> In *Stone Container Corp.*, 125 F.T.C. 853 (1998), the Commission alleged that an invitation to collude consisting of both public and private communications was illegal.

be the most efficient route for would-be cartelists wishing to reach an accommodation. But it is clear that anticompetitive coordination also can be arranged through public signals and public communications, including speeches, press releases, trade association meetings and the like<sup>8</sup>. Given the obligation under the securities laws not to make false and misleading statements with regard to material facts, Valassis' invitation to collude, made in the context of a conference call with analysts, may have been viewed by News America as even more credible than a private communication. If such public invitations to collude were per se lawful, then covert invitations to collude would be unnecessary.

In evaluating cartels, antitrust law does not afford immunity to agreements that are brokered in public; courts recognize that a public venue does not necessarily mitigate the threat to competition. The same approach should govern invitations to collude. Liability should depend upon the substance and context of the communication, including issues of intent, likely effect, and business justification, and should not turn solely on the arena in which the communication occurs.

In its earnings call, Valassis communicated to rival News America proposed terms of coordination for the FSI market, a longstanding duopoly, and did so with extraordinary specificity: Valassis would cease competing for News America customers, provided that News America likewise ceased competing for Valassis customers. In addition, Valassis proposed that prices should be restored by both firms to the pre-price war level of \$6.00 per page

See, e.g., David F. Lean, Jonathan D. Ogur, and Robert P. Rogers, *Does Collusion Pay*.... *Does Antitrust Work?*, 51 SOUTHERN JOURNAL OF ECONOMICS 828, 839 (1985).

<sup>See FTC v. Superior Court Trial Lawyers Ass'n,
493 U.S. 411 (1990); In re Petroleum Products Antitrust Litig.,
906 F.2d 432 (9<sup>th</sup> Cir. 1990); San Juan Racing Assoc. v.
Asociacion de Jinetes, Inc., 590 F.2d 31, 32 (1<sup>st</sup> Cir. 1979).</sup> 

#### Analysis to Aid Public Comment

and \$3.90 per half page per thousand booklets and described how business with shared customers and outstanding bids to News America's customers would be handled. Much of this information would not have been publicly communicated, even to investors and analysts interested in Valassis' business strategy, but for Valassis' effort to induce collusion. Under such limited circumstances, the Commission may challenge an invitation to collude under Section 5 of the FTC Act even where the conduct did not result in competitive harm.

Corporations have many obvious and important reasons for discussing business strategies and financial results with shareholders, securities analysts, and others. For this reason, the Commission is extremely sensitive to the fact that antitrust intervention involving a corporation's public communications must take great care not to unduly chill legitimate speech<sup>10</sup>.

In this case, the public statements made by Valassis went far beyond a legitimate business disclosure and presented substantial danger of competitive harm. The Commission's complaint alleges that Valassis made a strategic decision to use and did use its analyst call to communicate to News America information that was essential for News America to understand how Valassis proposed to divide up the market and how it proposed to transition from competition to coordination. For example, Valassis specified how it proposed to split the business of those customers it shared with News America and explained what its pricing would be with regard to pending bids to four News America customers. Valassis historically had not provided information of this type to the securities community, analysts had no need for the information and did not report it, and

For example, the Commission would likely not interfere with a public communication that is required by the securities laws. Here, the Commission has been cited to no other instance where a corporation disclosed publicly in securities filings or other fora the detailed descriptions of its future pricing plans and business strategies alleged in this complaint.

Analysis to Aid Public Comment

Valassis had no legitimate business justification to disclose the information. Valassis would not have disclosed the detailed information except in the expectation that News America would be monitoring the call and except for the purpose of conveying its proposal to News America.

# **III.** The Proposed Consent Order

Valassis has signed a consent agreement containing the proposed consent order. The proposed consent order enjoins Valassis from inviting collusion and from actually entering into or implementing a collusive scheme.

More specifically, Valassis would be enjoined from inviting an FSI competitor to divide markets, to allocate customers, or to fix prices. The proposed consent order also prohibits Valassis from entering into, participating in, implementing, or otherwise facilitating an agreement with any FSI competitor to divide markets, to allocate customers, or to fix prices.

The proposed order would not interfere with Valassis' efforts to negotiate prices with prospective customers, and it would permit Valassis to provide investors with considerable information about company strategy. The proposed order also includes a safe harbor provision permitting Valassis to communicate publicly any information the public disclosure of which is required by the federal securities laws.

The proposed order will expire in 20 years.

### IN THE MATTER OF

# DYNAMIC HEALTH OF FLORIDA, LLC

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket D-9317; File No. 0423002 Complaint, June 15, 2004--Decision, May 15, 2006

This consent order addresses the respondents' marketing of a purported children's weight loss product called "Pedia Loss" and a purported female libido enhancer called "Fabulously Feminine." The order requires that the respondents possess and rely on competent and reliable scientific evidence to support representations that Pedia Loss or any other covered product causes weight loss, suppresses appetite, increases fat burning, or slows carbohydrate absorption in overweight children ages 6 and over. Similarly, the order requires that the respondents possess and rely on competent and reliable scientific evidence to support representations that Fabulously Feminine or any other covered product increases a woman's libido, sexual desire, or sexual satisfaction. The order prohibits the respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test or studies, but permits them to make certain claims for food or drugs that are permitted in labeling under laws and/or regulations administered by the U.S. Food and Drug Administration, Additional provisions are requirements that respondents maintain copies of advertising making representations covered by the order and any materials relied upon in disseminating these representations; distribute copies of the order to certain company officials; notify the Commission of changes in corporate structure or changes in the individual respondent's business or employment; and file one or more reports detailing their compliance with the order.

# **Participants**

For the Commission: *Richard Cleland, Mary K. Engle, Janet M. Evans*, and *Sydney Knight*.

For the Respondents: Max Kravitz, Kravitz & Kravitz; and Debra Bass and Tony Martinez, Martinez and Bass.

### **COMPLAINT**

The Federal Trade Commission, having reason to believe that Dynamic Health of Florida, LLC, Chhabra Group, LLC, DBS

Laboratories, LLC, Vineet K. Chhabra a/k/a Vincent K. Chhabra, and Jonathan Barash (collectively, "respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

- 1. Respondent Dynamic Health of Florida, LLC ("Dynamic Health") is a Florida limited liability company with offices located at 1455 North Park Dr., Weston, Florida.
- 2. Respondent Chhabra Group, LLC ("Chhabra Group") is a Florida limited liability company located at 1455 North Park Dr., Weston, Florida.
- 3. Respondent DBS Laboratories, LLC ("DBS Laboratories") is a Florida limited liability company with offices located at 1485 North Park Dr., Weston, Florida.
- 4. Respondent Vineet K. Chhabra a/k/a Vincent K. Chhabra is an officer of Dynamic Health and Chhabra Group. Individually, or in concert with others, he has formulated, directed, participated in, or controlled the acts or practices of Dynamic Health and Chhabra Group, including the acts and practices alleged in this complaint. His principal office or place of business is 1455 North Park Dr., Weston, Florida.
- 5. Respondent Jonathan Barash is an owner and officer of DBS Laboratories, LLC and has participated in its day to day operations. Individually, or in concert with others, he has formulated, directed, participated in, or controlled the acts or practices of DBS Laboratories LLC, including the acts or practices challenged in the complaint. His principal office or place of business is 6599 NW 97th Drive, Parkland, Florida 33076.
- 6. Respondents have advertised, labeled, offered for sale, sold, and distributed products to the public, including Pedia Loss, a weight loss supplement, and Fabulously Feminine, a female sexual

enhancement supplement. Pedia Loss and Fabulously Feminine are either a "food" or a "drug" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act, 15 U.S.C. §§ 52 and 55.

7. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

## PEDIA LOSS

8. Respondents have disseminated or caused to be disseminated advertisements for Pedia Loss through various Internet websites, including <a href="www.pedialoss.com">www.pedialoss.com</a>, <a href="www.dynamichealthproducts.com">www.dynamichealthproducts.com</a>, and <a href="www.dbslabs.com">www.dynamichealthproducts.com</a>, and <a href="www.dbslabs.com">www.dynamichealthproducts.com</a>, and <a href="www.dbslabs.com">www.dynamichealthproducts.com</a>, and <a href="www.dynamichealthproducts.com">www.dynamichealthproducts.com</a>, and <a h

### a. Pedia Loss

\* \* \*

Child obesity is a growing problem in North America. Pedia Loss is an appetite suppressant for children 6 years and older. Allow children to enjoy their favorite foods without gaining weight. This revolutionary new formula slows the absorption of carbohydrates, allowing more to be burned for energy and less to be stored as fat. This highly effective and natural dietary supplement comes in berry-flavored chewable tablets for easy consumption. In conjunction with a proper diet and exercise program, Pedia Loss can keep your child from becoming a statistic.

Please consult your healthcare provider before giving Pedia Loss to your child.

\* \* \*

This synergistic formula was designed to aide in a child's glucose metabolism. Since many of their favorite foods are rich in carbohydrates but very low in dietary fiber, their digestive tracts and insulin never function properly. Now with Pedia Loss children can still enjoy their favorite food but with the help of Inulin their bodies with [sic] slow down the absorption of carbohydrate, allowing more to be burned for energy and less to be stored as fat, and give a great source of soluble fiber. In addition to this highly advanced ingredient, we have included supplemental amounts of both glutamine and FOS, which have both been proven to drastically improve intestinal health. Finally this product contains a highly effective compound called HCA. This compound has been shown to safely burn fat without any form of stimulants.

(Exhibit A: web page from www.dynamichealthproducts.com)

b. Pedia Loss is highly effective for children 6 years of age and older. Children can still enjoy their favorite food in moderation while slowing the absorption of carbohydrates, allowing more to be burned for energy and less to be stored as fat. For best results use in conjunction with an exercise program and a low fat low calorie diet. Please consult your healthcare provider before giving this product for your child.

(Exhibit B: product label)

# c. Child Obesity

an american [sic] reality

According to the Centers for Disease Control and Prevention, childhood obesity is a growing problem in the U.S., with one in ten pre-schoolers considered clinically obese. Pedia Loss addresses this growing health care issue in children 6 years of age and older. Children can still enjoy their favorite foods in moderation, while slowing the absorption of carbohydrates. The use of Pedia Loss enables more carbs to be burned for energy and less to be stored as fat. This highly effective and natural dietary supplement comes in berry-flavored chewable tablets that will appeal to children. Best of all is the feeling of strength and confidence they'll experience by overcoming childhood weight problems. . . .

(Exhibit C: ad in Cosmopolitan Magazine)

- 9. Through the means described in Paragraph 8, respondents have represented, expressly or by implication, that:
  - a. Pedia Loss causes weight loss in overweight or obese children ages 6 and over, and
  - b. When taken by overweight or obese children ages 6 and over, Pedia Loss causes weight loss by suppressing appetite, increasing fat burning, and slowing carbohydrate absorption.
- 10. Through the means described in Paragraph 8, respondents have represented, expressly or by implication, that they possessed

and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 9, at the time the representations were made.

11. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 9, at the time the representations were made. Therefore, the representation set forth in Paragraph 10 was, and is, false or misleading.

## **FABULOUSLY FEMININE**

12. Respondents have disseminated or caused to be disseminated advertisements for Fabulously Feminine through various Internet websites, including <a href="www.usaprescription.com">www.usaprescription.com</a>, <a href="www.dbslabs.com">www.dbslabs.com</a>, and <a href="www.medprescribe.com">www.medprescribe.com</a>, as well as print ads in various newspaper publications. According to the product labels, Fabulously Feminine contains L-arginine, ginseng, damiana leaf, gingko biloba leaf, and horny goat weed, among other ingredients. Advertisements for Fabulously Feminine products include, but are not necessarily limited to, the attached Exhibits D through F. The advertisements contain the following statements, among others:

# a. Fabulously Feminine

Do you crave more from sexual intimacy? Rev up your sex drive with FABULOUSLY FEMININE. All-natural FABULOUSLY FEMININE can help you build the stamina you need to make your sexual experiences more intense and lasting. . . It's all a matter of stimulating blood flow and increasing sensitivity, and FABULOUSLY FEMININE'S herbal and amino acid formula accomplishes this naturally, yet powerfully. . . .

\* \* \*

### PRODUCT INFORMATION

Fabulously Feminine is a safe, natural way to enhance sexual desire, satisfaction and enjoyment. The ingredients in Fabulously Feminine, when taken daily with a multivitamin, have been shown in a double-blind, placebo-controlled Stanford University study to enhance satisfaction with sex life, the level of sexual desire and frequency of sexual encounters.

It is estimated that 43% of women experience a loss of sexual vitality at some time in their lives. External factors such as stress and fatigue may contribute to the decline in sexual interest. . . .

(Exhibit D : web page from www.usaprescription.com)

b. It is not unusual for men and women, young or old, to lose desire, arousal and overall satisfaction in the bedroom. Let **DBS Laboratories** give you the fuel you need to rekindle the fire inside you.

LIBIDO ENHANCER
FABULOUSLY
FEMININE
Dietary Supplement

Millions of women are dealing with the same issues you are. Put your confidence and your relationship in the hands of **Fabulously Feminine** – The safe, natural way to enhance sexual desire, satisfaction and enjoyment. A special libido enhancing formula designed specifically for women, **Fabulously Feminine** contains a proprietary blend of traditional libido

enhancing herbs. Not being in the mood for sex is often times the result of poor stimulation; lack of energy, and hormonal imbalance. This product was specially formulated to address these issues. These all-natural ingredients are known to stimulate blood flow and increase sensitivity, making this product one of the most potent available on the market.

(Exhibit E: National Examiner newspaper ad)

# c. LIBIDO ENHANCER FABULOUSLY ™ FEMININE

Dietary Supplement

A scientific formula designed especially for women, **Fabulously Feminine** contains a proprietary blend of clinically proven ingredients for libido health. Not being in the mood for sex is oftentimes the result of poor stimulation, lack of energy, and hormonal imbalance. This product has been formulated to address these issues. . . .

(Exhibit F: National Enquirer newspaper ad)

- 13. Through the means described in Paragraph 12, respondents have represented, expressly or by implication, that clinical testing proves that Fabulously Feminine enhances a woman's satisfaction with her sex life and level of sexual desire.
- 14. In truth and in fact, clinical testing does not prove that Fabulously Feminine enhances a woman's satisfaction with her sex life and level of sexual desire. Therefore, the representation set forth in Paragraph 13 was, and is, false or misleading.

- 15. Through the means described in Paragraph 12, respondents have represented, expressly or by implication, that Fabulously Feminine will increase a woman's libido, sexual desire, and sexual satisfaction by stimulating blood flow and increasing sensitivity.
- 16. Through the means described in Paragraph 12, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representation set forth in Paragraph 15, at the time the representation was made.
- 17. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representation set forth in Paragraph 15, at the time the representation was made. Therefore, the representation set forth in Paragraph 16 was, and is, false or misleading.
- 18. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

# **NOTICE**

Proceedings on the charges asserted against Dynamic Health of Florida, LLC, Chhabra Group, LLC, DBS Laboratories, LLC, limited liability companies, and Vineet K. Chhabra a/k/a Vincent K. Chhabra in this complaint will be held before an Administrative Law Judge (ALJ) of the Federal Trade Commission, under Part 3 of the Commission's Rules of Practice, 16 C.F.R. Part 3. A copy of Part 3 of the Rules is enclosed with this complaint.

You may file an answer to this complaint. Any such answer must be filed within 20 days after service of the complaint on you. If you contest the complaint's allegations of fact, your answer must concisely state the facts constituting each ground of defense, and must specifically admit, deny, explain, or disclaim knowledge of

each fact alleged in the complaint. You will be deemed to have admitted any allegations of the complaint that you do not so answer.

If you elect not to contest the allegations of fact set forth in the complaint, your answer shall state that you admit all of the material allegations to be true. Such an answer will constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the ALJ will file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. Such an answer may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice.

If you do not answer within the specified time, you waive your right to appear and contest the allegations of the complaint. The ALJ is then authorized, without further notice to you, to find that the facts are as alleged in the complaint and to enter an initial decision and a cease and desist order.

The ALJ will schedule an initial prehearing scheduling conference to be held not later than 14 days after the answers are due. Unless otherwise directed by the ALJ, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within 5 days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

A hearing on the complaint will begin on the fifteenth day of September, 2004, at 10:00 A.M. in Room 532, or such other date as determined by the ALJ. At the hearing, you will have the right to contest the allegations of the complaint and to show cause why a cease and desist order should not be entered against you.

The following is the form of order which the Commission has reason to believe should issue if the facts are found to be as alleged in the complaint. If, however, the Commission should conclude from the record facts developed in any adjudicative proceedings in this matter that the proposed order provisions as to Dynamic Health of Florida, LLC, Chhabra Group, LLC, DBS Laboratories, LLC, limited liability companies; and Vineet K. Chhabra a/k/a Vincent K. Chhabra, individually and as a director or officer of Dynamic Health of Florida, LLC and Chhabra Group, LLC might be inadequate to fully protect the consuming public, the Commission may order such other relief as it finds necessary or appropriate.

Moreover, the Commission has reason to believe that, if the facts are found as alleged in the complaint, it may be necessary and appropriate for the Commission to seek relief to redress injury to consumers, or other persons, partnerships or corporations, in the form of restitution and refunds for past, present, and future consumers and such other types of relief as are set forth in Section 19(b) of the Federal Trade Commission Act. The Commission will determine whether to apply to a court for such relief on the basis of the adjudicative proceedings in this matter and such other factors as are relevant to consider the necessity and appropriateness of such action.

## **ORDER**

# **DEFINITIONS**

For purposes of this Order, the following definitions shall apply:

A. Unless otherwise specified, "respondents" shall mean Dynamic Health of Florida, LLC, Chhabra Group, LLC, DBS Laboratories, LLC, limited liability companies, their successors and assigns and their officers; and Vineet K. Chhabra, a/k/a Vincent K. Chhabra, individually and as a director or officer of Dynamic Health of Florida, LLC and Chhabra Group, LLC, and

each of the above's agents, representatives, and employees.

- B. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
- C. "Pedia Loss" shall mean "Pedia Loss Dietary Supplement" and any other product containing one or more of the ingredients in the current product that is marketed for weight loss or control.
- D. "Fabulously Feminine" shall mean "Fabulously Feminine Dietary Supplement" and any other product containing one or more of the ingredients in the current product that is marketed for sexual enhancement.
- E. "Food," "drug," and "device" shall mean as "food," "drug," and "device" are defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
- F. "Covered product or service" shall mean any dietary supplement, food, drug, or device, and any health-related service or program promoting weight loss or sexual enhancement.
- G. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- H. "Endorsement" shall mean as defined in 16 C.F.R. § 255.0(b).

- I. The term "including" in this Order shall mean "without limitation."
- J. The terms "and" and "or" in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

#### **IT IS ORDERED** that:

- A. Respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Pedia Loss or any other covered product or service, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements or the product name, that:
  - 1. Such product or service causes weight loss, suppresses appetite, increases fat burning, or slows carbohydrate absorption;
  - 2. Such product or service causes weight loss in overweight or obese children ages 6 and over; or
  - 3. Such product or service, when taken by overweight or obese children ages 6 and over, suppresses appetite, increases fat burning, or slows carbohydrate absorption,

unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation; and

B. Respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Fabulously Feminine or any other covered product or service, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements or the product name, that such product or service will increase a woman's libido, sexual desire, or sexual satisfaction, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements or the product name, about the benefits, performance, or efficacy of such product or service, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

### III.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service, in or affecting commerce, shall not misrepresent, in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study.

### IV.

### **IT IS FURTHER ORDERED** that:

- A. Nothing in this Order shall prohibit respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and
- B. Nothing in this Order shall prohibit respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

V.

**IT IS FURTHER ORDERED** that respondents Dynamic Health of Florida, LLC, Chhabra Group, LLC, DBS Laboratories, LLC and their successors and assigns, and respondent Vineet K. Chhabra shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the

representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

## VI.

IT IS FURTHER ORDERED that respondents Dynamic Health of Florida, LLC, Chhabra Group, LLC and DBS Laboratories, LLC and their successors and assigns, and respondent Vineet K. Chhabra shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

#### VII.

IT IS FURTHER ORDERED that respondents Dynamic Health of Florida, LLC, Chhabra Group, LLC, and DBS Laboratories, LLC and their successors and assigns, and respondent Vineet K. Chhabra shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part

shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Attention: In the Matter of Dynamic Health of Florida, LLC.

#### VIII.

IT IS FURTHER ORDERED that respondent Vineet K. Chhabra, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities.

### IX.

IT IS FURTHER ORDERED that respondent Dynamic Health of Florida, LLC, Chhabra Group, LLC, and DBS Laboratories, LLC and their successors and assigns, and respondent Vineet K. Chhabra shall, within sixty (60) days after service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

#### X.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

A. Any Part in this order that terminates in less than twenty (20) years;

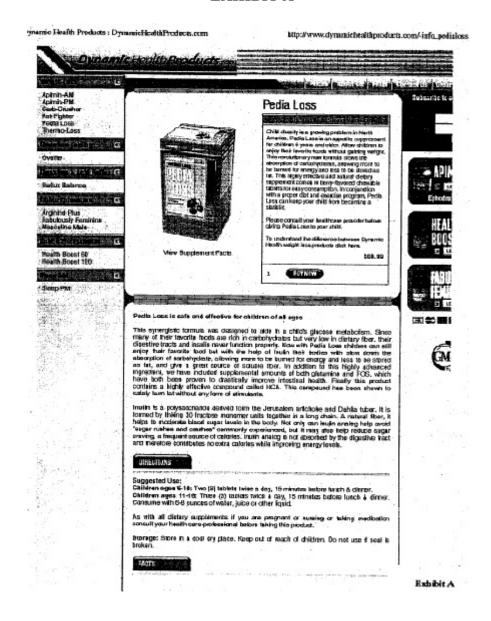
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondents did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

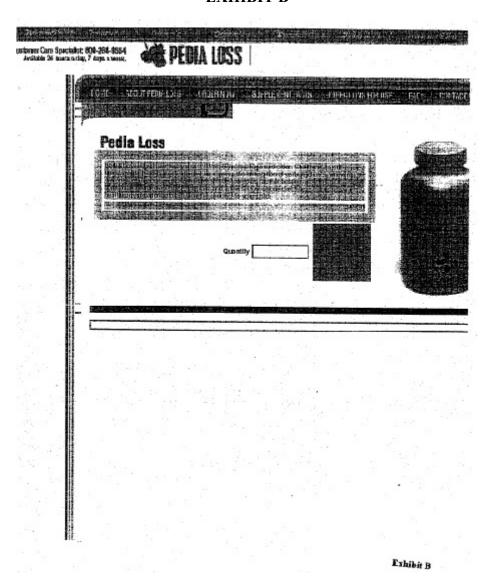
THEREFORE, the Federal Trade Commission this fifteenth day of June, 2004, has issued this complaint against respondents.

By the Commission.

### **EXHIBIT A**



# **EXHIBIT B**



# **EXHIBIT C**

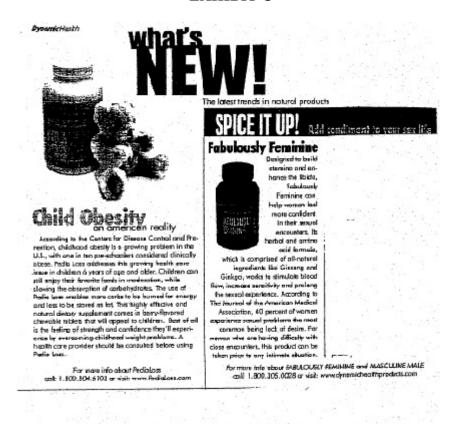
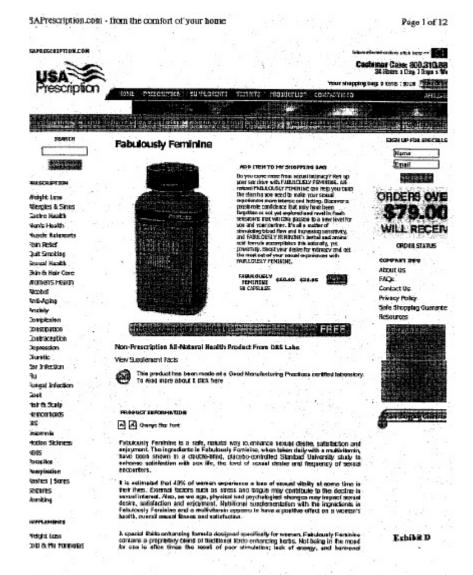


Exhibit C

DBS 0409

# **EXHIBIT D**



# **EXHIBIT E**



# **EXHIBIT F**



#### **DECISION AND ORDER**

The Commission having heretofore issued its Complaint charging the Respondents, Dynamic Health of Florida, Inc; Chhabra Group, LLC; and Vineet Chhabra a/k/a Vincent Chhabra named in the caption hereof with violations of Sections 5(a) and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45(a) and 52 as amended, and Respondents having been served with a copy of that Complaint, together with a notice of contemplated relief; and

Respondents, their attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order, an admission by Respondents of all the jurisdictional facts set forth in the Complaint, a statement that the signing of said Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Secretary of the Commission having thereafter withdrawn this matter from adjudication in accordance with § 3.25(c) of its Rules; and

The Commission having considered the matter and having thereupon accepted the executed Consent Agreement and placed such Agreement on the public record for a period of thirty (30) days, now in further conformity with the procedure prescribed in § 3.25(f) of its Rules, the Commission hereby makes the following jurisdictional findings and enters the following Order:

1. Respondent Dynamic Health of Florida, LLC ("Dynamic Health") is a Florida limited liability company with offices located at 1455 North Park Dr., Weston, Florida 33326.

- 2. Respondent Chhabra Group, LLC ("Chhabra Group") is a Florida limited liability company located at 1455 North Park Dr., Weston, Florida 33326.
- 3. Respondent Vineet K. Chhabra a/k/a Vincent K. Chhabra is an officer of Dynamic Health and Chhabra Group. Individually, or in concert with others, he has formulated, directed, participated in, or controlled the acts or practices of Dynamic Health and Chhabra Group, including the acts and practices alleged in this complaint. His principal office or place of business is 1455 North Park Dr., Weston, Florida 3326.
- 4. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

### **ORDER**

### **DEFINITIONS**

For purposes of this Order, the following definitions shall apply:

- A. Unless otherwise specified, "respondents" shall mean Dynamic Health of Florida, LLC ("Dynamic Health"), its successors and assigns and its officers; Chhabra Group, LLC ("Chhabra Group"), its successors and assigns and its officers; and Vineet K. Chhabra a/k/a Vincent K. Chhabra, individually and as a director or officer of Dynamic Health or Chhabra Group; and each of the above's agents, representatives, and employees.
- B. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures

generally accepted in the profession to yield accurate and reliable results.

- C. "Pedia Loss" shall mean "Pedia Loss Dietary Supplement" and any other product containing one or more of the ingredients in the current product that is marketed for weight loss or control.
- D. "Fabulously Feminine" shall mean "Fabulously Feminine Dietary Supplement" and any other product containing one or more of the ingredients in the current product that is marketed for sexual enhancement.
- E. "Food" and "drug" shall mean as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
- F. "Covered product" shall mean any dietary supplement, food, or drug.
- G. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- H. "Endorsement" shall mean as defined in 16 C.F.R. § 255.0(b).
- I The term "including" in this Order shall mean "without limitation."
- J. The terms "and" and "or" in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

### **IT IS ORDERED** that:

- A. Respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Pedia Loss or any other covered product, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements or the product name, that:
  - 1. Such product causes weight loss, suppresses appetite, increases fat burning, or slows carbohydrate absorption;
  - 2. Such product causes weight loss in overweight or obese children ages 6 and over; or
  - 3. Such product, when taken by overweight or obese children ages 6 and over, suppresses appetite, increases fat burning, or slows carbohydrate absorption,

unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

B. Respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Fabulously Feminine or any other covered product, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through

the use of endorsements or the product name, that such product will increase a woman's libido, sexual desire, or sexual satisfaction, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements or the product name, about the benefits, performance, or efficacy of such product, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

### III.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product, in or affecting commerce, shall not misrepresent, in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study.

#### IV.

# IT IS FURTHER ORDERED that:

A. Nothing in this Order shall prohibit respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug

Administration, or under any new drug application approved by the Food and Drug Administration; and

B. Nothing in this Order shall prohibit respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

V.

IT IS FURTHER ORDERED that respondents Dynamic Health, Chhabra Group, and their successors and assigns, and respondent Vineet K. Chhabra shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

### VI.

### **IT IS FURTHER ORDERED** that:

- A. For a period of three (3) years after the date upon which this order becomes final, respondents Dynamic Health, Chhabra Group, and their successors and assigns shall deliver a copy of this order to all current and future principals, officers, directors, and managers;
- B. For a period of three (3) years after the date upon which this order becomes final, respondent Vineet K. Chhabra shall deliver a copy of this order to all current and future principals, officers, directors, and managers of any business where (1) he is the majority owner of the business, or directly or indirectly manages or controls the business, and (2) the business is engaged in the advertising, marketing, promotion, offering for sale, sale, or distribution of any covered product;
- C. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities; and
- D. Respondents shall obtain a signed and dated statement acknowledging the receipt of the order as required in subparts A, B, and C above.

#### VII.

IT IS FURTHER ORDERED that respondents Dynamic Health, Chhabra Group, and their successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the

emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however*, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Attention: In the Matter of Dynamic Health of Florida, LLC.

#### VIII.

IT IS FURTHER ORDERED that respondent Vineet K. Chhabra, for a period three (3) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Attention: In the Matter of Dynamic Health of Florida, LLC.

### IX.

IT IS FURTHER ORDERED that respondents Dynamic Health, Chhabra Group, and their successors and assigns, and respondent Vineet K. Chhabra shall, within sixty (60) days after service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in

writing, setting forth in detail the manner and form in which they have complied with this order.

### X.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

*Provided, further*, that if such complaint is dismissed or a federal court rules that the respondents did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Analysis to Aid Public Comment

# Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order with Dynamic Health of Florida, LLC; Chhabra Group, LLC; and Vineet Chhabra a/k/a Vincent Chhabra ("respondents"). The proposed order resolves the allegations of the complaint issued against these respondents and others on June 15, 2004. *In the Matter of Dynamic Health of Florida, LLC,* D-9317 (June 15, 2004).

The proposed consent order has been placed on the public record for thirty (30) days for submission of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will review the agreement in light of any comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

This matter concerns the respondents' marketing of a purported children's weight loss product called "Pedia Loss" and a purported female libido enhancer called "Fabulously Feminine." Commission's complaint charged that advertising for Pedia Loss made unsubstantiated claims that (1) Pedia Loss causes weight loss in overweight or obese children ages 6 and over, and (2) when taken by overweight or obese children ages 6 and over, Pedia Loss causes weight loss by suppressing appetite, increasing fat burning, and slowing carbohydrate absorption. The Commission's complaint also charged that advertising for Fabulously Feminine falsely represented that clinical testing proves that Fabulously Feminine enhances a woman's satisfaction with her sex life and level of sexual desire. In addition, the complaint challenged the unsubstantiated claim that Fabulously Feminine will increase a woman's libido, sexual desire, and sexual satisfaction by stimulating blood flow and increasing sensitivity.

Part I.A. of the proposed order requires that respondents possess and rely on competent and reliable scientific evidence to support representations that Pedia Loss or any other covered product causes weight loss, suppresses appetite, increases fat burning, or slows carbohydrate absorption; causes weight loss in overweight or obese children ages 6 and over; or causes weight loss by suppressing appetite, increasing fat burning, or slowing carbohydrate absorption, when taken by overweight or obese children ages 6 and over. "Covered product" is defined as any dietary supplement, food, or drug. Part I.B. of the order requires that proposed respondents possess and rely on competent and reliable scientific evidence to support representations that Fabulously Feminine or any other covered product will increase a woman's libido, sexual desire, or sexual satisfaction.

Part II of the proposed order requires that respondents possess and rely on competent and reliable scientific evidence to support benefits, performance, or efficacy representations for any covered product.

Part III of the proposed order prohibits respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test or studies. Part IV of the proposed order permits respondents to make certain claims for food or drugs that are permitted in labeling under laws and/or regulations administered by the U.S. Food and Drug Administration.

The remainder of the proposed order contains requirements that respondents maintain copies of advertising making representations covered by the order and any materials relied upon in disseminating these representations (Part V); distribute copies of the order to certain company officials (Part VI); notify the Commission of changes in corporate structure (Part VII); notify the Commission of changes in the individual respondent's business or employment (Part VIII); and file one or more reports detailing their compliance with the order (Part IX). Part X of the proposed order is a provision whereby the order, absent certain circumstances, terminates twenty years from the date of issuance.

The purpose of this analysis is to facilitate public comment on the proposed order, and is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

## IN THE MATTER OF

# NATIONS TITLE AGENCY, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4160; File No. 0523117 Complaint, June 19, 2006--Decision, June 19, 2006

This consent order relates to personal information on consumers collected by Nations Title Agency, Inc., Nations Holding Company, and Christopher M. Likens. The respondents provide services in connection with financing home purchases and refinancing existing home mortgages and routinely obtain sensitive consumer information from banks and other sources. The respondents failed to employ reasonable and appropriate security measures to protect such information. The order requires that respondents not misrepresent the extent to which they maintain and protect the privacy, confidentiality, or integrity of any personal information collected from or about consumers. It requires respondents to establish and maintain a comprehensive information security program in writing that is reasonably designed to protect the security, confidentiality, and integrity of personal information they collect from or about consumers. The order also requires that respondents not violate any provision of the Gramm-Leach-Bliley Safeguards Rule and Privacy Rule, as well as the Fair and Accurate Credit Transactions Act's Disposal Rule. In addition, the respondents must obtain periodic assessments and reports from a qualified, objective, independent third-party professional, certifying, among other things, that they have in place a security program that provides protections that meet or exceed the protections required by this order, and their security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of consumers' personal information have been protected. Additional provisions relate to reporting and compliance.

# **Participants**

For the Commission: Molly Crawford, Loretta Garrison, Jessica Rich, Alain Sheen, and Joel Winston.

For the Respondents: David H. Cox, Jackson & Campbell, P.C.

# **COMPLAINT**

The Federal Trade Commission ("Commission"), having reason to believe that Nations Title Agency, Inc., Nations Holding

Company, and Christopher M. Likens have violated the provisions of the Commission's Standards for Safeguarding Customer Information Rule ("Safeguards Rule"), 16 C.F.R. Part 314, issued pursuant to Title V, Subtitle A of the Gramm-Leach-Bliley Act ("GLB Act"), 15 U.S.C. § 6801-6809; the Commission's Privacy of Customer Financial Information Rule ("Privacy Rule"), 16 C.F.R. Part 313, issued pursuant to the GLB Act; and the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

- 1. Respondent Nations Title Agency, Inc. ("NTA") is a Kansas corporation with its principal office or place of business at 9415 Nall Avenue, Prairie Village, Kansas 66207. Respondent NTA is a wholly-owned subsidiary of respondent Nations Holding Company.
- 2. Respondent Nations Holding Company ("NHC") is a Kansas corporation with its principal office or place of business at 5370 West 95<sup>th</sup> Street, Prairie Village, Kansas 66207. NHC conducts business through its 57 wholly-owned subsidiaries, including NTA, in twenty states. During all relevant time, NHC controlled the practices at issue in this complaint.
- 3. Respondent Christopher M. Likens ("Likens") is president and sole owner of NHC, a Subchapter "S" corporation, and NHC's wholly-owned subsidiaries. He has the authority to control the conduct of NHC and its subsidiaries, including NTA. Individually or in concert with others he formulates, directs, or controls the policies, acts, or practices of the respondent corporations, including the acts or practices alleged in this complaint. His principal office or place of business is the same as NHC.
- 4. Respondents provide services in connection with financing home purchases and refinancing existing home mortgages, including, but not limited to, real estate settlement services, residential closings, title abstracts, title commitments, appraisals, foreclosure management, asset disposition, and real estate management. In providing these services, respondents routinely

obtain sensitive consumer information from banks and other lenders, real estate brokers, consumers, public records, and others, including but not limited to consumer names, Social Security numbers, bank and credit card account numbers, mortgage information, loan applications, purchase contracts, refinancing agreements, income histories, and credit histories (collectively, "personal information").

- 5. Since at least 2003, respondents have engaged in a number of practices that, taken together, failed to provide reasonable and appropriate security for consumers' personal information. Among other things, respondents failed to: (1) assess risks to the information they collected and stored both online and offline; (2) implement reasonable policies and procedures in key areas, such as employee screening and training and the collection, handling, and disposal of personal information; (3) implement simple, low-cost, and readily available defenses to common website attacks, or implement reasonable access controls, such as strong passwords, to prevent a hacker from gaining access to personal information stored on respondents' computer network; (4) employ reasonable measures to detect and respond to unauthorized access to personal information or to conduct security investigations; and (5) provide reasonable oversight for the handling of personal information by service providers, such as third parties employed to process the information and assist in real estate closings.
- 6. In April 2004, a hacker exploited the failures set forth in Paragraph 5 by using a common website attack to obtain unauthorized access to NHC's computer network. In addition, in February 2005, a Kansas City television station found intact documents containing sensitive personal information discarded in respondents' dumpster in an unsecured area adjacent to respondents' building.
- 7. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

# VIOLATIONS OF THE SAFEGUARDS RULE

- 8. The Safeguards Rule, which implements Section 501(b) of the GLB Act, 15 U.S.C. § 6801(b), was promulgated by the Commission on May 23, 2002, and became effective on May 23, 2003. The Rule requires financial institutions to protect the security, confidentiality, and integrity of customer information by developing a comprehensive written information security program that contains reasonable administrative, technical, and physical safeguards, including: (1) designating one or more employees to coordinate the information security program; (2) identifying reasonably foreseeable internal and external risks to the security, confidentiality, and integrity of customer information, and assessing the sufficiency of any safeguards in place to control those risks; (3) designing and implementing information safeguards to control the risks identified through risk assessment, and regularly testing or otherwise monitoring the effectiveness of the safeguards' key controls, systems, and procedures; (4) overseeing service providers, and requiring them by contract to protect the security and confidentiality of customer information; and (5) evaluating and adjusting the information security program in light of the results of testing and monitoring, changes to the business operation, and other relevant circumstances.
- 9. Respondents NHC and NTA are "financial institutions," as that term is defined in Section 509(3)(A) of the GLB Act.
- 10. As set forth in Paragraphs 5 and 6, respondents have failed to implement reasonable security policies and procedures, and have thereby engaged in violations of the Safeguards Rule, by, among other things:
  - a. Failing to identify reasonably foreseeable internal and external risks to the security, confidentiality, and integrity of customer information;

- b. Failing to design and implement information safeguards to control the risks to customer information and failing to regularly test and monitor them;
- Failing to investigate, evaluate, and adjust the information security program in light of known or identified risks;
- d. Failing to develop, implement, and maintain a comprehensive written information security program; and
- e. Failing to oversee service providers and to require them by contract to implement safeguards to protect respondent's customer information.

# VIOLATIONS OF THE FTC ACT

11. Since at least 2001, respondents NHC, NTA, and Likens have disseminated or caused to be disseminated to consumers privacy policies and statements, including, but not limited to the following:

NTA, at all times, strives to maintain the confidentiality and integrity of the personal information in its possession and has instituted measures to guard against its unauthorized access. We maintain physical, electronic and procedural safeguards in compliance with federal standards to protect the information. (Nations Title Agency Privacy Policy.)

- 12. Through the means set forth in Paragraph 11, respondents have represented, expressly or by implication, that they implement reasonable and appropriate measures to protect consumers' personal information from unauthorized access.
- 13. In truth and in fact, as set forth in Paragraphs 5 and 6, respondents did not implement reasonable and appropriate measures

to protect consumers' personal information from unauthorized access. Therefore, the representation set forth in Paragraph 12 was, and is, false or misleading, in violation of Section 5(a) of the Federal Trade Commission Act.

# VIOLATION OF THE PRIVACY RULE

- 14. The Privacy Rule, which implements Sections 501-509 of the GLB Act, 15 U.S.C. §§ 6801-6809, was promulgated by the Commission on May 24, 2000, and became effective on July 1, 2001. The Rule requires financial institutions to provide customers, no later than when a customer relationship arises and annually for the duration of that relationship, "a clear and conspicuous notice that accurately reflects [the financial institution's] privacy policies and practices" including its security policies and practices. 16 C.F.R. §§ 313.4(a); 313.5(a)(1); § 313.6(a)(8).
- 15. As set forth in Paragraphs 11 through13, respondents disseminated a privacy policy that contained false or misleading statements regarding the measures implemented to protect consumers' personal information. Therefore, respondents have disseminated a privacy policy that does not accurately reflect their privacy policies and practices, including their security policies and practices, in violation of the Privacy Rule.
- 16. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices, in or affecting commerce, in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this nineteenth day of June, 2006, has issued this complaint against respondents.

By the Commission.

## **DECISION AND ORDER**

The Federal Trade Commission having initiated an investigation of certain acts and practices of the Respondents named in the caption hereof, and the Respondents, having been furnished thereafter with a copy of a draft Complaint that the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the Respondents with violations of the Gramm-Leach Bliley Act, 15 U.S.C. 6801 *et seq.* and the Federal Trade Commission Act, 15 U.S.C. § 45 *et seq*;

The Respondents, their attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order ("Consent Agreement"), an admission by the Respondents of all the jurisdictional facts set forth in the aforesaid draft Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe that the Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days, and having duly considered the comments filed thereafter by interested persons pursuant to Section 2.34 of its Rules, now in further conformity with the procedure described in Section 2.34 of its Rules, the Commission hereby issues its Complaint, makes the following jurisdictional findings and enters the following Order:

1. Proposed respondent Nations Title Agency, Inc. ("Nations Title") is a Kansas corporation with its principal office or place of business at 9415 Nall

Avenue, Prairie Village, Kansas 66207. NTA is a wholly-owned subsidiary of Nations Holding Company.

- 2. Proposed respondent Nations Holding Company ("Nations Holding") is a Kansas corporation with its principal office or place of business at 5370 West 95<sup>th</sup> Street, Prairie Village, Kansas 66207. Nations Holding is a Subchapter "S" corporation.
- 3. Proposed respondent Christopher M. Likens is president and sole owner of Nations Holding. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of the respondent corporations. His principal office or place of business is the same as that of Nations Holding.

### **ORDER**

### **DEFINITIONS**

For purposes of this Order, the following definitions shall apply:

1. "Personally identifiable information" or "personal information" shall mean individually identifiable information from or about an individual consumer including, but not limited to: (a) a first and last name; (b) a home or other physical address, including street name and name of city or town; (c) an email address or other online contact information, such as an instant messaging user identifier or a screen name that reveals an individual's email address; (d) a telephone number; (e) a Social Security number; (f) a bank, loan, or credit card account number; (g) a persistent identifier, such as a customer number held in a "cookie" or processor serial number, that is combined with other available data that identifies an individual consumer; or (h) any information that is combined with any of (a) through (g) above.

- 2. Unless otherwise specified, "respondents" shall mean Nations Holding and Nations Title and their successors and assigns, officers, agents, representatives, subsidiaries, affiliates, and employees, and Christopher M. Likens, individually and as an officer of Nations Holding.
- 3. All other terms are synonymous in meaning and equal in scope to the usage of such terms in the Gramm-Leach-Bliley Act, 15 U.S.C. § 6801 *et seq*.
- 4. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the collection of personally identifiable information from or about consumers, in or affecting commerce, shall not misrepresent in any manner, expressly or by implication, the extent to which respondents maintain and protect the privacy, confidentiality, or integrity of any personal information collected from or about consumers.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, marketing, promotion, offering for sale, or sale of any product or service, in or affecting commerce, shall, no later than the date of service of this order, establish and implement, and thereafter maintain, a comprehensive information security program that is reasonably designed to protect the security, confidentiality, and integrity of personal information collected from or about consumers. Such program, the content and implementation of which must be fully documented in writing, shall contain administrative, technical, and physical safeguards appropriate to

respondents' size and complexity, the nature and scope of respondents' activities, and the sensitivity of the personal information collected from or about consumers, including:

- A. the designation of an employee or employees to coordinate and be accountable for the information security program.
- B. the identification of material internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of such information, and assessment of the sufficiency of any safeguards in place to control these risks. At a minimum, this risk assessment should include consideration of risks in each area of relevant operation, including, but not limited to: (1) employee training and management; (2) information systems, including network and software design, information processing, storage, transmission, and disposal; and (3) prevention, detection, and response to attacks, intrusions, or other systems failures.
- C. the design and implementation of reasonable safeguards to control the risks identified through risk assessment, and regular testing or monitoring of the effectiveness of the safeguards' key controls, systems, and procedures.
- D. the evaluation and adjustment of respondents' information security program in light of the results of the testing and monitoring required by Part II.C., any material changes to respondents' operations or business arrangements, or any other circumstances that respondents know or have reason to know may have a material impact on the effectiveness of their information security program.

### III.

**IT IS FURTHER ORDERED** that respondents shall not, directly or through any corporation, subsidiary, division, website, or other device, violate any provision of:

- A. the Gramm-Leach-Bliley Act's Standards for Safeguarding Customer Information Rule, 16 C.F.R. Part 314;
- B. the Gramm-Leach-Bliley Act's Privacy of Customer Financial Information Rule, 16 C.F.R. Part 313; or
- C. the Fair and Accurate Credit Transactions Act's Disposal of Consumer Report Information and Records Rule, 16 C.F.R. Part 682.

In the event that any of these Rules is hereafter amended or modified, respondents' compliance with that Rule as so amended or modified shall not be a violation of this order.

# IV.

IT IS FURTHER ORDERED that, in connection with their compliance with Parts II, III.A., and III.C. of this order, respondents shall obtain initial and biennial assessments and reports ("Assessments") from a qualified, objective, independent third-party professional, using procedures and standards generally accepted in the profession. The reporting period for the Assessments shall cover: (1) the first one hundred and eighty (180) days after service of the order for the initial Assessment, and (2) each two (2) year period thereafter for twenty (20) years after service of the order for the biennial Assessments. Each Assessment shall:

A. set forth the specific administrative, technical, and physical safeguards that respondents have implemented and maintained during the reporting period;

- B. explain how such safeguards are appropriate to respondents' size and complexity, the nature and scope of respondents' activities, and the sensitivity of the personal information collected from or about consumers;
- C. explain how the safeguards that have been implemented meet or exceed the protections required by the Parts II, III.A., and III.C. of this order; and
- D. certify that respondents' security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of personal information is protected and has so operated throughout the reporting period.

Each Assessment shall be prepared and completed within sixty (60) days after the end of the reporting period to which the Assessment applies by a person qualified as a Certified Information System Security Professional (CISSP) or as a Certified Information Systems Auditor (CISA); a person holding Global Information Assurance Certification (GIAC) from the SysAdmin, Audit, Network, Security (SANS) Institute; or a similarly qualified person or organization approved by the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

Respondents shall provide the initial Assessment, as well as all: plans, reports, studies, reviews, audits, audit trails, policies, training materials, and assessments, whether prepared by or on behalf of either respondent, relied upon to prepare such Assessment to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580, within ten (10) days after the Assessment has been prepared. All subsequent biennial Assessments shall be retained by respondents until the order is terminated and provided to the Associate Director of Enforcement within ten (10) days of request.

## V.

IT IS FURTHER ORDERED that respondents shall maintain, and upon request make available to the Federal Trade Commission for inspection and copying, a print or electronic copy of each document relating to compliance, including but not limited to:

- A. for a period of five (5) years: any documents, whether prepared by or on behalf of either respondent, that contradict, qualify, or call into question respondents' compliance with this order; and
- B. for a period of three (3) years after the date of preparation of each biennial Assessment required under Part IV of this order: all plans, reports, studies, reviews, audits, audit trails, policies, training materials, and assessments, whether prepared by or on behalf of either respondent, relating to respondents' compliance with Parts II, III.A., and III.C. of this order for the compliance period covered by such biennial Assessment.

# VI.

IT IS FURTHER ORDERED that respondents shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having supervisory responsibilities relating to the subject matter of this order. Respondents shall deliver this order to such current personnel within thirty (30) days after service of this order, and to such future personnel within thirty (30) days after the person assumes such position or responsibilities.

## VII.

IT IS FURTHER ORDERED that respondent Christopher M. Likens, for a period of ten (10) years, after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new

business or employment that provides financial products or services. The notice shall include respondent Christopher M. Likens's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

## VIII.

IT IS FURTHER ORDERED that respondents and their successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondents learn less than thirty (30) days prior to the date such action is to take place, respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

## IX.

IT IS FURTHER ORDERED that respondents and their successors and assigns shall, within one hundred and eighty (180) days after service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this order.

## X.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided*, *however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that one or both of the respondents did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order as to that respondent(s) will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

# Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, a consent agreement from Nations Title Agency, Inc ("Nations Title"), Nations Holding Company ("Nations Holding"), and Christopher M. Likens ("Likens").

The consent agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

According to the Commission's proposed complaint, Nations Holding, Nations Title, and Likens provide services in connection with financing home purchases and refinancing existing home mortgages, including, but not limited to, real estate settlement services, residential closings, title abstracts, title commitments, appraisals, foreclosure management, asset disposition, and real estate management. Likens wholly owns Nations Holding, a subchapter "S" corporation, and has the authority to control the conduct of Nations Holding and its subsidiaries, including Nations Title. In providing these services, Nations Title, Nations Holding, and Likens ("respondents") routinely obtain sensitive consumer information from banks and other lenders, real estate brokers, consumers, public records, and others, including but not limited to consumer names, Social Security numbers, bank and credit card account numbers, mortgage information, loan applications, purchase contracts, refinancing agreements, income histories, and credit histories (collectively, "personal information").

The Commission's proposed complaint alleges that respondents failed to employ reasonable and appropriate security measures to protect personal information. In particular, the proposed complaint

alleges that respondents have engaged in a number of practices that, taken together, failed to provide reasonable and appropriate security for consumers' personal information. Among other things, respondents failed to: (1) assess risks to the information they collected and stored both online and offline; (2) implement reasonable policies and procedures in key areas, such as employee screening and training and the collection, handling, and disposal of personal information; (3) implement simple, low-cost, and readily available defenses to common website attacks, or implement reasonable access controls, such as strong passwords, to prevent a hacker from gaining access to personal information stored on respondents' computer network; (4) employ reasonable measures to detect and respond to unauthorized access to personal information or to conduct security investigations; and (5) provide reasonable oversight for the handling of personal information by service providers, such as third parties employed to process the information and assist in real estate closings.

The proposed complaint alleges that in April 2004, a hacker exploited these failures by using a common website attack to obtain unauthorized access to Nations Holding's computer network. In addition, in February 2005, a Kansas City television station found documents containing sensitive personal information discarded in a dumpster used by respondents located in an unsecured area adjacent to their building.

According to the complaint, respondents' practices violated the Gramm-Leach-Bliley ("GLB") Safeguards Rule because respondents failed to: (1) identify reasonably foreseeable internal and external risks to the security, confidentiality, and integrity of customer information; (2) design and implement information safeguards to control the risks to customer information and regularly test and monitor them; (3) investigate, evaluate, and adjust the information security program in light of known or identified risks; (4) develop, implement, and maintain a comprehensive written information security program; and (5) oversee service providers and require them by contract to implement safeguards to protect respondent's customer information.

In addition, the proposed complaint alleges that respondents misrepresented that they implemented reasonable and appropriate measures to protect consumers' personal information from unauthorized access, in violation of Section 5 of the Federal Trade Commission Act ("FTC Act"). Further, the proposed complaint alleges that respondents disseminated a privacy policy that does not accurately reflect their privacy policies and practices, in violation of the GLB Privacy Rule.

The proposed order applies to personal information from or about consumers that respondents collect in connection with their real estate-related services. The proposed order contains provisions designed to prevent them from engaging in the future in practices similar to those alleged in the complaint.

Part I of the proposed order requires that respondents not misrepresent the extent to which they maintain and protect the privacy, confidentiality, or integrity of any personal information collected from or about consumers.

Part II of the proposed order requires respondents to establish and maintain a comprehensive information security program in writing that is reasonably designed to protect the security, confidentiality, and integrity of personal information they collect from or about consumers. The security program must contain administrative, technical, and physical safeguards appropriate to their size and complexity, the nature and scope of their activities, and the sensitivity of the personal information collected. Specifically, the order requires respondents to:

- Designate an employee or employees to coordinate and be accountable for the information security program.
- Identify material internal and external risks to the security, confidentiality, and integrity of consumer information that could result in unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of such

information, and assess the sufficiency of any safeguards in place to control these risks.

- Design and implement reasonable safeguards to control the risks identified through risk assessment, and regularly test or monitor the effectiveness of the safeguards' key controls, systems, and procedures.
- Evaluate and adjust their information security program in light of the results of testing and monitoring, any material changes to their operations or business arrangements, or any other circumstances that they know or have to reason to know may have a material impact on the effectiveness of their information security program.

Part III of the proposed order requires that respondents not violate any provision of the GLB Safeguards Rule and Privacy Rule, as well as the Fair and Accurate Credit Transactions Act's Disposal Rule.

Part IV of the proposed order requires that respondents obtain within 180 days, and on a biennial basis thereafter, an assessment and report from a qualified, objective, independent third-party professional, certifying, among other things, that: (1) they have in place a security program that provides protections that meet or exceed the protections required by Part II of the proposed order, and (2) their security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of consumers' personal information has been protected.

Parts V through X of the proposed order are reporting and compliance provisions. Part V requires respondents to retain documents relating to their compliance with the order. Part VI requires dissemination of the order now and in the future to persons with supervisory responsibilities relating to the subject matter of the order. Part VII requires Likens to notify the Commission of changes in his business or employment in connection with providing financial products or services. Part VIII requires respondents to

notify the Commission of changes in their corporate status. Part IX mandates that they submit compliance reports to the FTC. Part X is a provision "sunsetting" the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed order or to modify its terms in any way.

## IN THE MATTER OF

# **FRESENIUS AG**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4161; File No. 0510154 Complaint, March 13, 2006--Decision, June 19, 2006

This consent order addresses the acquisition by respondent Fresenius AG of Renal Care Group, Inc. The combined firm would be the largest provider of outpatient dialysis services in the United States and would likely be able to exercise unilateral market power. The order requires Fresenius to divest 91 outpatient dialysis clinics, and Renal Care Group's joint venture equity interests in 12 additional clinics, to National Renal Institutes, Inc. (NRI). To ensure that NRI will have the assets necessary to operate the divested clinics in a competitive manner, Fresenius is required to obtain the agreement of the medical directors affiliated with the divested clinics to continue providing physician services after the transfer of ownership, to obtain the consent of all lessors necessary to assign the leases for the real property associated with the divested clinics to NRI, and to provide NRI with the opportunity to interview and hire employees affiliated with the divested clinics. The order prevents Fresenius from contracting with the medical directors (or their practice groups) affiliated with the divested clinics for three years. The order requires Fresenius to provide NRI with a license to Fresenius's policies and procedures, as well as the option to obtain Fresenius's medical protocols. In addition, Fresenius will provide transition services to NRI for a period of 12 months to ensure continuity of patient care and records. The order also requires Fresenius to provide prior notice to the Commission of its planned acquisitions of dialysis clinics located in the 66 markets addressed by the order to ensure that subsequent acquisitions do not adversely impact competition in the markets at issue and undermine the remedial goals of this order.

# **Participants**

For the Commission: Linda B. Blumenreich, Robert S. Canterman, Mary Connelly-Draper, Richard Cunningham, Jeffrey Dahnke, Daniel P. Ducore, Erin Dwyer-Frazier, Melea E. Greenfeld, Stephen F. Krebs, John Lambright, William Layher, Martha H. Oppenheim, David R. Pender, Eric Rohlck, Elizabeth Schneirov, Gary H. Schorr, and Karan R. Singh.

For the Respondent: Robert Bloch and Scott Perlman, Mayer, Brown, Rowe & Maw LLP.

## **COMPLAINT**

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 et seq., and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that Fresenius AG ("Fresenius AG"), a corporation, and entities controlled by Fresenius AG, including Fresenius Medical Care AG & Co. KGaA ("FME KGaA"), a partnership; Fresenius Medical Care Holdings, Inc. ("FME"), a corporation; and Florence Acquisition, Inc. ("FAI"), a corporation, (collectively "Fresenius"), all subject to the jurisdiction of the Commission, have agreed to acquire Renal Care Group, Inc. ("RCG"), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act ("FTC Act"), as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues this Complaint stating its charges as follows:

# I. NATURE OF THE CASE

1. This matter concerns an agreement whereby Fresenius would acquire RCG; if consummated, this acquisition would substantially lessen competition for services relating to administering outpatient chronic kidney dialysis treatment ("outpatient dialysis services") to end stage renal disease ("ESRD") patients in 66 local geographic markets across the United States. ESRD is a disease characterized by a near total loss of function of the kidneys. Outpatient chronic dialysis treatments are a life-sustaining therapy that replaces the function of the kidneys by removing toxins and excess fluid from the blood ("dialysis"). Fresenius and RCG are two of the three largest operators of clinics providing outpatient dialysis services throughout the United States. The post-acquisition firm would be

able to exercise unilateral market power in the relevant geographic markets, which would result in higher prices and reduced incentives to improve service or quality for outpatient dialysis services.

# II. RESPONDENTS

- 2. Respondent Fresenius AG is a corporation organized, existing, and doing business under and by virtue of the laws of the Federal Republic of Germany, with its office and principal place of business located at Else-Kröner-Straße 1, 61352 Bad Homburg, Germany. Fresenius AG is the ultimate parent of Respondents (1) FME KGaA, a partnership limited by shares, organized, existing, and doing business under and by virtue of the laws of the Federal Republic of Germany, the general partner of which is majority owned by Fresenius AG, with its office and principal place of business located at Else-Kröner-Straße 1, 61352 Bad Homburg, Germany; (2) FME, a corporation organized, existing, and doing business under and by virtue of the laws of the State of New York, majority owned by FME KGaA, with its office and principal place of business located at 95 Hayden Avenue, Lexington, MA 02420; and (3) FAI, a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, wholly owned by FME, with its office and principal place of business located at 95 Hayden Avenue, Lexington, MA 02420.
- 3. After acquiring RCG, Respondent Fresenius will be the largest provider of outpatient dialysis services in the United States. In 2005, Fresenius had approximately \$4.1 billion in revenues from the provision of outpatient dialysis services to approximately 89,000 ESRD patients at approximately 1,155 outpatient dialysis clinics nationwide.
- 4. Respondents are, and at all times herein have been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and are corporations or a partnership whose businesses are in or affect commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

# III. THE ACQUIRED COMPANY

- 5. RCG is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 2100 West End Avenue, Suite 600, Nashville, Tennessee 37203.
- 6. RCG is the third largest provider of outpatient dialysis services in the United States, with approximately 450 outpatient dialysis clinics nationwide, at which approximately 32,000 ESRD patients receive treatment. In 2005, RCG had approximately \$1.5 billion in revenues from the provision of outpatient dialysis services.
- 7. RCG is, and at all times herein has been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affects commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

# IV. THE PROPOSED ACQUISITION

8. Fresenius entered into an agreement with RCG dated May 3, 2005 (the "Agreement"), to acquire RCG in a transaction valued at approximately \$3.5 billion (the "Acquisition").

## V. THE RELEVANT MARKET

9. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the Acquisition is the provision of outpatient dialysis services. The only alternative to outpatient dialysis treatments for ESRD patients is a kidney transplant. However, the wait-time for donor kidneys – during which ESRD patients must receive dialysis treatments – can exceed five years. Additionally, many ESRD patients are not viable transplant

candidates. As a result, many ESRD patients have no alternative to outpatient dialysis treatments.

- 10. For the purposes of this Complaint, the relevant geographic market for the provision of outpatient dialysis services is defined by the distance ESRD patients are willing and/or able to travel to receive dialysis treatments, and is thus local in nature. Most ESRD patients receive dialysis treatments in an outpatient dialysis clinic three times per week, in sessions lasting between three and five hours. Because ESRD patients often suffer from multiple health problems and may require assistance traveling to and from the dialysis clinic, these patients are unwilling and/or unable to travel long distances to receive dialysis treatment. The time and distance a patient will travel in a particular location are significantly affected by traffic patterns; whether an area is urban, suburban, or rural; local geography; and a patient's proximity to the nearest dialysis clinic. The size and dimensions of relevant geographic markets are also influenced by a variety of other factors including population density, roads, geographic features, and political boundaries.
- 11. For the purposes of this Complaint, the 66 geographic markets within which to assess the competitive effects of the proposed merger are the following 39 metropolitan statistical areas ("MSAs"), other areas, or particular geographic areas contained therein: (1) Birmingham-Hoover, Alabama MSA; (2) Osceola and Blytheville, Arkansas; (3) Phoenix-Mesa-Scottsdale, Arizona MSA; (4) Prescott, Arizona MSA; (5) Naples-Marco Island, Florida MSA; (6) Sarasota-Bradenton-Venice, Florida MSA; (7) Tampa-St. Petersburg-Clearwater, Florida MSA; (8) Atlanta-Sandy Springs-Marietta, Georgia MSA; (9) Chicago-Naperville-Joliet, Illinois MSA; (10) Lake County-Kenosha County, Illinois-Wisconsin MSA; (11) Auburn, Indiana; (12) Fort Wayne, Indiana MSA; (13) Huntington, Indiana; (14) Indianapolis, Indiana MSA; (15) Logansport, Indiana; (16) Seymour and Scottsburg, Indiana; (17) Louisville, Kentucky-Indiana MSA; (18) Baton Rouge, Louisiana MSA; (19) Houma-Bayou Cane-Thibodaux, Louisiana MSA; (20) Essex County, Massachusetts MSA; (21) Jackson, Mississippi MSA; (22) Carthage and Philadelphia, Mississippi; (23) Lexington and

Kosciusko, Mississippi; (24) Kansas City, MO-KS MSA; (25) Las Cruces, New Mexico MSA; (26) Las Vegas-Paradise, Nevada MSA; (27) Akron, Ohio MSA; (28) Portland-Vancouver-Beaverton, Oregon-Washington MSA; (29) Philadelphia, Pennsylvania MSA; (30) Providence-New Bedford-Fall River, Rhode Island-Massachusetts MSA; (31) Greenville, South Carolina MSA; (32) Memphis, Tennessee-Mississippi-Arkansas MSA; (33) Alice, Texas; (34) Brownsville-Harlingen, Texas MSA; (35) Corpus Christi, Texas MSA; (36) McAllen-Edinburg-Mission, Texas MSA; (37) El Paso, Texas MSA; (38) Terrell and Sulphur Springs, Texas; and (39) Spokane, Washington MSA.

## VI. THE STRUCTURE OF THE MARKET

- 12. The market for the provision of outpatient dialysis services in each of the relevant geographic markets identified in Paragraph 11 is highly concentrated, as measured by the Herfindahl-Hirschman Index ("HHI"). The Acquisition would increase concentration significantly in each relevant market, leaving Fresenius as the dominant provider of outpatient dialysis services.
- 13. Fresenius and RCG are actual and substantial competitors in each of the relevant markets.

# VII. ENTRY CONDITIONS

14. The most significant barrier to entry into the relevant markets is locating a nephrologist with an established referral base who is willing and able to enter into a contract with a dialysis clinic to serve as the clinic's medical director. Federal law requires each dialysis clinic to have a physician medical director. Having a nephrologist serve as medical director is essential to the competitiveness of the clinic, because he or she is the clinic's primary source of referrals. A medical director's contract with a clinic typically prevents the medical director (and often his or her partners) from serving as a medical director for a competing clinic while serving as the clinic's medical director. The lack of available

nephrologists with an established referral stream is a significant barrier to entry into each of the relevant geographic markets identified in Paragraph 11.

- 15. Additionally, certain attributes are necessary to attract new entry into particular relevant markets, including a rapidly growing ESRD population, a favorable regulatory environment (including no state certificate of need requirements regulating the development of new clinics), average or lower nursing and labor costs, and a relatively low penetration of managed care. The absence of any of these attributes constitutes an additional barrier to entry into particular relevant markets.
- 16. New entry into the relevant markets sufficient to deter or counteract the anticompetitive effects described in Paragraph 17 is unlikely to occur, and would not occur in a timely manner because it would take over two years to enter and achieve significant market impact.

# VIII. EFFECTS OF THE ACQUISITION

- 17. The effects of the Acquisition, if consummated, may be substantially to lessen competition and tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:
  - a. eliminating actual, direct, and substantial competition between Fresenius and RCG;
  - b. increasing the ability of the merged entity unilaterally to raise prices; and
  - c. reducing incentives to improve service or quality.

# IX. VIOLATIONS CHARGED

- 18. The Agreement described in Paragraph 8 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.
- 19. The Acquisition described in Paragraph 8, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirtieth day of March, 2006, issues its Complaint against said Respondents.

By the Commission.

### **DECISION AND ORDER**

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition of Renal Care Group, Inc. by Fresenius AG and entities controlled by Fresenius AG, including (1) Fresenius Medical Care AG & Co. KGaA, a partnership limited by shares organized under the laws of the Federal Republic of Germany, the general partner of which is majority owned by Fresenius AG, (2) Fresenius Medical Care Holdings, Inc., a New York corporation majority owned by Fresenius Medical Care AG & Co. KGaA, a partnership limited by shares organized under the laws of the Federal Republic of Germany, and (3) Florence Acquisition, Inc., a Delaware corporation that is wholly owned by Fresenius Medical Care Holdings, Inc., and Fresnius AG (hereafter referred to as "Respondent") having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission, having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent

Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

- 1. Respondent Fresenius AG is a corporation organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany, with its office and principal place of business located at Else-Kröner-Straße 1, 61352 Bad Homburg, Germany. Fresenius AG is the ultimate parent of (1) Fresenius Medical Care AG & Co. KGaA, a partnership limited by shares organized under the laws of the Federal Republic of Germany, the general partner of which is majority owned by Fresenius AG, with its office and principal place of business located at Else-Kröner-Straße 1, 61352 Bad Homburg, Germany, (2) Fresenius Medical Care Holdings, Inc., a New York corporation majority owned by Fresenius Medical Care AG & Co. KGaA, a partnership limited by shares organized under the laws of the Federal Republic of Germany, with its office and principal place of business located at 95 Hayden Avenue, Lexington, MA 02420, and (3) Florence Acquisition, Inc., a Delaware corporation that is wholly owned by Fresenius Medical Care Holdings, Inc, with its office and principal place of business located at 95 Hayden Avenue, Lexington, MA 02420.
- 2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

### **ORDER**

I.

**IT IS ORDERED** that, as used in this Order, the following definitions shall apply:

- A. "Fresenius" means Fresenius AG, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries (including, but not limited to Fresenius Medical Care AG & Co. KGaA, a partnership limited by shares organized under the laws of the Federal Republic of Germany, Fresenius Medical Care Holdings, Inc., and Florence Acquisition, Inc.), divisions, groups, and affiliates controlled by Fresenius AG (including, after the Effective Date, Renal Care Group, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. "RCG" means Renal Care Group, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Renal Care Group, Inc.(including, but not limited to Renal Dimensions, LLC, and Summit Renal Care, LLC), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. "Commission" means the Federal Trade Commission.
- D. "Acquirer" and "Acquirers" means NRI, and each Person that receives the prior approval of the Commission to acquire any of the Appendix A Clinic Assets pursuant to Paragraphs II or V of this Order.
- E. "Appendix A Clinics" means the Clinics listed in Appendix A to this Order.

- F. "Appendix A Clinic Assets" means the Appendix A Clinics, and all Assets Associated with each of those Clinics;
- G. "Assets Associated" means the following assets Relating To the Operation Of A Clinic:
  - 1. all rights under the Clinic's Physician Contracts;
  - 2. leases for the Real Property Of The Clinic;
  - 3. consumable or disposable inventory, including, but not limited to, janitorial, office, and medical supplies, and at least ten (10) normal treatment day requirements of dialysis supplies and pharmaceuticals, including, but not limited to, erythropoietin;
  - 4. all rights, title, and interest of Fresenius in any tangible property (except for consumable or disposable inventory) that has been on the premises of the Clinic at any time since October 1, 2005, including, but not limited to, all equipment, furnishings, fixtures, improvements, and appurtenances;
  - 5. any interest (other than leases) held by Fresenius in the Real Property Of The Clinic;
  - 6. books, records, files, correspondence, manuals, computer printouts, databases, and other documents Relating To the Operation Of The Clinic located on the premises of the Clinic or in the possession of the Regional Manager responsible for such Clinic (or copies thereof where Fresenius has a legal

obligation to maintain the original document), including, but not limited to:

- a. documents containing information Relating To patients (to the extent transferable under applicable law), including, but not limited to, medical records,
- b. financial records,
- c. personnel files,
- d. Physician lists and other records of the Clinic's dealings with Physicians,
- e. maintenance records,
- f. documents Relating To policies and procedures,
- g. documents Relating To quality control,
- h. documents Relating To Payors,
- i. documents Relating To Suppliers,
- j. documents Relating To the Clinic To Be Divested that are also related to the Operation Of A Clinic that is not a Clinic To Be Divested, provided, however, if such documents are located other than on the premises of the Clinic To Be Divested, Fresenius may submit a copy of the document with the portions not Relating To the Clinic To Be Divested redacted, and
- copies of contracts with Payors and Suppliers, unless such contracts cannot, according to their terms, be disclosed to third parties even with the permission of Fresenius to make such disclosure;

- 7. Fresenius's Medicare and Medicaid provider numbers, to the extent transferable;
- 8. all permits and licenses, to the extent transferable;
- 9. Intangible Property (other than Software, Licensed Intangible Property, and Unrelated Intangible Property) relating exclusively to the Operation Of The Clinic;
- any contract Fresenius or RCG has to provide inhospital dialysis services Relating To the Clinic To Be Divested; and
- 11. assets that are used in, or necessary for, the Operation Of The Clinic.

*Provided, however,* that "Assets Associated" does not include Excluded Assets.

- H. "Assets To Be Divested" means the Appendix A Clinic Assets.
- I. "Clinic" means a facility that provides hemodialysis or peritoneal dialysis services to patients suffering from kidney disease.
- J. "Clinic's Physician Contracts" means all agreements to provide the services of a Physician to a Clinic, regardless of whether any of the agreements are with a Physician or with a medical group, including, but not limited to, agreements for the services of a medical director for the Clinic and "joiner" agreements with Physicians in the same medical practice as a medical director of the Clinic.

- K. "Clinic To Be Divested" and "Clinics To Be Divested" means the Appendix A Clinics.
- L. "Contract Services" means services performed pursuant to any Clinic's Physician Contract.
- M. "Divestiture Agreement" and "Divestiture Agreements" mean any agreement pursuant to which Fresenius divests any Appendix A Clinic Assets and the Joint Venture Equity Interests pursuant to this Order and with the prior approval of the Commission.
- N. "Effective Date" means the date on which Fresenius acquires RCG.
- O. "Employee Of A Clinic To Be Divested" and "Employee Of The Clinic To Be Divested" mean any individual (including, but not limited to, a clinic director, manager, nurse, technician, clerk, or social worker) who is not a Regional Manager, who is employed by Fresenius, by an Acquirer, or by another manager or owner of such Clinic To Be Divested, and who has worked part-time or full-time on the premises of such Clinic To Be Divested at any time since October 1, 2005, regardless of whether the individual has also worked on the premises of any other Clinic.
- P. "Excluded Assets" means:
  - 1. all cash, cash equivalents, and short term investments of cash;
  - 2. accounts receivable;
  - 3. income tax refunds and tax deposits due Fresenius;

- 4. unbilled costs and fees, and Medicare bad debt recovery claims, arising before a Clinic is divested to an Acquirer;
- 5. Fresenius's Medical Protocols (except if requested by an Acquirer pursuant to Paragraph II.B.17.b. of this Order);
- 6. rights to the names "Fresenius," and "Renal Care Group" and any variation of those names, and any names, phrases, marks, trade names, and trademarks to the extent they include the following, "fresenius medical care," "fresenius medical services, "biomedical applications," everest healthcare," "spectra," "national medical care," "ultraCare;" or "national nephrology associates," "neomedica," and "qualicenters," and any variation of those names.
- 7. insurance policies and all claims thereunder, except as set forth in the NRI Divestiture Agreements;
- 8. prepaid items or rebates;
- 9. minute books (other than governing body minute books of the Clinic To Be Divested), tax returns, and other corporate books and records;
- 10. any inter-company balances due to or from Fresenius or its affiliates;
- 11. all benefits plans;
- 12. all writings and other items that are protected by the attorney-client privilege, the attorney work product doctrine or any other cognizable privilege or protection, except to the extent such information is

necessary to the Operation Of A Clinic that is divested;

- 13. telecommunication systems equipment and applications, and information systems equipment including, but not limited to computer hardware, not physically located at a Clinic To Be Divested but shared with the Clinic To Be Divested through local and/or wide area networking systems;
- 14. e-mail addresses and telephone numbers of Fresenius's employees;
- 15. Software;
- 16. computer hardware used in the Operation Of The Clinic that is (a) not located at the Clinic, and (b) not otherwise to be divested pursuant to a Divestiture Agreement;
- 17. all Supplier or provider numbers issued to Fresenius or RCG by a Supplier or Payor with respect to any Clinic To Be Divested, except for Fresenius's Medicare and Medicaid provider numbers for each Clinic To Be Divested, to the extent transferable;
- 18. rights under agreements with Payors and Suppliers that are not assignable even if Fresenius and RCG approve such assignment or, that, according to their terms, cannot be disclosed to third parties even with the permission of Fresenius or RCG to make such disclosures;
- 19. office equipment and furniture that (a) is not, in the Ordinary Course Of Business, physically located at the Clinic To Be Divested, (b) is shared with Clinics other than the Clinic To Be Divested, and (c) is not

necessary to the Operation Of The Clinic To Be Divested;

- 20. Licensed Intangible Property (subject to the requirements of Paragraph II.B.15);
- 21. Unrelated Intangible Property;
- 22. Intangible Property not relating exclusively to the Operation Of The Clinic (subject to the requirements of Paragraph II.B.18); and
- 23. strategic planning documents that
  - a. Relate To the Operation Of The Clinic other than the Clinic To Be Divested, and
  - b. are not located on the premises of the Clinic To Be Divested.
- Q. "Fresenius Employee Of A Clinic To Be Divested" and "Fresenius Employee Of The Clinic To Be Divested" means an Employee Of A Clinic To Be Divested who is employed by Fresenius.
- R. "Fresenius's Medical Protocols" means medical protocols promulgated by either Fresenius or RCG, whether in hard copy or embedded in software, that have been in effect at any time since October 1, 2005. *Provided, however,* "Fresenius's Medical Protocols" does not mean medical protocols adopted or promulgated, at any time, by any Physician or by any Acquirer, even if such medical protocols are identical, in whole or in part, to medical protocols promulgated by either Fresenius or RCG

- S. "Governmental Approvals" means any permissions or sanctions issued by any government or governmental organization, including, but not limited to, licenses, permits, accreditations, authorizations, registrations, certifications, certificates of occupancy, and certificates of need.
- T. "Government Approvals For Continued Operation" means any Governmental Approvals, other than Government Approvals For Divestiture, that an Acquirer must have to continue to operate a Clinic To Be Divested.
- U. "Governmental Approvals For Divestiture" means any Governmental Approvals that an Acquirer must have to own, and to initially operate, a Clinic To Be Divested, including, but not limited to, state-issued licenses and state-issued certificates of need.
- V. "Illinois Clinic Assets" means the Clinics listed in Appendix C, and all Assets Associated with those Clinics.
- W. "Illinois Governmental Approvals For Divestiture" means any Governmental Approvals For Divestiture issued by the State of Illinois.
- X. "Illinois Joint Venture Equity Interest" means the joint venture equity interest owned by RCG in each of the following joint ventures located in the State of Illinois:
  (1) Renal Care Group Buffalo Grove, LLC, and (2) Renal Care Group Schaumburg, LLC.
- Y. "Intangible Property" means intangible property Relating To the Operation Of A Clinic To Be Divested including, but not limited to, intellectual property, software, computer programs, patents, know-how, goodwill, technology, trade secrets, technical

information, marketing information, protocols, quality control information, trademarks, trade names, service marks, logos, and the modifications or improvements to such intangible property.

- Z. "Joint Venture Equity Interest" means the joint venture equity interest owned by RCG in each of the following joint ventures: (1) RCG Brandon LLC (Brandon, MS), (2) Renal Care Group Schaumburg, LLC, (3) Brownsville Kidney Center, Ltd., (4) El Paso Kidney Center East, Ltd., (5) Renal Care Group Buffalo Grove, LLC, (6) Renal Care Group South Tampa, LLC, (7) Renal Care Group Canton, LLC (Georgia), (8) Renal Care Group Galleria, LLC., and (9) Summit Renal Care, LLC. The joint ventures are more fully described in Appendix D.
- AA. "Licensed Intangible Property" means intangible property licensed to Fresenius from a third party Relating To the Operation Of A Clinic To Be Divested including, but not limited to, intellectual property, software, computer programs, patents, know-how, goodwill, technology, trade secrets, technical information, marketing information, protocols, quality control information, trademarks, trade names, service marks, logos, and the modifications or improvements to such intangible property that are licensed to Fresenius. "Licensed Intangible Property" does not mean modifications and improvements to intangible property that are not licensed to Fresenius, or Unrelated Intangible Property.
- BB. "Material Confidential Information" means competitively sensitive, proprietary, and all other information that is not in the public domain owned by or pertaining to a Person or a Person's business, and includes, but is not limited to, all customer lists, price

- lists, contracts, cost information, marketing methods, patents, technologies, processes, or other trade secrets.
- CC. "Monitor Agreement" means the Monitor Agreement dated March 7, 2006, between Fresenius, and Richard A. Shermer, of R. Shermer & Co. The Monitor Agreement is attached as Appendix E to this Order.
- DD. "NRI" means National Renal Institutes, Inc., located at 511 Union Street, Suite 1800, Nashville, TN 37219, and which is a wholly owned subsidiary of DSI Holding Company, Inc.
- EE. "NRI Divestiture Agreements" means the Amended and Restated Asset Purchase Agreement dated March 9, 2006, but effective as of February 14, 2006, by and among National Renal Institutes, Inc., Renal Care Group, Inc. and Fresenius Medical Care Holdings, Inc., including all Exhibits (including, but not limited to, the Assignment and Assumption Agreement, Bill of Sale, License Agreement, Transition Services Agreement, Escrow Agreement, Lab Services Agreement, Supply Agreement, Transfer Documents for Real Property, and Partial Waiver Agreement) and Schedules.
- FF. "Operation Of A Clinic" and "Operation Of The Clinic" mean all activities Relating To the business of a Clinic, including, but not limited to:
  - 1. attracting patients to the Clinic for dialysis services, providing dialysis services to patients of the Clinic, and dealing with their Physicians, including, but not limited to, services Relating To hemodialysis and peritoneal dialysis;
  - 2. providing medical products to patients of the Clinic;

- 3. maintaining the equipment on the premises of the Clinic, including, but not limited to, the equipment used in providing dialysis services to patients;
- 4. purchasing supplies and equipment for the Clinic;
- 5. negotiating leases for the premises of the Clinic;
- 6. providing counseling and support services to patients receiving products or services from the Clinic;
- 7. contracting for the services of medical directors for the Clinic;
- 8. dealing with Payors that pay for products or services offered by the Clinic, including but not limited to, negotiating contracts with such Payors and submitting claims to such Payors; and
- 9. dealing with Governmental Approvals Relating To the Clinic or that otherwise regulate the Clinic.
- GG. "Ordinary Course Of Business" means actions taken by any Person in the ordinary course of the normal day-to-day Operation Of The Clinic that are consistent with past practices of such Person in the Operation Of The Clinic, including, but not limited to past practice with respect to amount, timing, and frequency.
- HH. "Other Contracts Of Each Clinic To Be Divested" means all contracts Relating To the Operation Of A Clinic, where such Clinic is a Clinic To Be Divested including, but not limited to, contracts for goods and services provided to the Clinic and contracts with Payors but does not mean the Clinic's Physician Contracts and the leases for the Real Property Of The Clinic.

- II. "Payor" means any Person that purchases, reimburses for, or otherwise pays for medical goods or services for themselves or for any other person, including, but not limited to: health insurance companies; preferred provider organizations; point of service organizations; prepaid hospital, medical, or other health service plans; health maintenance organizations; government health benefits programs; employers or other persons providing or administering self-insured health benefits programs; and patients who purchase medical goods or services for themselves.
- JJ. "Person" means any natural person, partnership, corporation, association, trust, joint venture, government, government agency, or other business or legal entity.
- KK. "Physician" means a doctor of allopathic medicine ("M.D.") or a doctor of osteopathic medicine ("D.O.").
- LL. "Real Property Of The Clinic" means real property on which, or in which, the Clinic is located, including real property used for parking and for other functions Relating To the Operation Of The Clinic.
- MM. "Relating To" means pertaining in any way to, and is not limited to that which pertains exclusively to or primarily to.
- NN. "Regional Manager" means any individual who has been employed by Fresenius or RCG with supervisory responsibility for three or more Clinics.
- OO. "Regional Manager Of A Clinic To Be Divested" and "Regional Manager Of The Clinic To Be Divested" mean a Regional Manager who has had direct supervisory responsibility for a Clinic To Be Divested at any time since October 1, 2005.

- PP. "Software" means executable computer code and the documentation for such computer code, but does not mean data processed by such computer code.
- QQ. "Supplier" means any Person that has sold to Fresenius or RCG any goods or services, other than Physician services, for use in a Clinic To Be Divested. *Provided, however,* "Supplier" does not mean an employee of Fresenius or RCG.
- RR. "Time Of Divestiture" means with respect to an Appendix A Clinic or a Joint Venture Equity Interest, the date upon which a Clinic or a Joint Venture Equity Interest is divested to an Acquirer pursuant to this Order.
- SS. "Unrelated Intangible Property" means Intangible Property that is Relating To:
  - Renal products produced and sold by Fresenius including, but not limited to, dialyzers, bloodlines, hemodialysis machines, peritoneal dialysis cyclers, catheters and tubing, concentrates, water treatment systems and dialysis fluids;
  - 2. Clinical laboratory testing services provided by Fresenius-owned laboratories;
  - 3. Perfusion services provided by Fresenius, including without limitation, operation of heart and lung machines during surgery;
  - 4. Auto transfusion services and products provided by Fresenius, including without limitation, blood processing devices allowing reinfusion of blood lost during surgery;

- 5. Ambulatory surgery services performed by Fresenius;
- 6. Disease and case management administrative and coordination services provided by Fresenius;
- 7. Pharmaceuticals produced and sold by Fresenius, including without limitation, peritoneal dialysis solutions, Vitamin D analogues and phosphate binders;
- 8. Biologicals produced and sold by Fresenius, including without limitation, therapies and products for the treatment of cancer and immunosuppression in organ and bone marrow transplantation;
- 9. Hospital and pharmaceutical industry facility development, engineering and management services provided by Fresenius;
- 10. Infusion therapy and products provided by Fresenius, including without limitation, anesthesia, electrolyte and glucose infusion solutions and nutritional infusion solutions;
- 11. Nutrition therapies and products provided by Fresenius, including without limitation, feeding tubes, feeding pumps, artificial feeding products and services;
- 12. Cell separation therapy and products provided by Fresenius, including without limitation, removal of diseased cells from blood in leukemia and autoimmune disease applications;
- 13. Adsorption therapies and products provided by Fresenius, including without limitation, products and therapies for the removal of undesirable substances

from the blood (e.g., cholesterol) and products and therapies for the treatment of arthritis;

- 14. Blood bank products and services provided by Fresenius, including without limitation, blood collection and storage services and products and blood transfusion services and products;
- 15. Hydroxyethyl starch (HES) substitutes produced and sold by Fresenius, which are maize-based solutions that can compensate for deficient blood volume and improve blood viscosity; and/or
- 16. Genetic engineering, antibody and cell therapy products for the treatment of cancer currently under development by Fresenius.

II.

# IT IS FURTHER ORDERED that:

# A. Fresenius shall:

- 1. within ten (10) days after the Effective Date, divest to NRI, absolutely, and in good faith, pursuant to and in accordance with the NRI Divestiture Agreements:
  - all the Appendix A Clinic Assets, except for the Illinois Clinic Assets, as on-going businesses; and
  - b. all of its Joint Venture Equity Interests, except for the Illinois Joint Venture Equity Interests;

Provided, however, if, at the time the Commission makes this Order final, the Commission determines that NRI is not an acceptable acquirer or that the NRI

Divestiture Agreements are not an acceptable manner of divestiture, and so notifies Fresenius, then Fresenius shall within six (6) months of the date Fresenius receives notice of such determination from the Commission, divest the Appendix A Clinic Assets, except for the Illinois Clinic Assets, absolutely and in good faith, at no minimum price, as on-going businesses and the Joint Venture Equity Interests, except for the Illinois Joint Venture Equity Interests, absolutely and in good faith, at no minimum price, to an Acquirer or Acquirers that receive the prior approval of the Commission and only in a manner that receives the prior approval of the Commission;

2. within ninety (90) days after the Effective Date, divest to NRI, absolutely, and in good faith, pursuant to and in accordance with the NRI Divestiture Agreements, the Illinois Clinic Assets, as on-going businesses, and the Illinois Joint Venture Equity Interests;

Provided, however, if, at the time the Commission makes this Order final, the Commission determines that NRI is not an acceptable acquirer or that the NRI Divestiture Agreements are not an acceptable manner of divestiture, and so notifies Fresenius, then Fresenius shall within eight (8) months of the date Fresenius receives notice of such determination from the Commission, divest the Illinois Clinic Assets absolutely and in good faith, at no minimum price, as on-going businesses, and the Illinois Joint Venture Equity Interests absolutely and in good faith, at no minimum price, to an Acquirer or Acquirers that receive the prior approval of the Commission and only in a manner that receives the prior approval of the Commission.

3. The NRI Divestiture Agreements are incorporated by reference into this Order and made a part hereof as

Non-Public Appendix F. Any failure by Fresenius to comply with the NRI Divestiture Agreements shall constitute a failure to comply with the Order. The NRI Divestiture Agreements shall not vary or contradict, or be construed to vary or contradict, the terms of this Order. Nothing in this Order shall reduce, or be construed to reduce, any rights or benefits of NRI, or any obligations of Fresenius, under the NRI Divestiture Agreements.

- 4. If Fresenius has divested the Appendix A Clinic Assets and the Joint Venture Equity Interests to NRI prior to the date this Order becomes final, and if, at the time the Commission makes this Order final, the Commission determines that NRI is not an acceptable acquirer or that the NRI Divestiture Agreements are not an acceptable manner of divestiture, and so notifies Fresenius, then Fresenius shall within three (3) business days of receiving such notification, rescind the transaction with NRI and shall divest the Appendix A Clinic Assets and the Joint Venture Equity Interests in accordance with the provisos to Paragraphs II.A.1 and II.A.2 of this Order.
- 5. If Fresenius has divested to NRI the following Clinics in Rhode Island: North Providence (1635 Mineral Spring Avenue, Providence, RI 02904) and Providence (45 Hemingway Drive, Providence, RI 02915) and the Assets Associated with such Clinics (collectively, the "Rhode Island Clinic Assets"), and:
  - a. if, after such divestiture, the Rhode Island Department of Health determines that NRI is not an acceptable acquirer or that the NRI Divestiture Agreements relating to the Rhode

Island Clinic Assets are not an acceptable manner of divestiture, and

- b. the Rhode Island Department of Health so notifies Fresenius that it must reacquire the Rhode Island Clinic Assets,
- c. then Fresenius shall, within six (6) months of the date Fresenius receives notice of such determination from the Rhode Island Department of Health, divest the Rhode Island Clinic Assets absolutely and in good faith, at no minimum price, as on-going businesses, to an Acquirer or Acquirers that receive the prior approval of the Commission and only in a manner that receives the prior approval of the Commission. *Provided, however,* unless otherwise prohibited by the Rhode Island Department of Health, NRI shall continue to manage such Clinics pending divestiture.
- B. Fresenius shall divest the Assets To Be Divested on the terms set forth in this Paragraph II.B, in addition to other terms that may be required by this Order and by the Divestiture Agreements; and Fresenius shall agree with the Acquirers, as part of the Divestiture Agreements, to comply with the terms set forth in this Paragraph II.B.
  - 1. Fresenius shall place no restrictions on the use by any Acquirer of any of the Assets To Be Divested or any of the Clinics To Be Divested.
  - 2. Fresenius shall cooperate with the Acquirer and assist the Acquirer, at no cost to the Acquirer, at the Time Of Divestiture of each Clinic To Be Divested, in obtaining all Government Approvals For Divestiture, and all Government Approvals For

Continued Operation, for each Clinic To Be Divested.

- 3. Fresenius shall, at the Time Of Divestiture of each Clinic To Be Divested and each Joint Venture Equity Interest:
  - a. assign to the Acquirer all rights, title, and interest to leases for the Real Property Of The Clinic, and shall obtain all approvals necessary for such assignments; *Provided, however*, that (1) if the Acquirer obtains all rights, title, and interest to a lease for Real Property Of A Clinic To Be Divested before the Assets To Be Divested are divested pursuant to Paragraph II.A. of this Order, and (2) the Acquirer certifies its receipt of such lease and attaches it as part of the Divestiture Agreement, then Fresenius shall not be required to make the assignments for such Clinic To Be Divested as required by this Paragraph II.B.3.a; and
  - b. assign to the Acquirer all of the Clinic's Physician Contracts, and shall obtain all approvals necessary for such assignment; *Provided, however*, that (1) if the Acquirer enters into a Clinic's Physician Contract for a Clinic To Be Divested before the Assets To Be Divested are divested pursuant to Paragraph II.A. of this Order, and (2) the Acquirer certifies its receipt of such contract and attaches it as part of the Divestiture Agreement, then Fresenius shall not be required to make the assignment for such Clinic To Be Divested as required by this Paragraph II.B.3.b; and

- c. shall obtain all approvals by joint venture partners necessary for the Acquirer to acquire the Clinics To Be Divested that are owned by a joint venture, and shall assign all such approvals to the Acquirer; and
- d. shall obtain all approvals by joint venture partners necessary for the Acquirer of Joint Venture Equity Interests to jointly own and operate the Clinics owned by the joint venture, and shall assign all such approvals to the Acquirer.
- 4. With respect to all Other Contracts Of Each Clinic To Be Divested, Fresenius shall, at the Acquirer's option and at the Time Of Divestiture of each Clinic To Be Divested:
  - a. if such contract can be assigned without third party approval, assign its rights under the contract to the Acquirer; and
  - b. if such contract can be assigned to the Acquirer only with third party approval, assist and cooperate with the Acquirer in obtaining:
    - (1) such third party approval and in assigning the contract to the Acquirer; or
    - (2) a new contract.

## 5. Fresenius shall:

 a. at the Time Of Divestiture of each Clinic To Be Divested, provide to the Acquirer of such Clinic contact information about Payors and Suppliers for the Clinic; and

- b. not object to the sharing of Payor and Supplier contract terms Relating To the Clinics To Be Divested (i) if the Payor or Supplier consents in writing to such disclosure upon a request by the Acquirer, and (ii) if the Acquirer enters into a confidentiality agreement with Fresenius not to disclose the information to any third party.
- 6. Until sixty (60) days after the Time Of Divestiture of each Clinic To Be Divested, Fresenius shall:
  - facilitate interviews between each Fresenius Employee Of A Clinic To Be Divested and the Acquirer of the Clinic, and shall not discourage such employee from participating in such interviews; and
  - b. not interfere in employment negotiations between each Fresenius Employee Of A Clinic To Be Divested and the Acquirer of the Clinic.
- 7. With respect to each Fresenius Employee Of A Clinic To Be Divested who receives, within sixty (60) days of the Time Of Divestiture of any Clinic at which he or she is employed, an offer of employment from the Acquirer of that Clinic:
  - a. Fresenius shall not prevent, prohibit or restrict or threaten to prevent, prohibit or restrict the Fresenius Employee Of The Clinic To Be Divested from being employed by the Acquirer of the Clinic, and shall not offer any incentive to the Fresenius Employee Of The Clinic To Be Divested to decline employment with the Acquirer of the Clinic;

- b. if the Fresenius Employee Of The Clinic To Be Divested accepts such offer of employment from the Acquirer, Fresenius shall cooperate with the Acquirer of the Clinic in effecting transfer of the Fresenius Employee Of The Clinic To Be Divested to the employ of the Acquirer of the Clinic;
- c. Fresenius shall eliminate any contractual provisions or other restrictions that would otherwise prevent the Fresenius Employee Of The Clinic To Be Divested from being employed by the Acquirer of the Clinic;
- d. Fresenius shall eliminate any confidentiality restrictions that would prevent the Fresenius Employee Of The Clinic To Be Divested who accepts employment with the Acquirer of the Clinic from using or transferring to the Acquirer any information Relating To the Operation Of The Clinic; and
- e. Fresenius shall pay, for the benefit of any Fresenius Employee Of The Clinic To Be Divested who accepts employment with the Acquirer of the Clinic, all accrued bonuses, vested pensions, and other accrued benefits, except extended sick leave, as to which NRI shall be solely responsible for its payment in full.
- 8. For a period of two (2) years following the Time Of Divestiture of each Clinic To Be Divested, Fresenius shall not, directly or indirectly, solicit, induce, or attempt to solicit or induce any Employee Of A Clinic To Be Divested who is employed by the Acquirer to terminate his or her employment relationship with the Acquirer, unless that employment relationship has already been

terminated by the Acquirer; provided, however, Fresenius may make general advertisements for employees including, but not limited to, in newspapers, trade publications, websites, or other media not targeted specifically at Acquirer's employees; provided further, however, Fresenius may hire employees who apply for employment with Fresenius, as long as such employees were not solicited by Fresenius in violation of this Paragraph II.B.8; provided further, however, Fresenius may offer employment to an Employee Of A Clinic To Be Divested who is employed by the Acquirer in only a part-time capacity, if the employment offered by Fresenius would not, in any way, interfere with the employee's ability to fulfill his or her employment responsibilities to the Acquirer.

- 9. For a period of not less than forty-five (45) days, which period may begin prior to the signing of the Consent Agreement and which shall end no earlier than ten (10) days after the Time Of Divestiture of each Clinic To Be Divested ("Forty-Five Day Hiring Period"), Fresenius shall:
  - facilitate interviews between each Regional Manager Of A Clinic To Be Divested and the Acquirer of the Clinic, and shall not discourage such Regional Manager from participating in such interviews; and
  - b. not interfere in employment negotiations between each Regional Manager Of A Clinic To Be Divested and the Acquirer of the Clinic.

Provided, however, the terms of this Paragraph II.B.9 shall not apply after Acquirers have hired ten (10)

Regional Managers who were each previously employed by Fresenius or RCG at any time since October 1, 2005.

- 10. With respect to each Regional Manager Of A Clinic To Be Divested who receives, within the Forty-Five Day Hiring Period required by Paragraph II.B.9. of this Order an offer of employment from the Acquirer of that Clinic:
  - a. Fresenius shall not prevent, prohibit or restrict or threaten to prevent, prohibit or restrict the Regional Manager Of The Clinic To Be Divested from being employed by the Acquirer of the Clinic, and shall not offer any incentive to the Regional Manager Of The Clinic To Be Divested to decline employment with the Acquirer of the Clinic;
  - b. if the Regional Manager Of The Clinic To Be Divested accepts such offer of employment from the Acquirer, Fresenius shall cooperate with the Acquirer of the Clinic in effecting transfer of the Regional Manager Of The Clinic To Be Divested to the employ of the Acquirer of the Clinic;
  - c. Fresenius shall eliminate any contractual provisions or other restrictions that would otherwise prevent the Regional Manager Of The Clinic To Be Divested from being employed by the Acquirer of the Clinic;
  - d. Fresenius shall eliminate any confidentiality restrictions that would prevent the Regional Manager Of The Clinic To Be Divested who accepts employment with the Acquirer of the Clinic from using or transferring to the Acquirer any information Relating To the Operation Of The Clinic:

- e. Fresenius shall pay, for the benefit of any Regional Manager Of The Clinic To Be Divested who accepts employment with the Acquirer of the Clinic, all accrued bonuses, vested pensions and other accrued benefits, except extended sick leave, as to which NRI shall be solely responsible for its payment in full; and
- f. for a period of two (2) years following the Time Of Divestiture of the Clinic To Be Divested. Fresenius shall not, directly or indirectly, solicit, induce, or attempt to solicit or induce any Regional Manager of the Acquirer who was previously a Regional Manager of A Clinic To Be Divested to terminate his or her employment relationship with the Acquirer unless the individual has been terminated by the Acquirer; provided, however, Fresenius may make general advertisements for Regional Managers including, but not limited to, in newspapers, trade publications, websites, or other media not targeted specifically at Acquirer's Regional Managers; provided further, however, Fresenius may hire Regional Managers who apply for employment with Fresenius, as long as such Regional Managers were not solicited by Fresenius in violation of this Paragraph II.B.10.f.

Provided, however, after the Acquirer has hired ten (10) Regional Managers who were each previously employed by Fresenius or RCG at any time since October 1, 2005, the terms of this Paragraph II.B.10 shall apply only to those ten (10) Regional Managers hired by the Acquirer.

11. With respect to each Physician who has provided services to a Clinic To Be Divested pursuant to any

of the Clinic's Physician Contracts in effect at any time during the four (4) months preceding the Time Of Divestiture of the Clinic ("Contract Physician"):

- a. Fresenius shall not offer any incentive to the Contract Physician, the Contract Physician's practice group, or other members of the Contract Physician's practice group to decline to provide services to the Clinic To Be Divested, and shall eliminate any confidentiality restrictions that would prevent the Contract Physician, the Contract Physician's practice group, or other members of the Contract Physician's practice group from using or transferring to the Acquirer of the Clinic To Be Divested any information Relating To the Operation Of The Clinic; and
- b. For a period of three (3) years following the Time Of Divestiture of each Clinic To Be Divested, Fresenius shall not contract for the services of the Contract Physician, the Contract Physician's practice group, or other members of the Contract Physician's practice group for the provision of Contract Services to be performed in any of the areas listed in Appendix B of this Order that correspond to such Clinic. Provided, however, if the Contract Physician, or the Contract Physician's practice group, or other members of the Contract Physician's practice group were providing services to one or more Clinics, other than or in addition to a Clinic To Be Divested, pursuant to a contract with Fresenius or RCG in effect as of October 1, 2005, then Fresenius may continue to contract with such Contract Physicians, or the Contract Physician's practice group, or other members of the Contract Physician's practice group for

services to be provided to such other or additional Clinics;

- 12. With respect to Material Confidential Information relating exclusively to any of the Clinics To Be Divested, Fresenius shall:
  - a. not disclose such information to any Person other than the Acquirer of such Clinic;
  - b. after the Time Of Divestiture of such Clinic:
    - (1) not use such information for any purpose other than complying with the terms of this Order or with any law; and
    - (2) destroy all records of such information, except to the extent that: (1) Fresenius is required by law to retain such information, and (2) Fresenius's inside or outside attorneys may keep one copy solely for archival purposes, but may not disclose such copy to the rest of Fresenius.
- 13. At the Time Of Divestiture of each Clinic To Be Divested, Fresenius shall provide the Acquirer of the Clinic with manuals, instructions, and specifications sufficient for the Acquirer to access and use any information
  - a. divested to the Acquirer pursuant to this Order, or
  - b. in the possession of the Acquirer, and previously used by Fresenius or RCG in the Operation Of The Clinic.

- 14. For two (2) years following the Time Of Divestiture of each Clinic To Be Divested, Fresenius shall not solicit the business of any patients that received any goods or services from such Clinic between October 1, 2005, and the date of such divestiture, provided, however, Fresenius may (i) make general advertisements for the business of such patients including, but not limited to, in newspapers, trade publications, websites, or other media not targeted specifically at such patients, and (ii) provide advertising and promotions directly to any patient that initiates discussions with, or makes a request to, any Fresenius employee. Fresenius shall convey to each Acquirer of a Clinic To Be Divested the right to use any Licensed Intangible Property (to the extent permitted by the third-party licensor), if such right is needed for the Operation Of The Clinic by the Acquirer and if the Acquirer is unable, using commercially reasonable efforts, to obtain equivalent rights from other third parties on commercially reasonable terms and conditions.
- 15. Fresenius shall do nothing to prevent or discourage Suppliers that, prior to the Time Of Divestiture of any Clinic To Be Divested, supplied goods and services for use in any Clinic To Be Divested from continuing to supply goods and services for use in such Clinic.
- 16. With respect to Fresenius's Medical Protocols:
  - a. Fresenius shall retain a copy of Fresenius's Medical Protocols until six (6) months after all of the Assets To Be Divested have been divested pursuant to this Order;
  - b. If any Acquirer of a Clinic To Be Divested requests in writing to Fresenius, within six (6)

months of the Time Of Divestiture of that Clinic to that Acquirer, that Fresenius license a copy of Fresenius's Medical Protocols to that Acquirer, Fresenius shall within five (5) business days of such request, grant to that Acquirer a royalty-free, perpetual, worldwide license for the use, without any limitation, of Fresenius's Medical Protocols (including the right to transfer or sublicense such protocols, exclusively or nonexclusively, to others by any means); and

- c. Fresenius shall create no disincentive for any Acquirer of a Clinic To Be Divested to make such a request for a license for Fresenius's Medical Protocols, and shall not enter into any agreement or understanding with any Acquirer that the Acquirer not make such a request.
- 17. Fresenius shall grant a royalty-free perpetual worldwide license for the use, without any limitation, of all Intangible Property (other than Software, Licensed Intangible Property, and Unrelated Intangible Property) not relating exclusively to the Operation Of The Clinic (including the right to transfer or sublicense such license rights in such Intangible Property, exclusively or nonexclusively, to others by any means).
- C. Fresenius shall not acquire RCG until it has obtained for all Clinics To Be Divested and all Joint Venture Equity Interests:
  - 1. all Governmental Approvals For Divestiture necessary for the Acquirers of such Clinics to be able to own, and immediately operate, the Clinics; *provided, however,* Fresenius shall not be required to

obtain Illinois Governmental Approvals For Divestiture prior to acquiring RCG;

- 2. all approvals for assignment of the leases for the Real Property Of The Clinics, as required by Paragraph II.B.3.a of this Order;
- 3. all approvals for the assignment of the Clinic's Physician Contracts, as required by Paragraph II.B.3.b of this Order; and
- 4. all approvals by joint venture partners necessary for (a) the Acquirer of such Clinics to be able to acquire the Clinics from the joint venture, and (b) the Acquirer of such Joint Venture Equity Interests to jointly own and operate the Clinics with the joint venture partners, as required by Paragraphs II.B.3.c and II.B.3.d of this Order.

Copies of all such approvals shall be incorporated into the Divestiture Agreements as appendices.

D. The purpose of Paragraph II of this Order is to ensure the continuation of the Clinics To Be Divested as, or as part of, ongoing viable enterprises engaged in the same business in which such assets were engaged at the time of the announcement of the acquisition by Fresenius of RCG, to ensure that the Clinics To Be Divested are operated independently of, and in competition with, Fresenius, and to remedy the lessening of competition alleged in the Commission's Complaint.

## III.

**IT IS FURTHER ORDERED** that, for a period of five (5) years from the date this Order is issued, Fresenius shall not, without providing advance written notification to the Commission in the manner described in this paragraph, directly or indirectly:

- A. acquire any assets of or financial interest in any Clinic located in any of the areas listed in Appendix B of this Order; or
- B. enter into any contract to participate in the management or Operation Of A Clinic located in any of the areas listed in Appendix B of this Order, except to the extent that the contract relates exclusively to:
  - 1. off-site lab services or social worker support materials; or
  - 2. billing services, collection services, bookkeeping services, accounting services, supply purchasing and logistics services, or the preparation of financial reports and accounts receivable reports (collectively "Such Services"), where appropriate firewalls and confidentiality agreements are implemented to prevent Material Confidential Information of the Clinic from being disclosed to anyone participating in any way in the operation or management of any Clinic owned by Fresenius or any Clinic other than the Clinic to which Such Services are being provided.

Said advance written notification shall contain (i) either a detailed term sheet for the proposed acquisition or the proposed agreement with all attachments, and (ii) documents that would be responsive to Item 4(c) of the Premerger Notification and Report Form under the Hart-Scott-Rodino Premerger Notification Act, Section 7A of the Clayton Act, 15 U.S.C. § 18a, and Rules, 16 C.F.R. § 801-803, relating to the proposed transaction (hereinafter referred to as "the Notification), *provided, however*, (i) no filing fee will be required for the Notification, (ii) an original and one copy of the Notification shall be filed only with the Secretary of the Commission and need not be submitted to the United States Department of Justice, and

(iii) the Notification is required from Fresenius and not from any other party to the transaction. Fresenius shall provide the Notification to the Commission at least thirty (30) days prior to consummating the transaction (hereinafter referred to as the "first waiting period"). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Fresenius shall not consummate the transaction until thirty (30) days after submitting such additional information or documentary material. Early termination of the waiting periods in this paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition.

*Provided, however*, that prior notification shall not be required by this paragraph for a transaction for which Notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

## IV.

## **IT IS FURTHER ORDERED** that:

- A. Richard Shermer, of R. Shermer & Co., shall be appointed Monitor to assure that Fresenius expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order.
- B. No later than one (1) day after this Order is made final, Fresenius shall, pursuant to the Monitor Agreement and to this Order, transfer to the Monitor all the rights, powers, and authorities necessary to permit the Monitor to perform his duties and responsibilities in a manner consistent with the purposes of this Order.
- C. In the event a substitute Monitor is required, the Commission shall select the Monitor, subject to the consent of Fresenius, which consent shall not be unreasonably withheld. If Fresenius has not opposed, in

writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Fresenius of the identity of any proposed Monitor, Fresenius shall be deemed to have consented to the selection of the proposed Monitor. Not later than ten (10) days after appointment of a substitute Monitor, Fresenius shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Fresenius's compliance with the terms of this Order, the Order to Maintain Assets, and the Divestiture Agreements in a manner consistent with the purposes of this Order.

- D. Fresenius shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
  - 1. The Monitor shall have the power and authority to monitor Fresenius's compliance with the terms of this Order, the Order to Maintain Assets, and the Divestiture Agreements, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of this Order and in consultation with the Commission, including, but not limited to:
    - Assuring that Fresenius expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order, the Order to Maintain Assets, and the Divestiture Agreements;
    - b. Monitoring any transition services agreements;

- c. Assuring that Material Confidential Information is not received or used by Fresenius or the Acquirers, except as allowed in this Order and in the Order to Maintain Assets, in this matter.
- 2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
- 3. The Monitor shall serve for such time as is necessary to monitor Fresenius's compliance with the provisions of this Order, the Order to Maintain Assets, and the Divestiture Agreements.
- 4. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Fresenius's personnel, books, documents, records kept in the Ordinary Course Of Business, facilities and technical information, and such other relevant information as the Monitors may reasonably request, related to Fresenius's compliance with its obligations under this Order, the Order to Maintain Assets, and the Divestiture Agreements. Fresenius shall cooperate with any reasonable request of the Monitors and shall take no action to interfere with or impede the Monitor's ability to monitor Fresenius's compliance with this Order, the Order to Maintain Assets, and the Divestiture Agreements.
- 5. The Monitor shall serve, without bond or other security, at the expense of Fresenius on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Fresenius, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitors' duties and responsibilities. The Monitor shall account for all

expenses incurred, including fees for services rendered, subject to the approval of the Commission.

- 6. Fresenius shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Monitor.
- 7. Fresenius shall report to the Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Fresenius, and any reports submitted by the Acquirer with respect to the performance of Fresenius's obligations under this Order, the Order to Maintain Assets, and the Divestiture Agreements.
- 8. Within one (1) month from the date the Monitor is appointed pursuant to this paragraph, every sixty (60) days thereafter, and otherwise as requested by the Commission, the Monitor shall report in writing to the Commission concerning performance by Fresenius of its obligations under this Order, the Order to Maintain Assets, and the Divestiture Agreements.
- 9. Fresenius may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and

other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Monitor from providing any information to the Commission.

- E. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement Relating To Commission materials and information received in connection with the performance of the Monitor's duties.
- F. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph IV.
- G. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order, the Order to Maintain Assets, and the Divestiture Agreements.
- H. A Monitor appointed pursuant to this Order may be the same Person appointed as a trustee pursuant to Paragraph V of this Order and may be the same Person or Persons appointed as Monitor under the Order to Maintain Assets.

V.

## IT IS FURTHER ORDERED that:

A. If Fresenius has not divested, absolutely and in good faith and with the Commission's prior approval, all of

the Assets To Be Divested pursuant to Paragraph II of this Order, the Commission may appoint a trustee to divest any of the Assets To Be Divested that have not been divested pursuant to Paragraph II of this Order in a manner that satisfies the requirements of Paragraph II of this Order. In the event that the Commission or the Attorney General brings an action pursuant to Section 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Fresenius shall consent to the appointment of a trustee in such action to divest the relevant assets in accordance with the terms of this Order. Neither the appointment of a trustee nor a decision not to appoint a trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed trustee, pursuant to  $\S 5(l)$  of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Fresenius to comply with this Order.

- B. The Commission shall select the trustee, subject to the consent of Fresenius, which consent shall not be unreasonably withheld. The trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Fresenius has not opposed, in writing, including the reasons for opposing, the selection of any proposed trustee within ten (10) days after receipt of notice by the staff of the Commission to Fresenius of the identity of any proposed trustee, Fresenius shall be deemed to have consented to the selection of the proposed trustee.
- C. Within ten (10) days after appointment of a trustee, Fresenius shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the

trustee all rights and powers necessary to permit the trustee to effect the divestitures required by this Order.

- D. If a trustee is appointed by the Commission or a court pursuant to this Order, Fresenius shall consent to the following terms and conditions regarding the trustee's powers, duties, authority, and responsibilities:
  - 1. Subject to the prior approval of the Commission, the trustee shall have the exclusive power and authority to divest any of the Assets To Be Divested that have not been divested pursuant to Paragraph II of this Order.
  - 2. The trustee shall have twelve (12) months from the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve (12) month period, the trustee has submitted a divestiture plan or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; provided, however, the Commission may extend the divestiture period only two (2) times.
  - 3. Subject to any demonstrated legally recognized privilege, the trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be divested by this Order, and to any other relevant information, as the trustee may request. Fresenius shall develop such financial or other information as the trustee may request and shall cooperate with the trustee. Fresenius shall take no action to interfere with or impede the trustee's accomplishment of the divestiture. Any delays in divestiture caused by Fresenius shall extend the time for divestiture under

this Paragraph V in an amount equal to the delay, as determined by the Commission or, for a court-appointed trustee, by the court.

- 4. The trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Fresenius's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer or Acquirers as required by this Order; provided, however, if the trustee receives bona fide offers for particular assets from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity for such assets, the trustee shall divest the assets to the acquiring entity selected by Fresenius from among those approved by the Commission; provided further, however, that Fresenius shall select such entity within five (5) days of receiving notification of the Commission's approval.
- 5. The trustee shall serve, without bond or other security, at the cost and expense of Fresenius, on such reasonable and customary terms and conditions as the Commission or a court may set. The trustee shall have the authority to employ, at the cost and expense of Fresenius, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the trustee's duties and responsibilities. The trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed trustee, by the court, of the account of the trustee, including fees for the

trustee's services, all remaining monies shall be paid at the direction of Fresenius, and the trustee's power shall be terminated. The compensation of the trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

- 6. Fresenius shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the trustee.
- 7. The trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
- 8. The trustee shall report in writing to Fresenius and to the Commission every sixty (60) days concerning the trustee's efforts to accomplish the divestiture.
- 9. Fresenius may require the trustee and each of the trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the trustee from providing any information to the Commission.
- E. If the Commission determines that a trustee has ceased to act or failed to act diligently, the Commission may

appoint a substitute trustee in the same manner as provided in this Paragraph V.

- F. The Commission or, in the case of a court-appointed trustee, the court, may on its own initiative or at the request of the trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.
- G. The trustee appointed pursuant to this Paragraph may be the same Person appointed as the Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets.

#### VI.

#### IT IS FURTHER ORDERED that:

- A. Beginning thirty (30) days after the date this Order becomes final, and every thirty (30) days thereafter until Fresenius has fully complied with Paragraphs II.A., II.B.3, II.B.5.a, II.B.6, II.B.9, II.B.13, and II.B.17 of this Order, Fresenius shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with the terms of this Order, the Order to Maintain Assets, and the Divestiture Agreements. Fresenius shall submit at the same time a copy of these reports to the Monitor, if any Monitor has been appointed.
- B. Beginning twelve (12) months after the date this Order becomes final, and annually thereafter on the anniversary of the date this Order becomes final, for the next four (4) years, Fresenius shall submit to the Commission verified written reports setting forth in detail the manner and form in which it is complying and has complied with this

Order, the Order to Maintain Assets, and the Divestiture Agreements. Fresenius shall submit at the same time a copy of these reports to the Monitor, if any Monitor has been appointed.

#### VII.

**IT IS FURTHER ORDERED** that Fresenius shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Fresenius,
- B. Any proposed acquisition, merger, or consolidation of Fresenius, or
- C. Any other change in Fresenius that may affect compliance obligations arising out of this Order, including but, not limited to, assignment, the creation or dissolution of subsidiaries, or any other change in Fresenius.

#### VIII.

- IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Fresenius, Fresenius shall permit any duly authorized representative of the Commission:
  - A. Access, during office hours of Fresenius and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of Fresenius related to compliance with this Order; and
  - B. Upon five (5) days' notice to Fresenius and without restraint or interference from Fresenius, to interview

officers, directors, or employees of Fresenius, who may have counsel present, regarding such matters.

IX.

**IT IS FURTHER ORDERED** that this Order shall terminate ten (10) years from the date the Order is issued.

By the Commission.

## APPENDIX A

#### APPENDIX A CLINICS

	Clinic Name (Medicare Provider Number)	Clinic Address
1	FMC-Norwood Clinic Dialysis Unit (012516)	1424 North Carraway Blvd. Birmingham, AL 35234
2	FMC-Chilton Peach (012587)	107 Medical Center Dr. Clanton, AL 35045
3	FMC-Walker County Dialysis (012533)	589 Highway 78W Jasper, AL 35501
4	RCG-Marion (042573)	2921 Highway 77, Suite 8 Marion, AR 72364
5	RCG-Osceola Dialysis Center (231656)	1420 West Keiser Avenue Osceola, AR 72370
6	RCG-Avondale (032608)	13055 West McDowell Road Avondale, AZ 85323
7	RCG-Mesa (032551)	1337 South Gilbert Road Mesa, AZ 85204
8	RCG-Southwest Mesa (032526)	1457 West Southern Avenue Mesa, AZ 85202
9	RCG-Northeast Phoenix (032596)	3305 East Greenway Road Phoenix, AZ 85032

	Clinic Name (Medicare Provider Number)	Clinic Address
10	RCG-Phoenix North (032555)	8046 North 19 <sup>th</sup> Avenue Phoenix, AZ 85021
11	RCG-South Phoenix (032583)	4621 South Central Avenue Phoenix, AZ85040
12	FMC-Tempe (032586)	8820 South Kyrene Road Tempe, AZ 85284
13	RCG-Cottonwood (032562)	203 South Candy Lane Cottonwood, AZ 86326
14	RCG-Prescott (R032523)	980 Willow Creek Road Prescott, AZ 86301
15	RCG-Naples (102809)	6625 Hillway Circle Naples, FL 34112
16	FMC-Lakewood (102733)	8131 Cooper Creek Boulevard University Park, FL 34201
17	RCG-Tampa Central (102761)	4705 North Armenia Avenue Tampa, FL 33603
18	RCG-Cartersville (112691)	203 South Tennessee Street Cartersville, GA 30120
19	RCG-Covington (112708)	4179 Baker Street Covington, GA 30014

	Clinic Name (Medicare Provider Number)	Clinic Address	
20	RCG-Cobb County (112675)	506 Roswell Street Marietta, GA 30060	
21	FMC-Neomedica Evanston (142511)	1715 Central Street Evanston, IL 60201	
22	RCG- Arlington Heights (142628)	17 West Gulf Road Arlington, IL 60006	
23	RCG-Scottsdale (142518)	7929 South Cicero Chicago, IL 60652	
24	RCG-Markham (142575)	3053-3055 West 159 <sup>th</sup> Street Markham, IL 60426	
25	RCG- Hazelcrest (142622)	3470 West 183 <sup>rd</sup> Street Hazelcrest, IL 60429	
26	RCG-South Holland (142544)	16136 South Park Avenue South Holland, IL 60473	
27	RCG-Loop (142505)	55 East Washington Street Chicago, IL 60602	
28	RCG-Waukegan (142577)	1616 Grand Avenue Waukegan, IL 60085	
29	RCG Waukegan Home (142567)	1616 Grand Avenue Waukegan, IL 60085	
30	FMC-Quad Counties Dialysis (152539)	528 North Grandstaff Auburn, IN 46706	

	Clinic Name (Medicare Provider Number)  Clinic Address	
31	FMC-Central Fort Wayne (152580)	1940 Blufton Road Fort Wayne, IN 46809
32	FMC-Lake Avenue Dialysis (152508)	3525 Lake Avenue Fort Wayne, IN 46805
33	FMC-Lake Avenue Home (152563)	2414 Lake Avenue Fort Wayne, IN 46805
34	FMC-South Anthony (152533)	7017 South Anthony Boulevard Fort Wayne, IN 46816
35	FMC-Huntington (152575)	3040 West Park Drive Huntington, IN 46750
36	FMC-Noblesville (152555)	865 Westfield Road Noblesville, IN 46060
37	FMC-Blue River Valley Dialysis (152545)	2309 South Miller Street Shelbyville, IN 46176
38	FMC-Marion County (152512)	3834 South Emerson Avenue Indianapolis, IN 46203
39	FMC-Greenwood (152572)	125 Airport Parkway Greenwood, IN 46143
40	FMC-Northwest Indianapolis (152524)	6488 Corporate Way Indianapolis, IN 46278
41	FMC Logansport (152570)	1025 Michigan Logansport, IN 46947

	Clinic Name (Medicare Provider Number)	Clinic Address
42	FMC Scottsburg (152529)	1451 North Gardner Scottsburg, IN 47170
43	RCG-Louisville (182537)	635 South 3 <sup>rd</sup> Street Louisville, KY 40202
44	RCG-Baton Rouge (192616)	1333 Oneal Lane Baton Rouge, LA 70816
45	RCG-Houma (192509)	108 Picone Road Houma, LA 70363
46	RCG-Thibodaux (192535)	406 North Acadia Road Thibodaux, LA 70301
47	RCG-Amesbury (222532)	24 Morrill Place Amesbury, MA 01913
48	RCG-North Andover (222545)	201 Sutton Street North Andover, MA 01845
49	RCG-Canton (252521)	620 East Peace Street Canton, MS 39046
50	RCG-Hazlehurst (252551)	201 North Haley Street Hazlehurst, MS 39083
51	RCG-Jackson North (252501)	571 East Beasely Road Jackson, MS 39206
52	RCG-Jackson South (252535)	2460 Terry Road Jackson, MS 39204
53	RCG-Jackson Southwest (252533)	1828 Raymond Road Jackson, MS 39204

	Clinic Name (Medicare Provider Number)	Clinic Address	
54	FMC-Carthage (252562)	312 Ellis Street Carthage, MS 39051	
55	RCG-Lexington (252539)	22579 Dept Street Lexington, MS 39095	
56	RCG-Lees Summit (no CMS number)	100 N.E. Missouri Road Lees Summit, MO 64086	
57	RCG-Kansas City (262564)	4333 Madison Kansas City, MO 64111	
58	FMC Las Cruces (322527)	3961 East Lohman Las Cruces, NM 88011	
59	FMC-Preferred Dialysis of Green Valley (292517)	1489 West Warm Springs Henderson, NV 89014	
60	FMC-Preferred Owned (292507)	2333 Renaissance Drive Las Vegas, NV 89119	
61	FMC-Northeast Portland (382540)	703 NE Hancock Street Portland, OR 97212	
62	FMC-Oregon Kidney Center (382500)	5318 NE Irving Portland, OR 97213	
63	FMC-Sunnyside/SE Portland/Lake Rd (382534)	6902 SE Lake Road Milwaukie, OR 97267	
64	FMC-Willamette Valley (382520)	1510 Division Street Oregon City, OR 97045	

	Clinic Name (Medicare Provider Number) Clinic Address	
65	FMC-Sellersville (392617)	700 Lawn Avenue Sellersville, PA 18960
66	RCG-Philadelphia (392601)	3310-24 Memphis Street Philadelphia, PA 19134
67	FMC-Northern Philadelphia (392509) 5933 North Broad Philadelphia, PA 19	
68	FMC-North Providence (412506)	1635 Mineral Spring Avenue North Providence, RI 02904
69	FMC-Providence (412500)	40 Hemingway Drive East Providence, RI 02915
70	FMC-Easley D.C. (152541)	125 Whitmire Road Easley, SC 29640
71	FMC-Greenville (422503)	3 Butternut Drive Greenville, SC 29605
72	FMC-Simpsonville (422579)	209 North Maple Street Simpsonville, SC 29681
73	RCG-Memphis North (442640)	4913 Raleigh common Drive Memphis, TN 38128
74	RCG-Memphis Central (442637)	1331 Union Avenue Memphis, TN 38104

	Clinic Name (Medicare Provider Number)  Clinic Address	
75	RCG-Memphis Whitehaven (442655)	3420 Elvis Presley Boulevard Memphis, TN 38116
76	RCG-Memphis Midtown (442646)	1166 Monroe Avenue Memphis, TN 38104
77	RCG-Memphis Graceland (442650)	4180 Auburn Road Memphis, TN 38116
78	RCG-Memphis South (442605)	3960 Knight Arnold Road Memphis, TN 38118
79	FMC-Alice (452537)  2345 Alice Regi Boulevard Alice, TX 78332	
80	FMC-Corpus Christi (452514)	2733 Swantner Drive Corpus Christi, TX 78404
81	FMC-D.S. of Riverside (452751)	13434 Up River Road Corpus Christi, TX 78410
82	FMC-D.S. of South Texas (452715)	4300 South Padre Island Corpus Christi, TX 78411
83	FMC-D.S. of South Texas- Central (452800)	2222 South Morgan Corpus Christi, TX 78405
84	FMC-North East Texas (452694)	4805 Wesley Street Greenville, TX 75401
85	RCG-El Paso West (452809)	3100 North Stanton Street El Paso, TX 79902

	Clinic Name (Medicare Provider Number)	Clinic Address
86	RCG-Weslaco (452672)	910 South Utah Street Weslaco, TX 78596
87	RCG-McAllen (452654)	411 Lindberg Avenue McAllen, TX 78501
88	FMC-Edinburg Kidney Center (452764)	4302 South Sugar Road Edinburg, TX 78539
89	FMC-Downtown Spokane (502547)	601 West 5 <sup>th</sup> Avenue Spokane, WA 99204
90	FMC-North Spokane (502538)	7407 North Division Street Spokane, WA 99208
91	FMC-Spokane Valley (502537)	12610 East Mirabeau Spokane, WA99208

#### **APPENDIX B**

#### **AREA DEFINITIONS**

- Five digit numbers refer to zip codes.
- Geographic areas bounded by roads include all properties abutting the referenced road (*i.e.*, properties on both sides of the road).
- Zip codes or other areas fully surrounded by areas included in the area definition shall be considered part of the area definition.
- Area definitions are based on maps submitted to the Commission staff by Fresenius.

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
1	FMC-Norwood Clinic Dialysis Unit (012516)	The area in and/or near Birmingham, Alabama, consisting of: 35060, 35064, 35068, 35204, 35205, 35206, 35207, 35208, 35209, 35210, 35211, 35212, 35213, 35214, 35215, 35217, 35218, 35221, 35222, 35223, 35224, 35228, 35233, 35234, 35235.
2	FMC-Chilton Peach (012587)	The area in and/or near Clanton, Alabama, consisting of: Chilton County (Alabama).

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
3	FMC-Walker County Dialysis (012533)	The area in and/or near Jasper, Alabama, consisting of: Walker County (Alabama), and 35062, 35575, 35553, 35565.
4	RCG-Osceola Dialysis Center (231656)	The area in and/or near Osceola, Arkansas, consisting of Mississippi County (Arkansas).
5	RCG-Avondale (032608)	The area in and/or near Avondale, Arizona, consisting of: 85035, 85037, 85043, 85307, 85323, 85329, 85338, 85340, 85353.
6	RCG-Mesa (032551), Southwest Mesa (032526)	The area in and/or near Mesa, Arizona, consisting of: 85201, 85202, 85203, 85204, 85205, 85206, 85208, 85210, 85213, 85224, 85225, 85233, 85234, 85236, 85281, 85282, 85283, 85296.
7	RCG-Northeast Phoenix (032596)	The area in and/or near Phoenix, Arizona, consisting of: 85020, 85022, 85023, 85024, 85027, 85028, 85032, 85050, 85254.

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
8	RCG-Phoenix North (032555)	The area in and/or near Phoenix, Arizona, consisting of: 85012, 85013, 85014, 85015, 85016, 85017, 85019, 85020, 85021, 85022, 85023, 85028, 85029, 85051; the portions of 85003, 85004, 85007, 85009 that lie to the north of I-10.
9	RCG-South Phoenix (032583)	The area in and/or near Phoenix, Arizona, consisting of: 85040, 85041, 85042, 85339; the portion of 85009 that lies to the south of West Buckeye Road; the portions of 85007, 85003, 85004, and 85034 that lie to the south of I-17.
10	FMC-Tempe (032586)	The area in and/or near Tempe, Arizona, consisting of: 85202, 85040, 85044, 85048, 85224, 85225, 85226, 85248, 85281, 85282, 85283, 85284.
11	RCG- Cottonwood (032562), Prescott (R032523)	The area in and/or near Prescott, Arizona, consisting of Yavapai County (Arizona), and 86336.

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
12	RCG-Naples (102809)	The area in and/or near Naples, Florida, consisting of: 34102, 34103, 34104, 34105, 34108, 34109, 34110, 34112, 34113, 34114, 34116, 34117, 34119, 34120.
13	FMC-Lakewood (102733)	The area in and/or near Sarasota, Florida, consisting of: 34201, 34203, 34207, 34231, 34232, 34233, 34234, 34235, 34236, 34237, 34238, 34239, 34240, 34243; the portion of 34202 that lies to the south of State Road 64; the portion of 34208 that lies to the east of 57th Street East, the portion of 34241 that lies to the north of Clark Road/State Road 72.
14	RCG-Brandon (no CMS number)	The area in and/or near Brandon, Florida, consisting of: 33510, 33511, 33527, 33569, 33584, 33594, 33610, 33619.
15	RCG-Tampa Central (102761)	The area in and/or near Tampa, Florida, consisting of: 33602, 33603, 33604, 33605, 33606, 33607, 33609, 33610, 33611, 33614, 33615, 33616, 33619, 33629, 33634.

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
16	RCG-Canton (no CMS number)	The area in and/or near Canton, Georgia, consisting of: Cherokee County, Pickens County (Georgia), and 30102, 30139, 30171, and 30184.
17	RCG-Cartersville (112691)	The area in and/or near Cartersville, Georgia, consisting of: Bartow County (Georgia), and 30101, 30102, 30103, 30132, 30139, 30145, 30171, 30184.
18	RCG-Covington (112708)	The area in and/or near Covington, Georgia, consisting of: Newton County, Rockdale County (Georgia), and 30014, 30025, 30038, 30052, 30054, 30055, 30056, 30058, 30252, 30663; the portions of 30233 and 31064 that lie to the north of Route 16.
19	RCG-Cobb County (112675)	The area in and/or near Marietta, Georgia, consisting of: Cobb County (Georgia), and 30101, 30127, 30132, 30141, 30157.

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
20	FMC-Neomedica Evanston (142511)	The area in and/or near Chicago, Illinois, consisting of: 0022, 60025, 60029, 60043, 60053, 60062, 60076, 60077,60091 60093, 60201, 60202, 60203, 60625, 60626, 60640, 60645, 60646, 60659, 60660, 60712, 60714.
21	RCG-Buffalo Grove (142650), Schaumburg (142654), Schaumburg Home (141626), Arlington Heights (142628)	The area in and/or near Chicago, Illinois, consisting of: 60004, 60005, 60007, 60008, 60015, 60016, 60018, 60025, 60047, 60056, 60061, 60062, 60067, 60069, 60070, 60074, 60089, 60090, 60101, 60103, 60106, 60107, 60108, 60010, 60133, 60139, 60143, 60157, 60172, 60173, 60188, 60191, 60193, 60194, 60195.
22	RCG-Scottsdale (142518)	The area in and/or near Chicago, Illinois, consisting of: 60402, 60406, 60415, 60419, 60453, 60455, 60456, 60457, 60458, 60459, 60465, 60482, 60501, 60608, 60609, 60615, 60616, 60617, 60619, 60620, 60621, 60623, 60628, 60629, 60632, 60633, 60636, 60637, 60638, 60643, 60652, 60653, 60655, 60803, 60804, 60805, 60827.

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
23	RCG-Markham (142575), Hazelcrest (142622), South Holland (142544)	The area in and/or near Chicago, Illinois, consisting of: 60406, 60409, 60411, 60419, 60422, 60425, 60426, 60429, 60430, 60438, 60443, 60445, 60452, 60461, 60466, 60469, 60471, 60472, 60473, 60475, 60476, 60477, 60478, 60617, 60619, 60620, 60628, 60633,60643, 60655, 60803, 60805, 60827, 46320, 46321, 46324.
24	RCG-Loop (142505)	The area in and/or near Chicago, Illinois, consisting of: 60406, 60601, 60602, 60603, 60604, 60605, 60606, 60607, 60608, 60609, 60610, 60611, 60612, 60614, 60615, 60616, 60617, 60619, 60620, 60621, 60622, 60623, 60624, 60628, 60629, 60632, 60633, 60636, 60637, 60642, 60643, 60647, 60649, 60652, 60653, 60654, 60655, 60657, 60661, 60827.
25	RCG-Waukegan (142577), Waukegan Home (142567)	The area in and/or near Waukegan, Illinois, consisting of: Lake County (Illinois).

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
26	FMC-Quad Counties Dialysis (152539)	The area in and/or near Auburn, Indiana, consisting of: DeKalb County (Indiana).
27	FMC-Central Fort Wayne (152580), Lake Avenue Dialysis (152508), Lake Avenue Home (152563), South Anthony (152533)	The area in and/or near Fort Wayne, Indiana, consisting of: Allen, Wells, and Whitley Counties (Indiana).
28	FMC-Huntington (152575)	The area in and/or near Huntington, Indiana, consisting of: Huntington County (Indiana).
29	FMC-Noblesville (F152555)	The area in and/or near Indianapolis, Indiana, consisting of: Hamilton County (Indiana).
30	FMC-Blue River Valley Dialysis (152545)	The area in and/or near Indianapolis, Indiana, consisting of: Shelby County (Indiana).

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
31	FMC-Marion County (152512)	The area in and/or near Indianapolis, Indiana, consisting of: 46107, 46142, 46201, 46203, 46217, 46219, 46221, 46225, 46226, 46227, 46229, 46237, 46239; the portion of 46218 that lies to the south of E. Massachusetts Avenue.
32	FMC-Greenwood (152572)	The area in and/or near Indianapolis, Indiana, consisting of: 46113, 46131, 46142, 46143, 46184, 46217, 46221, 46227, 46237, 46259.
33	FMC- Northwest Indianapolis (152524)	The area in and/or near Indianapolis, Indiana, consisting of: 46214, 46222, 46224, 46228, 46234, 46241, 46254, 46260, 46268, 46278.
34	FMC Logansport (152570)	The area in and/or near Logansport, Indiana, consisting of: Cass County (Indiana), and 46917, 46916, 46939, 46947, 46951, 46970,46975, 46985, 46996.
35	FMC Scottsburg (152529)	The area in and/or near Scottsburg, Indiana, consisting of: 47102, 47170, 47220, 47270, 47229, 47274.

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
36	RCG-Lousiville (182537)	The area in and/or near Louisville, Kentucky, consisting of: Jefferson County (Kentucky).
37	RCG-Baton Rouge (192616)	The area in and/or near Baton Rouge, Louisiana, consisting of: East Baton Rouge Parish, Livingston Parish (Louisiana), and 70776, 70769.
38	RCG-Houma (192509)	The area in and/or near Houma, Lousiana, consisting of: Terrebonne Parish and Lafourche Parish (Louisiana).
39	Thibodaux (192535)	The area in and/or near Thibodaux, Lousiana, consisting of: Terrebonne Parish and Lafourche Parish (Louisiana).
40	RCG-Amesbury (222532)	The area in and/or near Amesbury, Massachusetts, consisting of: 01830, 01832, 01833, 01834, 01835, 01860, 01913, 01938, 01950, 01951, 01952, 01969, 01985, 03827 03848, 03858, 03865, 03874

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
41	RCG-North Andover (222545)	The area in and/or near North Andover, Massachusetts, consisting of: 01810, 01826, 01830, 01832, 01835, 01840, 01841, 01843, 01844, 01845, 01864, 01876, 01887, 01921, 01949, 03079, 03811, 03858, 03865.
42	FMC-Carthage (252562)	The area in and/or near Carthage, Mississippi, consisting of: Leake County and Neshoba County (Mississippi).
43	RCG-Brandon (252549), Canton (252521), Hazlehurst (252551), Jackson North (252501), Jackson South (252535), Jackson Southwest (252533)	The area in and/or near Jackson, Mississippi, consisting of: Madison County, Hinds County, Rankin County, Copiah County, and Simpson County (Mississippi).

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
44	RCG-Lexington (252539)	The area in and/or near Lexington, Mississippi, consisting of: Attala County and Holmes County (Mississippi).
45	RCG-Kansas City (262564), Lees Summit (no CMS number)	The area in and/or near Kansas City, Missouri, consisting of: Jackson County (Missouri), and 64012, 64034, 64080, 64082, 64083, 64116, 64117, 66102, 66103, 66106, 66118, 66205, 66206, 66207, 66208.
46	FMC Las Cruces (322527)	The area in and/or near Las Cruces, New Mexico, consisting of: Dona Ana County (New Mexico).
47	FMC-Preferred Dialysis of Green Valley (292517), Preferred Owned (292507)	The area in and/or near Las Vegas, Nevada, consisting of: 89005, 89011, 89012, 89014, 89015, 89030, 89052, 89101, 89102, 89103, 89104, 89106, 89107, 89109, 89110, 89118, 89119, 89120, 89121, 89122, 89123, 89139, 89141, 89142, 89156.

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
48	RCG-Munroe Falls (362651), Summit (362613), White Ponds (362623)	The area in and/or near Akron, OH, consisting of: Portage County and Summit County (Ohio).
49	FMC-Northeast Portland (382540), Oregon Kidney Center (382500)	The area in and/or near Portland, Oregon, consisting of: 97202, 97203, 97206, 97211, 97212, 97213, 97214, 97215, 97216, 97217, 97218, 97220, 97222, 97230, 97232, 97233, 97236, 97266.
50	FMC- Sunnyside/SE Portland/Lake Rd (382534), Willamette Valley (382520)	The area in and/or near Portland, Oregon, consisting of: 97015, 97027, 97034, 97045, 97062, 97068, 97070, 97202, 97206, 97222, 97233, 97236, 97266, 97267.
51	FMC-Sellersville (392617)	The area in and/or near Philadelphia, Pennsylvania, consisting of: 18054, 18073, 18914, 18915, 18917, 18927, 18932, 18936, 18944, 18951, 18955, 18960, 18962, 18964, 18969,18970, 19438. 19440, 19446.

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
52	RCG- Philadelphia (392601)	The area in and/or near Philadelphia, Pennsylvania, consisting of: 19111, 19120, 19121, 19122, 19123, 19124, 19125, 19129, 19130, 19132, 19133, 19134, 19137, 19140, 19141, 19144, 19149.
53	FMC-Northern Philadelphia (392509)	The area in and/or near Philadelphia, Pennsylvania, consisting of: 19012, 19095, 19111, 19027, 19038, 19118, 19119, 19120, 19124, 19126, 19128, 19129, 19132, 19138, 19140, 19141, 19144, 19150.
54	FMC-North Providence (412506), Providence (412500)	The area in and/or near Providence, Rhode Island, consisting of: 02703, 02760, 02763, 02769, 02771, 02777, 02806, 02809, 02814, 02826, 02828, 02838, 02857, 02860, 02861, 02863, 02864, 02865, 02876, 02885, 02888, 02895, 02896, 02901, 02903, 02904, 02905, 02906, 02907, 02908, 02909, 02910, 02911, 02914, 02915, 02916, 02917, 02919, 02920, 02921, 02940; the portion of 02830 that lies south of Route 102.

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
55	FMC-Easley D.C. (152541), Greenville (422503), Simpsonville (422579)	The area in and/or near Greenville, South Carolina, consisting of the following South Carolina Counties: Greenville County, Pickens County, Anderson County, Laurens County (South Carolina).
56	RCG-Galleria (442660), Memphis Central (442637), Memphis South (442605), Whitehaven (442655), Memphis Midtown (442646), Graceland (442650), Memphis North (442640)	The area in and/or near Memphis, Tennessee, consisting of Shelby County (Tennessee), and 38002, 38004, 38011, 38017, 38023, 38028, 38036, 38053, 38058.
57	RCG-Marion (042573)	The area in and/or near Marion, Arkansas, consisting of Crittenden County (Arkansas).

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
58	FMC-Alice (452537)	The area in and/or near Alice, Texas, consisting of: Jim Wells County (Texas), and 78349, 78357, 38384.
59	RCG- Brownsville (452737)	The area in and/or near Brownsville, Texas, consisting of: 78520, 78521, 78526, 78566, 78575, 78578, 78583, 78586.
60	FMC-Corpus Christi (452514), D.S. of Riverside (452751), D.S. of South Texas (452715), D.S. of South Texas- Central (452800)	The area in and/or near Corpus Christi, Texas, consisting of: Nueces County, San Patricio County, and Aransas County (Texas).
61	FMC-North East Texas (452694)	The area in and/or near Terrell, Texas, consisting of: Hunt County, Delta County, Rains County, Hopkins County, Rockwell County Texas); 75164, 75189, 75424, 75442; and the portion of Fannin County (Texas) south of I-82/Route 18.

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
62	RCG-El Paso East and El Paso Home (452749), El Paso West (452809)	The area in and/or near El Paso, Texas, consisting of: El Paso County (Texas).
63	RCG-Weslaco (452672)	The area in and/or near Weslaco, Texas, consisting of: 78516, 78537, 78538, 78539, 78543, 78558, 78559, 78562, 78570, 78579, 78589, 78592, 78593, 78596, 78594; the portion of 78569 that lies to the west of US-77.
64	RCG-McAllen (452654)	The area in and/or near McAllen, Texas, consisting of: 78501, 78503, 78504, 78516, 78537, 78538, 78539, 78543, 78557, 78558, 78562, 78570, 78577, 78579, 78589, 78596; the portion of 78569 that lies within Hidalgo County (Texas).

	Divested Clinics (Medicare provider numbers)	Corresponding Area Definition
65	FMC-Edinburg Kidney Center (452764)	The area in and/or near Edinburg, Texas, consisting of: 78501, 78503, 78504, 78516, 78537, 78538, 78539, 78543, 78557, 78558, 78562, 78570, 78577, 78579, 78589, 78596; the portion of 78572 that lies to the east of Doffing Road until Doffing Road's northeast terminus; the portion of 78569 that lies within Hidalgo County (Texas).
66	FMC Downtown Spokane (502547), North Spokane (502538), Spokane Valley (502537)	The area in and/or near Spokane, Washington, consisting of: Spokane County (Washington).

## APPENDIX C

#### **ILLINOIS CLINICS**

	Clinic Name (Medicare provider number)	Clinic Address
1	FMC-Neomedica Evanston (142511)	1715 Central Street Evanston, IL 60201
2	RCG- Arlington Heights (142628)	17 West Gulf Road Arlington, IL 60006
3	RCG-Scottsdale (142518)	7929 South Cicero Chicago, IL 60652
4	RCG-Markham (142575)	3053-3055 West 159 <sup>th</sup> Street Markham, IL 60426
5	RCG- Hazelcrest (142622)	3470 West 183 <sup>rd</sup> Street Hazelcrest, IL 60429
6	RCG-South Holland (142628)	16136 South Park Avenue South Holland, IL 60473
7	RCG-Loop (142505)	55 East Washington Street Chicago, IL 60602
8	RCG-Waukegan (142577)	1616 Grand Avenue Waukegan, IL 60085
9	RCG Waukegan Home (142567)	1616 Grand Avenue Waukegan, IL 60085

APPENDIX D

# JOINT VENTURES FROM WHICH FRESENIUS WILL DIVEST ITS JOINT VENTURE EQUITY INTERESTS AND CLINICS OWNED BY JOINT VENTURES

	Joint Venture Name	Clinic Name (Medicare provider number)	Clinic Address
1	Renal Care Group Canton, LLC	RCG-Canton (no CMS number)	260 Hospital Road Canton, GA 30114
2	Brownsville Kidney Center, Ltd.	RCG- Brownsville (452737)	2945 Central Boulevard Brownsville, TX 78520
3	Renal Care Group Buffalo Grove, LLC	RCG-Buffalo Grove (142650)	1291 West Dundee Road Buffalo Grove, IL 60089
4	Renal Care Group Schaumburg, LLC	RCG- Schaumburg (142654)	1156 South Roselle Road Schaumburg, IL 60193
5	Renal Care Group Schaumburg, LLC	RCG- Schaumburg Home (142654)	17 West Golf Road Arlington Heights, IL 60006
6	El Paso Kidney Center East, Ltd.	RCG-El Paso East (452749)	10737 Gateway Boulevard West El Paso, TX 79935

#### APPENDIX D

	Joint Venture Name	Clinic Name (Medicare provider number)	Clinic Address
7	RCG Brandon, LLC	RCG- Brandon (252549)	101 Christian Drive Brandon, MS 39042
8	Renal Care Group Galleria, LLC	RCG- Galleria (422660)	8592 Ricky Bell Cove Memphis, TN 38133
9	RCG Brandon LLC	RCG- Brandon (no CMS number)	731 West Lumsden Road Brandon, FL 33511
10	Summit Renal Care, LLC	RCG-Munroe Falls (362651)	265 North Main Street Munroe Falls, OH 44262
11	Summit Renal Care, LLC	RCG-Summit (362613)	73 Massillon Road Akron, OH 44312
12	Summit Renal Care, LLC	RCG-White Ponds (362623)	534 White Pond Drive Akron, OH 44320

#### APPENDIX E

## MONITOR AGREEMENT [PUBLIC RECORD VERSION]

#### MONITOR AGREEMENT

MONITOR AGREEMENT (this "Agreement"), dated as of March 7, 2006, between Fresenius Medical Care Holdings, Inc. ("FMCH or Respondent"), and Richard A. Shermer of R. Shermer & Company ("Monitor").

#### PRELIMINARY STATEMENT

WHEREAS the Federal Trade Commission (the "Commission") is considering for public comment an Agreement Containing Consent Orders with Respondent, which provides, among other things, that Respondent divest a number of dialysis clinics and assets associated with those clinics, Respondent terminate management contracts Respondent has with certain dialysis clinics, enter into agreements – if necessary – providing the acquirers of the dialysis clinics with transition services, and engage a monitor to monitor Respondent's compliance with its obligations under (a) the Decision and Order and (b) the Order to Maintain Assets (collectively, the "Orders");

WHEREAS, the Commission is expected to issue the Agreement Containing Consent Orders and appoint the Monitor pursuant to the Orders to monitor Respondent's compliance with the terms of the Orders, and the Monitor has consented to such appointment;

WHEREAS, the Orders further provide that Respondent shall execute an agreement, subject to prior approval of the Commission, conferring all the rights and powers necessary to permit Monitor to carry out its duties and responsibilities pursuant to the Orders;

WHEREAS, this Agreement, although executed by Monitor and Respondent, is not effective for any purpose, including but not limited to imposing rights and responsibilities on Respondent or Monitor under the Orders, until the Order to Maintain Assets has been issued and this Agreement has been approved by the Commission;

WHEREAS, the parties to this Agreement intend to be legally bound, subject only to the Commission's approval of this Agreement.

#### DEFINITIONS

- "Respondent" means Fresenius Medical Care Holdings, Inc., a
  corporation organized, existing and doing business under and by virtue of the laws of the
  State of New York, with its office and principal place of business located at 95 Hayden
  Avenue, Lexington, MA, its directors, officers, employees, agents, attorneys,
  representatives, predecessors, successors, and assigns; its joint ventures, divisions, groups
  and affiliates controlled by FMCH, and the respective directors, officers, employees,
  agents, attorneys, representatives, predecessors, successors, and assigns of each.
- "Other Parties" means any Person that receives approval of the Commission to acquire any of the Assets to Be Divested or is a party to the Relevant Agreements pursuant to Paragraph II and V of the Decision and Order.

#### APPENDIX E

- "Acquisition Date" means the date on which the first of the Relevant Agreements pursuant to Paragraph II and V of the Decision and Order goes into effect.
- 4. "Relevant Agreements" means: all the divestiture agreements, management termination agreements, and transition services agreements entered into pursuant to Paragraphs II and V of the Decision and Order, including, but not limited to, the National Renal Institutes, Inc. Divestiture Agreements, and the Transition Services Agreement between National Renal Institutes, Inc. and FMCH.
- All other capitalized words or phrases appearing in this Agreement that are not otherwise defined herein are deemed to have the defined meanings assigned to them in the Orders.

#### ARTICLE I

- 1.1 Powers of the Monitor. Monitor shall have the rights, duties, powers and authority conferred upon Monitor by the Orders that are necessary for Monitor to monitor Respondent's compliance with the Orders. No later than one day after the Order to Maintain Assets becomes final, Respondent bereby transfers to Monitor all rights, powers, and authorities necessary to permit Monitor to perform its duties and responsibilities pursuant to the Order to Maintain Assets and consistent with the purposes of the Decision and Order. Any descriptions thereof contained in this Agreement in no way modify Monitor's powers and authority or Respondent' obligations under the Orders.
- 1.2 <u>Monitor's Duties</u>. Monitor shall monitor Respondent's compliance with the Orders, including, but not limited to:
- Assuring that Respondent expeditiously complies with all of the obligations, and performs all of responsibilities, of Respondent as required by the Orders in this matter;
  - b. Monitoring Relevant Agreements; and
- Assuring that Confidential Business Information is not received or used by Respondent or Other Parties, except as allowed in the Orders in this matter.
- 1.3 <u>Duration of Monitor's Authority</u>. Monitor shall have all powers and duties described above and consistent with the Orders for the term set forth in the Orders.
- 1.4 Confidential and Proprietary Information. Monitor shall enter into confidentiality agreements, attached hereto as Confidential Exhibit A, agreeing to be bound by the terms and conditions of the Orders. Monitor must retain and maintain all Material Confidential Information it receives from either Respondent or Other Parties on a confidential basis, except as is permitted by the Orders. Monitor may disclose confidential information only to persons employed by or working with Monitor under this Agreement, to persons employed at the Commission, and as permitted by Respondent or

#### APPENDIX E

Other Parties with respect to information they provided Monitor. Monitor shall require any person retained by Monitor to assist in carrying out the duties and responsibilities of Monitor to execute a confidentiality agreement that requires the same standard of care and obligations of confidentiality to which Monitor must adhere under this Agreement. Monitor shall maintain the confidentiality, for a period of five (5) years after the termination of this Agreement, of all other aspects of the performance of its duties under this Agreement and shall not disclose any confidential information relating thereto.

- 1.5 <u>Restrictions</u>. Monitor shall not be involved in any way in the management, production, supply and trading, sales marketing, and financial operations of the competing products of Respondent.
- 1.6 <u>Reports.</u> Monitor shall report to the Commission pursuant to the terms of the Orders and as otherwise requested by the Commission staff.
- 1.7 Access to Records, Documents and Facilities. Subject to any demonstrated legally recognized privilege, Monitor shall have full and complete access to Respondent's personnel, to include those employees designated to be transferred to an acquirer, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as Monitor may reasonably request, related to Respondent's compliance with the obligations of Respondent under the Orders in this matter. Documents, records and other relevant information are to be provided in an electronic format if they exist in that form. Respondent shall cooperate with any reasonable request of Monitor and shall take no action to interfere with or impede Monitor's ability to monitor Respondent's compliance with the Orders.

#### ARTICLE II

- 2.1 Retention and Payment of Counsel, Consultants, and other Assistants.
  Monitor shall have the authority to employ, at the cost and expense of the Respondent, such attorneys, consultants, accountants, and other representatives and assistants as are necessary to carry out the Monitor's duties and responsibilities as allowed pursuant to the Orders.
- 2.2 Compensation. Monitor shall be compensated by Respondent for his services under this Agreement, including all work in connection with the negotiation and preparation of this Monitor Agreement, pursuant to the fee schedule attached as Confidential Exhibit B for time spent in connection with the discharge of its duties under this Agreement and the Orders. In addition, Respondent will pay: (a) out-of-pocket expenses reasonably incurred by Monitor in the performance of its duties under the orders; and (b) fees and disbursements reasonably incurred by any advisor appointed by Monitor pursuant to the first paragraph in Article II. At its own expense, Respondent may retain an independent auditor to verify such invoices. Monitor shall provide Respondent with monthly invoices for time and expenses that include details and an explanation of all matters for which Monitor submits an invoice to Respondent. Respondent shall pay such invoices within thirty (30) days of receipt. The Monitor and

#### APPENDIX E

Respondent shall submit any disputes about invoices to the Commission for assistance in resolving such disputes.

2.3 To the extent available, Respondent will provide the Monitor with temporary workspace and access to office equipment owned or used by Respondent at sites the Monitor is required to visit in order to fulfill its obligations under this. Agreement. Monitor agrees to comply with all of Respondents' safety and security regulations, instructions and procedures while at Respondents' sites.

#### ARTICLE III

- Monitor's Liabilities and Indemnification. Respondent shall indemnify the Monitor and hold Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of Monitor's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by Monitor The Monitor's maximum liability to Respondents relating to services rendered in accordance with this Agreement (regardless of form of action, whether in contract, statutory law, or tort) shall be limited to an amount equal to the total sum of the fees paid to the Monitor by the Respondent. Any claim arising from this Agreement that Respondents may have against the Monitor must be brought no later than one (1) year following the termination or expiration of this Agreement. In the performance of its duties under this Agreement, the Monitor shall exercise the standard of care and diligence that would be expected of a reasonable person in the conduct of his own business affairs. The Monitor shall not be liable for any delays or other failures to perform resulting from circumstances or causes beyond its reasonable control, including, without limitation, fire or other casualty, act of God, strike or labor dispute, war or other violence, or any law, order or requirement of any governmental agency or authority. The Monitor warrants that it will perform its obligations hereunder in good faith. R. Shermer & Company disclaims other warranties, expressed or implied, other than those expressly agreed to in writing between the Parties.
- 3.2 <u>Monitor's Removal</u>. If the Commission determines that Monitor ceases to act or fail to act diligently and consistent with the purpose of the Orders, Respondent shall terminate this Agreement and appoint a substitute Monitor, subject to Commission approval and consistent with the Orders.
- 3.3 Approval by the Commission. This Agreement shall have no force or effect until approved by the Commission, other than Respondent obligations under Confidential Exhibit A and the confidentiality provisions herein.
- 3.4 <u>Termination</u>: This Agreement shall terminate the earlier of: (a) thirty (30) days following the termination date set forth in the applicable Order; (b) Respondent's receipt of written notice from the Commission that the Commission has determined that Monitor has ceased to act or failed to act diligently, or is unwilling or unable to continue

## **APPENDIX E**

to serve as Monitor; (c) with at least thirty (30) days advance notice to be provided by Monitor to Respondent and to the Commission, upon resignation of the Monitor; or (d) when FMCH's last obligation under the Orders and the Relevant Agreements that pertains to the Monitors' service has been fully performed; provided, however, that the Commission may require that FMCH extend this Agreement or enter into an additional agreement with Monitor as may be necessary or appropriate to accomplish the purposes of the Orders. If this Agreement is terminated for any reason, the confidentiality obligations set forth in this Agreement will remain in force.

3.5 <u>Conflicts of Interest</u>: If Monitor becomes aware during the term of this Agreement that it has or may have a conflict of interest that may affect or could have the appearance of affecting performance by the Monitor of any of its duties under this Agreement, Monitor shall promptly inform Respondent and the Commission of any such conflict.

MONITOR

Decision and Order

## **APPENDIX E**

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first above written.

R. SHERMER & COMPANY
BY:

NAME: Richard A. Shermer, President

RESPONDENT

FRESENTUS MEDICAL CARE HOLDINGS, INC.

NAME: DOUGLAS C. KATT TITLE: ASST. SECRETARY

## **APPENDIX E**

# Confidential Exhibit A and Confidential Exhibit B To the Monitor Agreement

[Redacted From the Public Record Version of the Decision and Order But Incorporated By Reference]

## APPENDIX F NON-PUBLIC

**NRI Divestiture Agreements** 

[Redacted From the Public Record Version of the Decision and Order But Incorporated By Reference]

## **ORDER TO MAINTAIN ASSETS**

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition of Renal Care Group, Inc. by Fresenius AG and entities controlled by Fresenius AG, including (1) Fresenius Medical Care AG & Co. KGaA, a partnership limited by shares organized under the laws of the Federal Republic of Germany, the general partner of which is majority owned by Fresenius AG, (2) Fresenius Medical Care Holdings, Inc., a New York corporation majority owned by Fresenius Medical Care AG & Co. KGaA, a partnership limited by shares organized under the laws of the Federal Republic of Germany, and (3) Florence Acquisition, Inc., a Delaware corporation that is wholly owned by Fresenius Medical Care Holdings, Inc., and Fresenius AG (hereafter referred to as "Respondent") having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission, having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its

charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues the following Order to Maintain Assets:

- 1. Respondent Fresenius AG is a corporation organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany, with its office and principal place of business located at Else-Kröner-Straße 1, 61352 Bad Homburg, Germany. Fresenius AG is the ultimate parent of (1) Fresenius Medical Care AG & Co. KGaA, a partnership limited by shares organized under the laws of the Federal Republic of Germany, the general partner of which is majority owned by Fresenius AG, with its office and principal place of business located at Else-Kröner-Straße 1, 61352 Bad Homburg, Germany, (2) Fresenius Medical Care Holdings, Inc., a New York corporation majority owned by Fresenius Medical Care AG & Co. KGaA, a partnership limited by shares organized under the laws of the Federal Republic of Germany, with its office and principal place of business located at 95 Hayden Avenue, Lexington, MA 02420, and (3) Florence Acquisition, Inc., a Delaware corporation that is wholly owned by Fresenius Medical Care Holdings, Inc, with its office and principal place of business located at 95 Hayden Avenue, Lexington, MA 02420.
- 2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

#### **ORDER**

I.

IT IS ORDERED that, all capitalized terms used in this Order to Maintain Assets, but not defined herein, shall have the meanings attributed to such terms in the Decision and Order contained in the Consent Agreement.

II.

#### IT IS FURTHER ORDERED that:

- A. From the date Respondent signs the Consent Agreement until the Time of Divestiture of each Joint Venture Equity Interest and each Clinic To Be Divested and until all Assets Associated with each Clinic To Be Divested are divested pursuant to the Consent Agreement, Respondent shall:
  - 1. maintain (a) each Clinic To Be Divested and all Assets Associated with it, and (b) each Clinic and all Assets Associated with it owned by a joint venture in which the Joint Venture Equity Interest is being divested ("JV Clinic Assets") in substantially the same condition (except for normal wear and tear) existing at the time Fresenius signs the Consent Agreement;
  - 2. take such actions that are consistent with the past practices of Fresenius or RCG, respectively, in connection with the JV Clinic Assets and such Clinic To Be Divested and the Assets Associated with it and that are taken in the Ordinary Course Of Business and in the normal day-to-day operations of Fresenius or RCG;

- 3. keep available the services of the current officers, employees, and agents of Fresenius; and maintain the relations and good will with Suppliers, Payors, Physicians, landlords, patients, employees, agents, and others having business relations with the JV Clinic Assets and the Clinic To Be Divested and the Assets Associated with it in the Ordinary Course Of Business; and
- 4. preserve the JV Clinic Assets and the Clinic To Be Divested and all Assets Associated with it as an ongoing business and not take any affirmative action, or fail to take any action within Fresenius's control, as a result of which the viability, competitiveness, and marketability of the JV Clinic Assets and the Clinic To Be Divested or all Assets Associated with it would be diminished.
- B. From the date Fresenius signs the Consent Agreement until the date this Order to Maintain Assets terminates pursuant to Paragraph VII, Fresenius shall do the following:
  - 1. Until sixty (60) days after the Time Of Divestiture of each Clinic To Be Divested, Fresenius shall not interfere in employment negotiations between each Fresenius Employee Of A Clinic To Be Divested and the Acquirer of the Clinic.
  - 2. With respect to each Fresenius Employee Of A Clinic To Be Divested who receives, within sixty (60) days of the Time Of Divestiture of any Clinic at which he or she is employed, an offer of employment from the Acquirer of that Clinic, Fresenius shall not prevent, prohibit or restrict or threaten to prevent, prohibit or restrict the Fresenius Employee Of The Clinic To Be Divested from being employed by the Acquirer of the Clinic, and shall not offer any

incentive to the Fresenius Employee Of The Clinic To Be Divested to decline employment with the Acquirer of the Clinic.

- 3. For a period of two (2) years following the Time Of Divestiture of each Clinic To Be Divested, Fresenius shall not, directly or indirectly, solicit, induce, or attempt to solicit or induce any Employee Of A Clinic To Be Divested who is employed by the Acquirer to terminate his or her employment relationship with the Acquirer, unless that employment relationship has already been terminated by the Acquirer; provided, however, Fresenius may make general advertisements for employees including, but not limited to, in newspapers, trade publications, websites, or other media not targeted specifically at the Acquirer's employees; provided further, however, Fresenius may hire employees who apply for employment with Fresenius, as long as such employees were not solicited by Fresenius in violation of this Paragraph II.C.3.; provided further, however, Fresenius may offer employment to an Employee Of A Clinic To Be Divested who is employed by the Acquirer in only a part-time capacity, if the employment offered by Fresenius would not, in any way, interfere with the employee's ability to fulfill his or her employment responsibilities to the Acquirer.
- 4. For a period of not less than forty-five (45) days, which period may begin prior to the signing of the Consent Agreement and which shall end no earlier than ten (10) days after the Time Of Divestiture of each Clinic To Be Divested ("Forty-Five Day Hiring Period"), Fresenius shall not interfere in employment negotiations between each Regional Manager Of A Clinic To Be Divested and the Acquirer of the

Clinic; *provided, however,* the terms of this Paragraph II.C.4. shall not apply after Acquirers have hired ten (10) Regional Managers who were each previously employed by Fresenius or RCG at any time since October 1, 2005.

- 5. With respect to each Regional Manager Of A Clinic To Be Divested who receives, within the Forty-Five Day Hiring Period required by Paragraph II.C.4. of this Order to Maintain Assets an offer of employment from the Acquirer of that Clinic, for a period of two (2) years following the Time Of Divestiture of the Clinic To Be Divested, Fresenius shall not, directly or indirectly, solicit, induce, or attempt to solicit or induce any Regional Manager of the Acquirer who was previously a Regional Manager of A Clinic To Be Divested to terminate his or her employment relationship with the Acquirer unless the individual has been terminated by the Acquirer; provided, however, Fresenius may make general advertisements for Regional Managers including, but not limited to, in newspapers, trade publications, websites, or other media not targeted specifically at Acquirer's Regional Managers; provided further, however, Fresenius may hire Regional Managers who apply for employment with Fresenius, as long as such Regional Managers were not solicited by Fresenius in violation of this Paragraph II.C.5.; provided, however, after Acquirers have hired ten (10) Regional Managers who were each previously employed by Fresenius or RCG at any time since October 1, 2005, the terms of this Paragraph II.C.5. shall apply only to those ten (10) Regional Managers hired by the Acquirers.
- 6. With respect to each Physician who has provided services to a Clinic To Be Divested pursuant to any of the Clinic's Physician Contracts in effect at any

time during the four (4) months preceding the Time Of Divestiture of the Clinic ("Contract Physician"):

- a. Fresenius shall not offer any incentive to the Contract Physician, the Contract Physician's practice group, or other members of the Contract Physician's practice group to decline to provide services to the Clinic To Be Divested, and shall eliminate any confidentiality restrictions that would prevent the Contract Physician, the Contract Physician's practice group, or other members of the Contract Physician's practice group from using or transferring to the Acquirer of the Clinic To Be Divested any information Relating To the Operation Of The Clinic; and
- b. For a period of three (3) years following the Time Of Divestiture of each Clinic To Be Divested. Fresenius shall not contract for the services of the Contract Physician, the Contract Physician's practice group, or other members of the Contract Physician's practice group for the provision of Contract Services to be performed in any of the areas listed in Appendix B of this Order that correspond to such Clinic. *Provided*, however, if the Contract Physician, or the Contract Physician's practice group, or other members of the Contract Physician's practice group were providing services to one or more Clinics, other than or in addition to a Clinic To Be Divested, pursuant to a contract with Fresenius or RCG in effect as of October 1, 2005, then Fresenius may continue to contract with such Contract Physicians, or the Contract Physician's practice group, or other members of the Contract Physician's practice group for

services to be provided to such other or additional Clinics.

- 7. With respect to Material Confidential Information relating exclusively to any of the Clinics To Be Divested, Fresenius shall:
  - a. not disclose such information to any Person other than the Acquirer of such Clinic;
  - b. after the Time Of Divestiture of such Clinic:
    - (1) not use such information for any purpose other than complying with the terms of the Consent Agreement or with any law; and
    - (2) destroy all records of such information, except to the extent that: (1) Fresenius is required by law to retain such information, and (2) Fresenius's inside or outside attorneys may keep one copy solely for archival purposes, but may not disclose such copy to the rest of Fresenius.
- 8. For two (2) years following the Time Of Divestiture of each Clinic To Be Divested, Fresenius shall not solicit the business of any patients that received any goods or services from such Clinic between October 1, 2005, and the date of such divestiture, *provided, however*, Fresenius may (i) make general advertisements for the business of such patients including, but not limited to, in newspapers, trade publications, websites, or other media not targeted specifically at such patients, and (ii) provide advertising and promotions directly to any patient that initiates discussions with, or makes a request to, any Fresenius employee.

- 9. Fresenius shall do nothing to prevent or discourage Suppliers that, prior to the Time Of Divestiture of any Clinic To Be Divested, supplied goods and services for use in any Clinic To Be Divested from continuing to supply goods and services for use in such Clinic.
- C. The purpose of Paragraph II of this Order to Maintain Assets is:
  - 1. to preserve the Clinics To Be Divested and the Assets To Be Divested as viable, competitive, and ongoing businesses, to prevent their destruction, removal, wasting, deterioration, or impairment, and to prevent interim harm to competition, pending the relevant divestitures and other relief;
  - 2. to preserve the good will of the employees and Regional Managers of the Clinics To Be Divested and of the Physicians, Suppliers, and patients that do business with those Clinics; and
  - 3. to prevent Material Confidential Information relating exclusively to the Clinics To Be Divested from being exchanged with Fresenius's retained dialysis businesses.

#### III.

## IT IS FURTHER ORDERED that:

A. Richard Shermer, of R. Shermer & Co., shall be appointed Monitor to assure that Fresenius expeditiously complies with all of its obligations and performs all of its responsibilities as required by the Consent Agreement and this Order to Maintain Assets.

- B. No later than one (1) day after this Order to Maintain Assets is made final, Fresenius shall, pursuant to the Monitor Agreement and to this Order to Maintain Assets, transfer to the Monitor all the rights, powers, and authorities necessary to permit the Monitor to perform his duties and responsibilities in a manner consistent with the purposes of the Consent Agreement and this Order to Maintain Assets.
- C. In the event a substitute Monitor is required, the Commission shall select the Monitor, subject to the consent of Fresenius, which consent shall not be unreasonably withheld. If Fresenius has not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Fresenius of the identity of any proposed Monitor, Fresenius shall be deemed to have consented to the selection of the proposed Monitor. Not later than ten (10) days after appointment of a substitute Monitor, Fresenius shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights, powers, and authorities necessary to permit the Monitor to monitor Fresenius's compliance with the terms of the Consent Agreement and this Order to Maintain Assets, in a manner consistent with the purposes of this Order to Maintain Assets.
- D. Fresenius shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
  - 1. The Monitor shall have the power and authority to monitor Fresenius's compliance with the terms of the Consent Agreement and this Order to Maintain Assets, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of

the Consent Agreement and this Order to Maintain Assets and in consultation with the Commission, including, but not limited to:

- a. Assuring that Fresenius expeditiously complies with all of its obligations and perform all of its responsibilities as required by the Consent Agreement and this Order to Maintain Assets;
- b. Monitoring any transition services agreements; and
- c. Assuring that Material Confidential Information is not received or used by Fresenius or the Acquirers, except as allowed in the Consent Agreement and this Order to Maintain Assets.
- 2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
- 3. The Monitor shall serve for such time as is necessary to monitor Fresenius's compliance with the provisions of the Consent Agreement and the Order to Maintain Assets.
- 4. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Fresenius's personnel, books, documents, records kept in the Ordinary Course Of Business, facilities and technical information, and such other relevant information as the Monitors may reasonably request, related to Fresenius's compliance with its obligations under the Consent Agreement and this Order to Maintain Assets. Fresenius shall cooperate with any reasonable request of the Monitors and shall take no action to interfere with or impede the Monitor's ability to monitor Fresenius's compliance

with the Consent Agreement and this Order to Maintain Assets.

- 5. The Monitor shall serve, without bond or other security, at the expense of Fresenius on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Fresenius, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitors' duties and responsibilities. The Monitor shall account for all expenses incurred, including fees for services rendered, subject to the approval of the Commission.
- 6. Fresenius shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Monitor.
- 7. Fresenius shall report to the Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Fresenius, and any reports submitted by the Acquirer with respect to the performance of Fresenius's obligations under the Consent Agreement and this Order to Maintain Assets.

- 8. Within one (1) month from the date the Monitor is appointed pursuant to this paragraph, every sixty (60) days thereafter, and otherwise as requested by the Commission, the Monitor shall report in writing to the Commission concerning performance by Fresenius of its obligations under the Consent Agreement and this Order to Maintain Assets.
- 9. Fresenius may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement Relating To Commission materials and information received in connection with the performance of the Monitor's duties.
- F. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph III.
- G. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Consent Agreement and this Order to Maintain Assets.

#### IV.

IT IS FURTHER ORDERED that, beginning fifteen (15) days after the date on which Fresenius signs the Consent Agreement and every thirty (30) days thereafter until this Order to Maintain Assets terminates pursuant to Paragraph VII, Fresenius shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with the terms of this Order to Maintain Assets. Fresenius shall submit at the same time a copy of these reports to the Monitor.

V.

**IT IS FURTHER ORDERED** that Fresenius shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Fresenius,
- B. Any proposed acquisition, merger or consolidation of Fresenius, or
- C. Any other change in Fresenius that may affect compliance obligations arising out of this Order to Maintain Assets, including but not limited to assignment, the creation or dissolution of subsidiaries, or any other change in Fresenius.

## VI.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order to Maintain Assets, and subject to any legally recognized privilege, and upon written request with reasonable notice to Fresenius, Fresenius shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of Fresenius and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of Fresenius related to compliance with this Order to Maintain Assets; and
- B. Upon five (5) days' notice to Fresenius and without restraint or interference from Fresenius, to interview officers, directors, or employees of Fresenius, who may have counsel present, regarding such matters.

## VII.

**IT IS FURTHER ORDERED** that this Order to Maintain Assets shall terminate at the earlier of:

- A. three (3) business days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. such time as (1) all Assets To Be Divested have been divested pursuant to the terms of the Consent Agreement, and (2) the Decision and Order has been made final.

By the Commission.

## Analysis of Agreement Containing Consent Orders to Aid Public Comment

#### I. Introduction

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Fresenius AG and entities it controls, including Fresenius Medical Care AG & Co. KGaA, Fresenius Medical Care Holdings, Inc., and Florence Acquisition, Inc. ("Fresenius"). The purpose of the Consent Agreement is to prevent the anticompetitive effects that would result from Fresenius's purchase of Renal Care Group, Inc. ("RCG"). Under the terms of the Consent Agreement, Fresenius is required to divest 91 dialysis clinics, and RCG's joint venture equity interests in an additional 12 clinics, in 66 markets across the United States.

The Consent Agreement has been placed on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Consent Agreement and the comments received, and will decide whether it should withdraw from the Consent Agreement or make it final.

Pursuant to an Agreement dated May 3, 2005, Fresenius proposed to acquire RCG for approximately \$3.5 billion. The Commission's complaint alleges, as summarized in sections II and III below, that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by lessening competition in the market for the provision of outpatient dialysis services in local geographic markets across the United States.

#### II. The Parties

Fresenius, based in Germany, has its United States headquarters in Lexington, Massachusetts. After acquiring RCG, Fresenius will be the largest provider of outpatient dialysis services in the United States. In 2005, Fresenius had approximately \$4.1 billion in revenues from the provision of outpatient dialysis services to approximately 89,000 end stage renal disease ("ESRD") patients at approximately 1,155 outpatient dialysis clinics nationwide.

Headquartered in Nashville, Tennessee, RCG is the third-largest provider of outpatient dialysis services in the United States, with approximately 450 outpatient dialysis clinics nationwide, at which over 32,000 ESRD patients receive treatment. In 2005, RCG had approximately \$1.5 billion in revenues from the provision of outpatient dialysis services at approximately 450 clinics.

## **III. Outpatient Dialysis Services**

Outpatient dialysis services is the relevant product market in which to assess the effects of the proposed transaction. Most ESRD patients receive dialysis treatments in an outpatient dialysis clinic three times per week, in sessions lasting between three and five hours. The only alternative to outpatient dialysis treatments for ESRD patients is a kidney transplant. However, the wait-time for donor kidneys – during which ESRD patients must receive dialysis treatments – can exceed five years. Additionally, many ESRD patients are not viable transplant candidates. As a result, many ESRD patients have no alternative to ongoing dialysis treatments.

The Commission's complaint alleges that the relevant geographic markets for the provision of dialysis services are local in nature. They are circumscribed by the distance ESRD patients are able to travel to receive dialysis treatments. Most ESRD patients are quite ill and suffer from multiple health problems. As such, ESRD patients are unwilling and/or unable to travel long distances for dialysis treatment. The time and distance a patient will travel in a

particular location are significantly affected by traffic patterns; whether an area is urban, suburban, or rural; local geography; and a patient's proximity to the nearest center. The size and dimensions of relevant geographic markets are also influenced by a variety of other factors including population density, roads, geographic features, and political boundaries.

The Commission alleges that each of the 66 outpatient dialysis markets defined in the complaint is highly concentrated. With few exceptions, these markets have no more than one significant dialysis provider other than Fresenius and RCG. In each of these 66 markets, evidence that Fresenius and RCG are actual and substantial competitors in these markets, along with the high post-acquisition concentration levels, suggest that the combined firm likely would be able to exercise unilateral market power. The evidence shows that health plans and other private payors who pay dialysis providers for dialysis services used by their members benefit from direct competition between Fresenius and RCG when negotiating the rates of the dialysis provider. As a result, the proposed combination likely would result in higher prices and reduced incentives to improve service or quality for outpatient dialysis services in the 66 outpatient dialysis markets defined in the complaint.

In the outpatient dialysis services markets defined by the complaint, entry on a level sufficient to deter or counteract the likely anticompetitive effects of the proposed transaction is not likely to occur in a timely manner. The primary barrier to entry is the difficulty associated with locating nephrologists with established patient pools who are willing and able to serve as medical directors. Federal law requires each dialysis clinic to have a physician medical director. As a practical matter, having a nephrologist serve as medical director is essential to the success of a clinic because they are the primary source of referrals. Entry is also inhibited where certain attributes (such as a rapidly growing ESRD population, a favorable regulatory environment, average or below average nursing and labor costs, and a low penetration of managed care) are not present, as the Commission alleges is the case in particular geographic markets defined in the Commission's complaint.

## IV. The Consent Agreement

The Consent Agreement effectively prevents the anticompetitive effects that the proposed acquisition would otherwise be likely to have in the 66 markets where both Fresenius and RCG operate dialysis clinics, by requiring Fresenius to divest 91 outpatient dialysis clinics, and RCG's joint venture equity interests in 12 additional clinics, to National Renal Institutes, Inc. ("NRI"), a wholly-owned subsidiary of DSI Holding Company, Inc.

As part of these divestitures, Fresenius is required to obtain the agreement of the medical directors affiliated with the divested clinics to continue providing physician services after the transfer of ownership to NRI. Similarly, the Consent Agreement requires Fresenius to obtain the consent of all lessors necessary to assign the leases for the real property associated with the divested clinics to NRI. These provisions ensure that NRI will have the assets necessary to operate the divested clinics in a competitive manner.

The Consent Agreement contains several additional provisions designed to ensure that the divestitures will be successful. First, the Consent Agreement provides NRI with the opportunity to interview and hire employees affiliated with the divested clinics, and prevents Fresenius from offering these employees incentives to decline NRI's offer of employment. This will ensure that NRI has access to patient care and supervisory staff who are familiar with the clinic's patients and the local physicians. Second, the Consent Agreement prevents Fresenius from contracting with the medical directors (or their practice groups) affiliated with the divested clinics for three years. This provides NRI with sufficient time to build goodwill and a working relationship with its medical directors before Fresenius can attempt to capitalize on its prior relationships in soliciting their services. Third, the Consent Agreement requires Fresenius to provide NRI with a license to Fresenius's policies and procedures, as well as the option to obtain Fresenius's medical protocols, which will further enhance NRI's ability to provide continuity of care to patients.

Finally, the Consent Agreement requires Fresenius to provide prior notice to the Commission of its planned acquisitions of dialysis clinics located in the 66 markets addressed by the Consent Agreement. This provision ensures that subsequent acquisitions do not adversely impact competition in the markets at issue and undermine the remedial goals of the proposed order.

The Commission is satisfied that NRI is a qualified acquirer of the divested assets. NRI's management team has extensive experience in all facets of operating and developing outpatient dialysis clinics. In addition, Fresenius will provide transition services to NRI for a period of 12 months to ensure continuity of patient care and records as NRI implements its quality care, billing, and supply systems. Firewalls and confidentiality agreements will ensure that competitively sensitive information is not exchanged. NRI has received substantial financial backing from Centre Partners, a private equity firm focused on making investments in middle market companies.

The Commission has appointed Richard Shermer as Monitor to oversee the transition service agreements, and the implementation of, and compliance with, the Consent Agreement. Mr. Shermer is the President of R. Shermer & Company, a professional services firm that specializes in providing services for companies undergoing transitions in ownership through divestitures, mergers, or acquisitions. R. Shermer & Company has served as a monitor in connection with other Commission actions.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Decision and Order or the Order to Maintain Assets, or to modify their terms in any way.

## INTERLOCUTORY, MODIFYING, VACATING, AND MISCELLANEOUS ORDERS

#### EVANSTON NORTHWESTERN HEALTHCARE

Docket No. 9315. Order, January 5, 2006

Order denying respondent's request to remove its subsidiary from the caption of the administrative proceeding.

## ORDER DENYING MOTION BY ENH MEDICAL GROUP, INC. FOR REMOVAL OF NAME FROM CAPTION

On November 14, 2005, respondent ENH Medical Group, Inc. ("ENH Medical"), a subsidiary of respondent Evanston Northwestern Healthcare Corp. ("ENH"), filed a motion asking the Commission to remove its name from the caption of this proceeding. ENH Medical states that complaint counsel has consented to the requested relief. For the reasons stated below, the application is denied as premature.

On February 10, 2004, the Commission issued a three-count complaint against respondents ENH and ENH Medical. Counts I and II of the complaint asserted that ENH's January 2000 acquisition of the Highland Park Hospital substantially lessened competition in violation of Section 7 of the Clayton Act. As alleged in the complaint, following the merger of the hospitals, the parties folded the Highland Park Independent Physician Group into ENH Medical, which then negotiated prices for ENH salaried physicians as well as for independent physicians who are not clinically or financially integrated with ENH or ENH Medical, including physicians who formerly contracted through the Highland Park Independent Physician Association. Count III of the complaint charged that such joint price negotiations constitute unlawful price fixing in violation of Section 5 of the Federal Trade Commission Act. The allegations of Count III of the complaint were resolved by a consent order which, inter alia, prohibits ENH and ENH Medical Group from facilitating, or entering into agreements between or among physicians unless the physicians are participants in a clinically or financially integrated practice.

The present motion in essence requests that ENH Medical be dismissed from the case, but does not provide an adequate factual or legal basis for doing so. Although the consent order resolved the allegations of one count of a three-count complaint, as it affected ENH Medical, that respondent was not dismissed from the case at that time and it is premature to conclude that ENH Medical Group has no further relevance to this litigation. The Commission is now considering, in the context of ENH's appeal, whether ENH's acquisition of Highland Park Hospital violated Section 7 of the Clayton Act. If the Commission finds liability, it may become necessary to consider whether any additional or further relief with regard to ENH Medical is necessary in order to accomplish full relief and to restore competition in the relevant market.

Accordingly, for the foregoing reasons,

It is ordered that the instant motion to remove ENH Medical from the caption is denied; and

It is further ordered that the appeal of ENH Medical from the Initial Decision of the Administrative Law Judge, and from certain procedural and evidentiary rulings -- as detailed in the Notice of Appeal it filed on November 2, 2005 -- is hereby deemed to have been perfected by the filing of Respondent's Appeal Brief on December 16, 2005.

By the Commission.

## NORTH TEXAS SPECIALTY PHYSICIANS

Docket No. 9312 Order, January 20, 2006

Order granting stay of requirement that respondent terminate preexisting contracts with payors, and denying stay of remaining provisions of final Commission order pending appeal to the U.S. Court of Appeals for the Fifth Circuit, finding that respondent was unable to demonstrate likelihood of success on appeal, irreparable injury, and that staying the order would be in the public interest.

ORDER GRANTING IN PART AND DENYING IN PART RESPONDENT'S MOTION FOR STAY OF FINAL ORDER PENDING JUDICIAL REVIEW

On December 21, 2005, Respondent North Texas Specialty Physicians (NTSP) filed a motion to stay the Final Order in this matter, pending judicial review by an appropriate court of appeals¹. Thereafter, Complaint Counsel filed an answer opposing Respondent's motion, and Respondent filed a reply. For the reasons stated below, the Commission stays enforcement of and Respondent's obligation to comply with Paragraphs IV.B. and IV.C. of the Final Order until the U.S. Court of Appeals for the Fifth Circuit issues a ruling disposing of the petition for review. The Commission denies Respondent's motion in all other respects. Therefore, the Final Order will become effective on February 6, 2006, and Respondent will be required to comply with all its provisions except Paragraphs IV.B. and IV.C. during the pendency of the petition for review.

## **Applicable Standard**

Section 5(g) of the Federal Trade Commission Act, 15 U.S.C. § 45(g)(2), provides that Commission adjudicative orders (except divestiture orders) take effect "upon the sixtieth day after" their date of service, unless "stayed, in whole or in part and subject to such

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On January 10, 2006, NTSP filed a petition for review of the Commission's Final Order and Decision in the U.S. Court of Appeals for the Fifth Circuit.

conditions as may be appropriate, by . . . the Commission" or "an appropriate court of appeals." The Respondent and Respondent's counsel were served with the Final Order and the Opinion of the Commission on December 7, 2005, and the Final Order therefore will become effective on the sixtieth day thereafter; that is, on February 6, 2006. See 15 U.S.C. § 5(g)(2); Commission Rule 3.56(a), 16 C.F.R. § 3.56(a) (2006). A party seeking a stay must first apply for such relief to the Commission, as Respondent has done here.

Pursuant to Commission Rule 3.56(c), 16 C.F.R. § 3.56(c), a motion for a stay must address the following four factors: (1) "the likelihood of the applicant's success on appeal," (2) "whether the applicant will suffer irreparable harm if a stay is not granted," (3) "the degree of injury to other parties if a stay is granted," and (4) "why the stay is in the public interest." Rule 3.56(c) further provides that a motion for a stay must be supported by "supporting affidavits or other sworn statements, and a copy of the relevant portions of the record." *Id. See also In the Matter of Toys "R" Us, Inc.*, 126 F.T.C. 695, 696 (1998).

We consider each of these factors in turn below.

## Likelihood of Success on Appeal

The Commission considers its unanimous decision in this case to be correct, and if there were nothing more to consider in determining the likelihood of success on appeal, this would end the inquiry. However, the Commission additionally considers the complexity of the case; whether the Commission has ruled on a difficult legal question; and whether the balance of the equities supports a stay<sup>2</sup>. *California Dental*, 1996 FTC LEXIS 277, at \*9-10;

The Commission has stated that "the necessary degree or level of possibility of success will generally vary according to an assessment of the other three factors" and that "the probability of success that must be demonstrated is inversely

Toys "R" Us, 126 F.T.C. at 697<sup>3</sup>. Because of the relationship between balancing the equities and the other three factors the Commission considers in examining a motion for a stay (irreparable harm, degree of injury to other parties and the public interest), the Commission will balance the equities associated with each of those three factors.

NTSP argues that because the case involves a complex factual record – and difficult, serious legal questions on which it claims it can show a substantial case – it has met the requisite standard for likelihood of success on appeal. NTSP points to the length of the administrative hearing, the number of testifying witnesses, and the number of exhibits and pages of hearing transcript as evidence of a complex factual record, and states that the fact that this case involves the health care industry adds to its complexity and importance. NTSP also reiterates the primary arguments it made before the Commission, which the Commission has already rejected in its November 29, 2005 Opinion. These statements, however, offer the Commission no sufficient reason to question its prior decision or any of the bases for it, and Respondent's renewal of its legal arguments, without more, is insufficient to justify granting a stay.

proportional to the amount of irreparable injury suffered absent the stay." *In the Matter of California Dental Ass'n*, No. 9259, 1996 FTC LEXIS 277, at \*10 (May 22, 1996), *citing Michigan Coalition of Radioactive Material Users*, 945 F.2d 150, 153 (6<sup>th</sup> Cir. 1991). With one exception discussed below, the Commission has assessed the other three factors against NTSP.

The U.S. Court of Appeals for the Fifth Circuit has held that a movant for a stay "need only present a substantial case on the merits when a serious legal question is involved and show that the balance of equities weighs heavily in favor of granting the stay." *United States v. Baylor Univ. Med. Ctr.*, 711 F.2d 38, 39 (5<sup>th</sup> Cir. 1983), *quoting Ruiz v. Estelle*, 650 F.2d 555 (5<sup>th</sup> Cir. 1981). The Commission's standard is consistent with this approach.

See Toys "R" Us, 126 F.T.C. at 697; In re Detroit Auto Dealers Ass'n, Inc., No. 9189, 1995 FTC LEXIS 256, at \*4 (Aug. 23, 1995).

While the Commission does not question the seriousness or importance of either this case or the legal questions it presents, the case is not sufficiently complex, and the legal questions at issue are not sufficiently difficult as to warrant a stay on that basis alone. NTSP cites the *Novartis* case to support its position, but the present case does not involve the type of complex factual record at issue in that case. See generally In the Matter of Novartis Corp., 128 F.T.C. 233 (1999). There, the Commission had to evaluate numerous scientific studies of consumer behavior in order to assess and remedy potentially lingering misbeliefs fostered by deceptive advertising. Novartis, 128 F.T.C. at 234-35. By contrast, in this case there are no comparable sources of complexity, particularly given the Commission's extensive experience evaluating the types of conduct at issue in this case in the health care industry. The Commission has issued numerous consent orders over the last ten years addressing substantially similar conduct<sup>4</sup>. See Commission Opinion at 1, n.1.

As for the difficulty of the legal questions presented here, there is nothing novel about the Commission's legal analysis; indeed, the Supreme Court has in the past condemned conduct like that of NTSP as *per se* unlawful. *See Arizona v. Maricopa County Med. Soc'y*, 457 U.S. 332 (1982). Moreover, the Commission and the Department of

The Commission's antitrust enforcement expertise in the health care area is also reflected in the recent report on competition policy and health care that it issued with the Department of Justice. The report was based on 27 days of public hearings covering a broad range of health care topics, all focused on ways to promote innovative, cost effective and high quality health care services. The Fed. Trade Comm'n and the U.S. Dep't of Justice, *Improving Health Care: A Dose of Competition* (July 2004), <a href="http://www.ftc.gov/reports/healthcare/040723healthcare-rpt.pdf">http://www.ftc.gov/reports/healthcare/040723healthcare-rpt.pdf</a>.

Justice have issued extensive guidelines for antitrust enforcement policy in health care that contain specific guideposts for the conduct at issue in this case and clearly present the relevant legal principles. Commission Opinion at 14; U.S. Dep't of Justice & Fed. Trade Comm'n, *Statements of Antitrust Enforcement Policy in Health Care* (1996) *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,153. The Commission Opinion and the Final Order are consistent with these Statements.

Furthermore, the legal analysis the Commission applied – the framework in *Polygram Holding, Inc.*, 5 Trade Reg. Rep. (CCH) ¶ 15,453 (FTC 2003), *available at* http://www.ftc.gov/os/2003/07/polygramopinion.pdf, and recently affirmed by the D.C. Circuit<sup>5</sup> – merely follows the framework the Supreme Court established in *California Dental Ass'n v. FTC*, 526 U.S. 756 (1999), by synthesizing prior antitrust decisions. This analysis prescribes a flexible analytical approach that replaces a simple dichotomy between categories like "*per se*" and "rule of reason" with a far more legally and economically sophisticated continuum of conduct along which behavior can be analyzed. Applying this analysis in this case is neither controversial nor difficult, and the Commission consequently does not consider this case to be the type of "close case" that would justify a stay.

## Irreparable Injury to NTSP Absent a Stay, Degree of Injury to Other Parties and the Public Interest

The Commission addresses these three factors together in this section because NTSP's Motion for Stay examines all three factors together. To show irreparable injury, NTSP must demonstrate that denial of a stay would cause it irreparable harm. Simple assertions of harm or conclusory statements based on unsupported assumptions will not suffice. NTSP must show that the irreparable injury alleged is both substantial and likely to occur absent a stay. *See Michigan Coalition of Radioactive Material Users v. Griepentrog, Inc.*, 945

Polygram Holding Inc. v. FTC, 416 F.3d 29.

F.2d 150, 154 (6<sup>th</sup> Cir. 1991). The Commission considers the third and fourth prongs (harm to others and the public interest) together because Complaint Counsel represents the public interest in effective law enforcement. *See California Dental*, 1996 FTC LEXIS 277, at \*7-8.

NTSP argues that Paragraphs II, IV, and VI of the Commission's Final Order should be stayed because they allegedly will cause NTSP and third parties irreparable injury and are not in the public interest. NTSP argues that the Order's remaining provisions, which it characterizes as ancillary rather than substantive, should be stayed because they have no purpose or meaning if Paragraphs II, IV and VI of the Final Order are stayed. We discuss each relevant section of the Final Order below.

## Paragraph II of the Final Order

Paragraph II of the Order, among other things, requires NTSP to cease and desist from negotiating any term, condition or requirement upon which any physician deals, or is willing to deal, with any payor, and dealing, refusing to deal, or threatening to refuse to deal with any payor. Paragraph II also prohibits NTSP from exchanging or facilitating in any manner the exchange or transfer of information among physicians concerning any physician's willingness to deal with a payor, or the terms or conditions on which the physician is willing to deal. Paragraph II exempts any agreement that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or a qualified clinically-integrated joint arrangement.

NTSP argues that Paragraph II of the Order will cause NTSP to incur unrecoverable costs; create confusion among physicians, patients, and health plans regarding NTSP's functions and policies; adversely affect NTSP's reputation and viability; and prevent NTSP from participating in lawful and potentially lawful conduct, including exercise of its right to contract. NTSP also argues that third-party physicians, patients and health plans and the public interest will be harmed because the efficiencies created by NTSP's

spillover business model, relating to patient care and quality of care, will allegedly be lost.

NTSP further argues that the restrictions on its policies and physician agreements potentially will prevent it from making lawful unilateral decisions, and from disseminating information to physicians and patients, regarding both health care in general and particular payors and contracts. NTSP also argues that if it cannot terminate payor contracts, regardless of payor breaches of contract or illegal conduct, it will be exposed to potential liability and deprived of a contract right.

In addition, NTSP argues that the messengering requirements of the order will block its spillover business model, and thus present a significant danger to NTSP's reputation and continued viability. Finally, NTSP argues that the Order infringes its First Amendment rights by limiting NTSP communications with its hundreds of participating physicians, as well as with every payor in the Dallas-Fort Worth Metroplex.

NTSP has not demonstrated either that irreparable substantial injury to itself or harm to others will occur absent a stay of Paragraph II of the Order or that such a stay of Paragraph II would be in the public interest. The irreparable injury inquiry necessarily examines the consequences to NTSP in complying with the Order if it succeeds on the merits of its appeal. NTSP has not quantified the "unrecoverable costs and business losses" it claims, nor does it elaborate on how the grant or refusal of a stay would affect its reputation. Although NTSP cites *Novartis*, 128 F.T.C. 233, as support for its motion, in that case Novartis established that it would have to spend some \$8,000,000 for corrective advertising in order to inform millions of consumers of its misleading advertising. Novartis, 128 F.T.C. at 239 n.2. NTSP has not made a comparable showing of harm from compliance with Paragraph II. Moreover, the documentation appended to NTSP's motion from NTSP's Executive Director and from NTSP's Board Vice President contains only

conclusory and unsupported allegations of harm if Paragraph II of the Order is not stayed.

Furthermore, NTSP has not demonstrated any irreparable harm to itself or to others from the loss of benefits from its spillover model, or that a stay is in the public interest because of that model. Indeed, NTSP has not demonstrated how the conduct prohibited in Paragraph II of the Order relates to any of the spillover benefits it claims. See Commission Opinion at 28-32. To the extent that there is any "spillover" from NTSP's one risk-sharing contract, that "spillover" will occur regardless of whether NTSP engages in the conduct prohibited by Paragraph II of the Final Order; the Final Order does not apply to that contract because, *inter alia*, it involves financial integration<sup>6</sup>. Commission Opinion at 30. Furthermore, Paragraph II of the Final Order specifically allows NTSP to engage in conduct reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or a qualified clinically-integrated joint arrangement. Thus, NTSP will be able to engage in efficiency-enhancing activities for which it demonstrates sufficient financial or clinical integration. The Final Order also allows NTSP to act as a proper messenger as long as it provides the Commission notice at least sixty days prior to doing so, for a period of three years. See Final Order, Paragraph III.

NTSP claims its viability may be harmed if Paragraph II of the Order is not stayed, but NTSP has not attempted to elaborate on this claim. Moreover, Paragraph II of the Order does not apply to NTSP's risk-sharing contract, which NTSP's counsel stated at oral argument was significant to NTSP and the source of 90 percent of NTSP's revenue. Oral Argument at 12, 23. The requirements of Paragraph II of the Order rather go to the core of NTSP's illegal

NTSP's counsel admitted during oral argument before the Commission that risk-sharing contracts are out of favor in Fort Worth, Texas. Oral Argument at 23. Thus, it is difficult to see how third-party payors and health plans are irreparably harmed by the prohibitions in Paragraph II of the Order.

conduct. Consequently, it is appropriate to consider the substantial injury to competition and consumers that would result from NTSP's continued unlawful conduct if Paragraph II were stayed. The Commission finds that a stay of this provision is not in the public interest because it would cause substantial harm to consumers and outweigh any conceivable harm to NTSP.

NTSP does not provide any factual support for its argument that Paragraph II of the Order will prohibit its communications with physicians and payors, and its dissemination of health care information, in a manner that will cause irreparable harm, or demonstrate how compliance with Paragraph II will infringe its First Amendment rights. Moreover, NTSP's other arguments for staying Paragraph II of the Order consist of nothing more than simple assertions of harm and conclusory statements based on unsupported assumptions or misconceptions about the requirements of the Order.

## Paragraph IV of the Final Order

Paragraph IV.A. of the Final Order requires NTSP, within thirty days after the Order becomes final, to send, by first-class mail, return receipt requested, a copy of the Order and a copy of the administrative Complaint to NTSP's physicians, officers, directors, managers and employees, and to the chief executive of each payor with which NTSP has had contact since January 1, 2001. Paragraph IV.B. requires NTSP to terminate without penalty or charge and in compliance with any applicable laws, any preexisting contract with any payor for the provision of physician services – other than the contract identified in Appendix B to the Order – at the earliest of either receipt of a written request from a payor to terminate such contract (Paragraph IV.B.(1)), or the earliest termination or renewal date (including any automatic renewal date) of such contract (Paragraph IV.B.(2)). Paragraph IV.B. also provides that any payor who makes a request to extend a contract retains the right to terminate the contract at any time. Paragraph IV.C. requires NTSP to send by first-class mail, return receipt requested, a copy of any request from a payor pursuant to Paragraph IV.B.(1) to each

physician participating in NTSP as of the date NTSP receives the request.

Paragraph IV.D. requires NTSP, for three years after the Final Order becomes final, to send, by first-class mail, return receipt requested, copies of the Order and the Complaint to any new physicians, payors, officers, directors, managers, or employees of NTSP who did not previously receive copies of those documents. NTSP is also required to annually publish copies of the Order and the Complaint in an official annual report or newsletter. Paragraph IV.E. requires NTSP to file a written report with the Commission within sixty days after the Order becomes final, and annually thereafter for three years, describing the manner and form in which NTSP has complied and is complying with the Order, and to file with each such report copies of return receipts required by Paragraphs IV.A., IV.C. and IV.D. of the Order. Paragraph IV.F. requires NTSP to notify the Commission at least thirty days prior to any proposed change in NTSP that may affect compliance obligations arising out of the Final Order, including but not limited to dissolution, assignment or sale.

NTSP states that the Paragraph IV notification requirements would require NTSP to provide the specified notice to each of its hundreds of participating physicians and to every payor in the Dallas-Fort Worth Metroplex. NTSP argues that these requirements would impose unrecoverable costs and business losses on NTSP; would confuse physicians, patients, and payors; and would harm NTSP's reputation.

NTSP failed to demonstrate either that the Paragraph IV notification requirements would likely cause irreparable substantial injury to itself or harm to others or that a stay of these requirements would be in the public interest. While NTSP cites *California Dental*, 1996 FTC LEXIS 277, as support for its allegations, that reliance is misplaced, because in *California Dental* the respondent would have had to notify, and potentially renotify, up to 19,000 member dentists. By contrast, in this case, NTSP will have to notify, and potentially renotify, only approximately 400 member physicians, and a limited

number of payors in a limited geographic region. Thus, the burden and expense involved in implementing the notice provisions in the two cases are not facially comparable. Moreover, NTSP has adduced no support for its bald assertions that it will suffer business losses, and that the requisite notification efforts will cause physician, patient and payor confusion. In fact, the Commission has required similar notification efforts in numerous consent orders against other physician IPAs.

NTSP also argues that the termination of the 13 contracts that Paragraph IV.B. requires will harm NTSP and non-party physicians, patients, health plans, and the public interest, by disrupting the spillover effects that NTSP has achieved, thereby in turn damaging NTSP's reputation and marketplace viability. In addition, NTSP argues that terminating those contracts will disrupt the medical practices of the non-party physicians, as well as the operation of health plans and patient care for over 200,000 lives covered by those contracts and will impose financial harm on the non-party physicians and payors. NTSP also argues that continuation of thecontracts would not be harmful because the only contracts concerning which complaints have been registered have been terminated or replaced, or are already terminable at will by the payors.

As explained above and in the Commission Opinion (*see* discussion above re: Paragraph II of the Order, and Commission Opinion at 28-30), the Commission has found no support for NTSP's claims that its non-risk contract activities produce spillover efficiencies. Accordingly, the Commission concludes that the Paragraph IV contract termination provisions will not disrupt any spillover benefit from NTSP's business model. Nevertheless, the Commission recognizes that – apart from any inconvenience to NTSP or its member physicians – the cancellation of existing contracts may well affect the thousands of patients who are covered by the health plans under contract. While Paragraph IV.B. allows payors to submit written requests to extend particular contracts with NTSP to a specific date, that date can be no later than one year after

the date the Order becomes final. NTSP therefore might have to terminate some of its contracts at that point; such terminations might have disruptive effects on covered patients and it might be impossible to revive those contracts, once terminated. By staying Paragraphs IV.B. and C. of the Final Order pending appellate review, we ensure that the Court of Appeals will have the opportunity to give plenary consideration to NTSP's petition for review without concern for such disruptive effects from contract terminations in the interim. Moreover, the other core provisions of the Commission's Final Order will prevent NTSP from engaging in any further price-fixing conduct and thus protect the public interest. On balance, therefore, we find that the public interest favors staying of Paragraphs IV.B. and C. of the Final Order, allowing NTSP's contracts to continue in effect until the Court of Appeals disposes of NTSP's petition for review. The Commission undertakes this action without any intent to affect any preexisting rights that payors might hold.

# Paragraph VI of the Final Order

Paragraph VI.A. of the Final Order requires NTSP to grant Commission representatives access to its records for the purpose of determining or securing its compliance with the Order. Paragraph VI.B. of the Order requires NTSP to permit Commission representatives to interview NTSP or its employees upon five days notice and in the presence of counsel.

NTSP argues this provision should be stayed because it is "fatally flawed and disregards federal and state law." Motion for Stay at 17. NTSP also maintains that because attorney-client, physician-patient and other privileged and confidential documents and information are not exempt from coverage by the Final Order, the Order therefore infringes on the rights of patients, physicians and NTSP.

NTSP has not demonstrated an irreparable substantial injury to itself or harm to others that is likely to occur absent a stay as to the requirements of Paragraph VI of the Order, nor has it demonstrated

that a stay of this provision is in the public interest. Paragraphs VI.A. and B. of the Order are necessary for the purpose of determining or securing NTSP's compliance with the Order. Similar monitoring provisions are routinely included in Commission orders. These provisions typically do not expressly identify an exception for privileged and confidential information; however, this does not preclude the respondent from asserting any applicable privileges when – and if – the Commission subsequently invokes the monitoring provision<sup>7</sup>. Moreover, NTSP's argument ignores the Commission's regulations and internal procedures for protecting confidential information. A more fundamental flaw in NTSP's argument, however, is that its concerns regarding possible disclosures of privileged and confidential information are wholly premature and speculative. There is simply no indication that the Commission is likely to seek access to NTSP's records between now and the time that NTSP's petition for review is decided<sup>8</sup>. For all these reasons, we find that a stay of Paragraph VI of the Order is not warranted.

### Conclusion

For the foregoing reasons, the Commission has determined to stay enforcement of and Respondent's obligation to comply with Paragraphs IV.B. and IV.C. of the Final Order until the U.S. Court of Appeals for the Fifth Circuit issues a ruling disposing of the petition for review, and to deny Respondent's motion for stay in all other respects. Accordingly,

This does not mean that we agree with NTSP's conclusory argument – which it does not elaborate upon – that its compliance with this portion of the Order would violate federal and state law.

The cases NTSP cites that refer to a patient's constitutional right to privacy and the Health Insurance Portability and Accountability Act are not applicable in the context of the monitoring provisions of the Commission's Order.

It is ordered that enforcement of and Respondent's obligation to comply with Paragraphs IV.B. and IV.C. of the Final Order be, and they hereby are, stayed until the U.S. Court of Appeals for the Fifth Circuit issues a ruling disposing of the petition for review filed by Respondent; and

*It is further ordered that* Respondent's Motion for Stay be, and it hereby is, *denied* in all other respects.

By the Commission.

### NORTH TEXAS SPECIALTY PHYSICIANS

Docket No. 9312 Order, January 20, 2006

Order modifying portions of the Commission's final opinion and order to clarify language relating to messenger model physician contracts.

### ORDER MODIFYING OPINION OF THE COMMISSION

On November 29, 2005, the Commission issued a Final Order and Opinion holding that Respondent North Texas Specialty Physicians' (NTSP) contracting activities with payors constitute unlawful horizontal price fixing. In its Opinion, the Commission made it clear that these types of cases require case-by-case assessments, and based its conclusion that NTSP violated the law on a fact-intensive analysis.

On December 20, 2005, Complaint Counsel filed a Petition for Clarification of Certain Statements in the Commission Opinion, expressing concern that certain language in the Opinion – relating to the messenger model and describing the existence here of concerted action – may have created confusion as to the lawfulness of certain practices in contexts other than the factual circumstances present in this case. The Commission believes that the statements to which Complaint Counsel refers, properly read in context, are not

reasonably subject to the misinterpretations described in the Petition for Clarification. In particular, nothing in the Commission Opinion is intended to suggest an invariable rule that a physician network always violates the antitrust laws whenever it fails to transmit all payor offers. The Commission Opinion makes it patently clear that the Commission determination that NTSP misused the messenger model was inextricably intertwined with and based upon a comprehensive assessment of NTSP's conduct considered in its entirety, including in particular its use of a prospective price poll of physician members. Commission Opinion pp. 25-26. The Commission Opinion also makes clear that when a single organization is controlled by a group of competitors and serves as their agent, the organization is viewed as a combination of its members, the actions of which will violate the antitrust laws if they constitute an unreasonable restraint of trade. Commission Opinion p. 15. However, in order to ensure that there is not even a remote possibility of confusion surrounding the language of the Opinion, the Commission has determined to modify its Opinion in minor respects. 1 Accordingly,

*It is ordered that* the Opinion of the Commission issued on November 29, 2005, in this matter be, and it hereby is, modified as follows:

Section 5(b) of the Federal Trade Commission Act permits the Commission to modify its Opinion and Final Order in a given matter "[u]ntil the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, or, if a petition for review has been filed within such time then until the record in the proceeding has been filed in a court of appeals of the United States, as hereinafter provided, . . . ," 15 U.S.C. § 45(b); *accord*, Commission Rule 3.72(a), 16 C.F.R. § 3.72(a) (during the period prescribed by Section 5(b), the Commission may modify any part of its "findings as to the facts, conclusions, rule, order, or opinion issued by the Commission...").

1. The third, fourth and fifth sentences of the second full paragraph on Page 15, beginning with the phrase "The matter is easy to decide . . . " are modified by striking the sentences in their entirety and inserting in their place the following:

"The matter is easy to decide when two or more separate legal entities overtly agree on a restraint that each will adopt. However, an action nominally taken by a single entity is also construed as the product of agreement for purposes of the antitrust laws when the entity is controlled by a group of competitors and is serving as the agent of the group."

2. The first and second sentences of the second full paragraph on Page 26, beginning with the phrase "NTSP's refusal to messenger contracts where it determined . . ." are modified by striking the sentences in their entirety and inserting in their place the following:

"NTSP's refusal to messenger contracts where it determined, based on the results of its prospective price poll, that less than 50 percent of NTSP physicians would join, eliminates the ability of NTSP physicians to decide unilaterally whether to accept the unmessengered contracts and hinders the ability of payors to contract individually with NTSP physicians. [footnote 40]"

- 3. The sixth and seventh lines of the second full paragraph on page 34 are modified by striking "(2) all payor offers were messengered to the physicians, regardless of how many physicians are deemed likely to accept the offer based on the poll results" and inserting in its place the following:
  - "(2) NTSP did not use the polling results as a basis for determining which payor offers it would elect to messenger to the physicians".4. The third and fourth lines of the second full paragraph on page 35 are modified by striking "the key to a lawful messenger model is that the IPA must be willing to messenger *all* payor offers, and refrain" and inserting in its place the following:

"a key to a lawful messenger model is that the IPA must refrain from using prospective polling results in determining which payor offers it would elect to messenger, and refrain".

By the Commission.

# EVANSTON NORTHWESTERN HEALTHCARE CORPORATION

Docket No. 9315 Order, January 24, 2006

Order granting leave for third parties to file *amicus curiae* briefs in the administrative proceeding, and denying third party hospital association's request to participate in the oral argument before the Commission.

# ORDER GRANTING MOTIONS FOR LEAVE TO FILE BRIEFS AMICI CURIAE

On December 16, 2005, the Advisory Board Company, the American Hospital Association ("AHA"), the Business Roundtable, the City of Highland Park, and the Joint Commission on Accreditation of Health Care Organizations ("Joint Commission") filed timely motions for leave to file briefs *amici curiae* in this matter, and attached copies of the briefs that they respectively propose to file. The AHA's motion also requests that it be allowed to participate in the oral argument before the Commission. On December 30, 2005, Complaint Counsel filed a response to these motions, and on January 9 and January 12, 2006, the AHA and the Advisory Board Company respectively filed replies to that

response<sup>1</sup>. For the reasons detailed below, the Commission grants all of the motions to file briefs *amici curiae*, and it denies the portion of the AHA's motion that requests that the Commission allow it to participate in the oral argument.

# 1. Requests for Leave to File Briefs Amici Curiae

The moving parties describe themselves as follows:

- a. The Advisory Board Company is a for-profit research organization that provides best practices research and analysis to the health care industry. The Board has 2,500 member hospitals and health systems, including one of the respondents, Evanston Northwestern Healthcare ("ENH"). Advisory Board Motion at 1.
- b. The AHA represents approximately 4,800 hospitals and health systems. AHA Motion at 1.
- c. The Business Roundtable is an association of chief executive officers of U.S. corporations, whose members are major consumers of health care in the United States. Business Roundtable Motion at 1-2.
- d. The City of Highland Park is a residential community of approximately 32,000 residents located 23 miles north of Chicago, on Lake Michigan's North Shore. Highland Park Hospital, which merged with ENH in 2000, is located in the City of Highland Park. City of Highland Park Motion at 1.

Commission Rule 3.22(c), 16 C.F.R.

<sup>§ 3.22(</sup>c)(2005), provides that a "moving party shall have no right to reply, except as permitted by the Administrative Law Judge or the Commission." The Commission has determined, as a matter of discretion, to permit the AHA and the Advisory Board Company to file their Replies.

e. The Joint Commission is an Illinois not-for-profit corporation whose members include the American College of Physicians, the American College of Surgeons, the American Dental Association, the American Hospital Association, and the American Medical Association. Joint Commission Motion at 1.

Complaint Counsel do not directly oppose any of the motions in their entirety. With respect to the motions of the Advisory Board, the AHA, and the Joint Commission, Complaint Counsel "suggest" that the Commission

should duly consider the portions [of their respective briefs] that truly serve the traditional purposes of *amicus* briefs but give little if any consideration to the portions . . . that sidestep the Commission's own evidentiary and procedural rules.

Complaint Counsel Response at 3.<sup>2</sup> Complaint Counsel also state that they disagree with the views of the Business Roundtable and the City of Highland Park, but Complaint Counsel do not oppose their motions because, in the view of Complaint Counsel, their briefs "do not compromise the evidentiary and procedural protections afforded the parties . . . ." *Id.* at 2, n.1.

The Commission will grant all five requests for leave to file briefs *amici curiae* because each motion satisfies the Commission's requirement that the public interest will benefit from the

In its Reply to Complaint Counsel's brief, the AHA states that the Commission should "consider AHA's proposed brief *amicus curiae* in its entirety." AHA Reply at 3. In its Reply, the Advisory Board Company states that the Commission should not prejudge the merits of its brief in the context of a motion for leave to file the brief. Advisory Board Reply at 1.

Commission's consideration of the attached brief<sup>3</sup>. The Commission takes no position on the substantive or procedural merit of any of the arguments presented in any of the pleadings, except those arguments that concern the right of the moving parties to file the pleadings and to participate in the oral argument.

# 2.AHA's Request to Participate in Oral Argument

The AHA also requests permission to participate in the oral argument. AHA Motion at 1-2. To support its request, the AHA refers to "the complexity of the issues" in this case, and "the significant interest that the AHA and its member hospitals have" in how hospital mergers are evaluated. AHA Motion at 2.

Commission Rule 3.52(j) provides that "[a] motion for an *amicus curiae* to participate in oral argument will be granted only for extraordinary reasons." 16 C.F.R. § 3.52(j) (2005). The Commission expects that the parties to this proceeding will provide a comprehensive discussion of the relevant issues during the oral argument. Therefore, there is no extraordinary reason for the AHA to participate in the argument.

Accordingly,

It is ordered that the Advisory Board Company, Business Roundtable, City of Highland Park, and Joint Commission motions for leave -- and the portion of the AHA motion requesting leave -- to file briefs *amici curiae* are *granted*; and

See, e.g., In the Matter of Telebrands Corp., et al., Docket No. 9313, Order Granting Motion for Leave to File Brief Amicus Curiae and Revising Briefing Schedule (Dec. 1, 2004); In the Matter of Rambus Incorporated, Docket No. 9302, Order Granting Motions for Leave to File Briefs Amici Curiae and Scheduling Oral Argument (April 30, 2004), and Order Granting Motions for Leave to File Briefs Amici Curiae (June 21, 2004), In the Matter of Rambus Incorporated, Docket No. 9302.

It is further ordered that the portion of the AHA motion requesting permission to participate in the oral argument is denied.

By the Commission.

### RAMBUS INCORPORATED

Docket No. 9302 Order, February 2, 2006

Order admitting newly found documents into evidence; denying respondent's request to admit into evidence documents that are subject to a protective order in a related federal court proceeding; and granting complaint counsel leave to file a supplemental response to respondent's motion.

Order Granting in Part Complaint Counsel's Motion to Reopen the Record to Admit Documents from Rambus's Newly-found Back-up Tapes Pertaining to Rambus's Spoliation of Evidence; and Denying Without Prejudice Rambus's Motion to Reopen the Record to Admit Newly Obtained Evidence Rebutting Complaint Counsel's Proposed Findings and Undermining Complaint Counsel's Proposed Remedy

[Formerly In Camera]
[Placed On Public Record By Notice Issued On February 7, 2007]

On July 28, 2005, Complaint Counsel asked the Commission to delay the briefing schedule set forth in the Order entered on July 20, 2005. This delay was requested so Complaint Counsel could move the admission of additional documents they were still receiving from Rambus as part of a rolling production of documents which were "newly-found" on Rambus's back-up tapes in discovery for *Hynix Semiconductor Inc. v. Rambus Inc.*, Dkt. No. CV 00-20905 RMW (N.D. Cal.) ("*Hynix* litigation"). The Commission's Order Denying

Complaint Counsel's Petition to Modify the Schedule in the Commission's July 20, 2005 Order (August 4, 2005) expressed no view "on whether the record can or should be reopened at a later date to admit materials that are currently being produced by Rambus in discovery in the *Hynix* litigation." *Id.* at 1, n. 1. In September 2005, Complaint Counsel and Rambus each filed a motion to reopen the record in this matter. We address each of these motions separately.

# Complaint Counsel's Motion to Reopen

Complaint Counsel's current motion to admit additional evidence from the *Hynix* litigation was filed on September 29, 2005. Complaint Counsel asks the Commission to admit into evidence eighteen (18) documents designated Exhibits CX-5100 - 5117. Complaint Counsel claim they have satisfied the legal standard for reopening as reflected in the Commission's Order of May 13, 2005<sup>1</sup>. Rambus opposes reopening on the grounds that Exhibits CX-5100 - 5116 are cumulative and irrelevant and that Complaint Counsel has offered no explanation or justification for offering CX-5117 into evidence.<sup>2</sup>

"Reopening the record to admit supplemental evidence at this stage of the proceeding should only be . . . countenanced where (1) the party offering the evidence has acted with due diligence; (2) the supplemental evidence is relevant, probative and non-cumulative; and (3) the supplemental evidence can be admitted without undue prejudice to the other party." We find those criteria satisfied with

Order Granting In Part Complaint Counsel's Motion to Compel Production of, and to Reopen the Record to Admit, Documents Relating to Rambus Inc.'s Spoliation of Evidence; and Granting Rambus's Unopposed Motion for Release of Testimony (May 13, 2005) at 2 ("Reopen Order I").

Memorandum by Rambus Inc. in Opposition to Complaint Counsel's Motion to Reopen the Record to Admit Documents from Rambus's Back-Up Tapes (Oct. 11, 2005) ("Rambus Memo in Opposition").

Reopen Order I at 2 (citations omitted).

respect to 17 of the 18 documents that Complaint Counsel has sought to add to the record.

First, the Commission finds that Complaint Counsel has acted with due diligence in offering this evidence. In late 2002, Rambus's in-house counsel was searching for documents in this case and discovered an open box of materials, including tapes, in a cubicle. Without reviewing the tapes, he deemed the materials non-responsive to Complaint Counsel's discovery requests<sup>4</sup>. In March 2005, Rambus revisited that decision in preparation for a hearing in the *Hynix* case and made further searches for other tapes<sup>5</sup>. Thus, long after the close of discovery in this matter, Rambus found additional evidence on approximately 1,400 back-up tapes and other removable electronic media. Rambus completed production to Hynix and to Complaint Counsel late in September 2005<sup>6</sup>. Since Rambus only recently produced these documents and Complaint Counsel promptly brought them to our attention, we find that Complaint Counsel acted with due diligence.

Second, we find that 17 of the 18 proffered documents are relevant and probative of issues in this case. Rambus appears to concede the probative value of CX-5107 – an email reflecting engineer Billy Garrett's understanding of JEDEC's disclosure policy – by stating that the document reflects "an important confirmation for Rambus that disclosure at JEDEC meetings was *voluntary*, not required." Rambus does not object to the admission of CX-5107.

<sup>&</sup>lt;sup>4</sup> Attachment A to Complaint Counsel's Motion to Reopen, at 3.

Attachment A to Complaint Counsel's Motion to Reopen, at 4.

<sup>6</sup> Complaint Counsel's Motion to Reopen at 6-7.

Rambus Memo in Opposition at 7 (emphasis in original).

To the contrary, Rambus offers an additional copy of virtually the same email, RX-2554, which it requests the Commission to admit into evidence<sup>8</sup>. These two emails differ only in the identity of the addressees and the fact that RX-2554 contains an apology from Garrett, author of both emails, to Rambus's primary JEDEC representative Richard Crisp for not having copied Crisp on his first email, CX-5107.

Like CX-5107, other documents appear to shed some light on Rambus employees' views of JEDEC's disclosure rules and their effects. *See*, *e.g.*, CX-5105 (email from Crisp stating his understanding of JEDEC disclosure rules); CX-5108 at 3 (email from Crisp reflecting his hope that a firm's offer to license patents "in accordance with JEDEC rules" would "inhibit the standardization" effort); and CX-5113 (email from Crisp stating his understanding of the rationale for the JEDEC policy).

Still other documents reflect on effectuation of Rambus's strategies regarding JEDEC standardization efforts. See, e.g., CX-5100 (email from Rambus CEO Geoff Tate on "advising JEDEC on claim(s) in our filed patents that cover proposals before JEDEC"); CX-5101 (email from Tate asking about patent extensions in connection with JEDEC); CX-5102 at 8 (Rambus board meeting item concerning "goal" of "leverag[ing] the JEDEC committee to our advantage"); CX-5103 at 2 (reflecting Rambus board agenda item regarding "[s]trategy for JEDEC/Sync DRAM"); CX-5104 at 1 (identifying Rambus employee responsible for "work[ing] to add modifications to [Rambus's] patents to provide better coverage" against SDRAMs); CX-5106 (identifying CEO Tate's apparent objective of securing "patents vs. SDRAM"); CX-5110 (Tate email discussing "block[ing]/get[ting] royalties from competitive memory"); CX-5111 (email from Rambus employee Rick Barth offering opinion about whether a list of patents should be provided to JEDEC); CX-5112 (email reporting on "work[] with Richard Crisp on enhancing claim coverage"); CX-5114 (email stating that in an upcoming meeting, Crisp would discuss IP "litigation tactics"); CX-

<sup>&</sup>lt;sup>8</sup> Rambus Memo in Opposition at 6, n. 3.

5115 (email stating that Crisp was expected to discuss at an upcoming meeting how Rambus's intellectual property blocks "SDRAM-2"); and CX-5116 (email stating that Crisp would discuss in upcoming meeting the "[h]azards" of standards groups). CX-5109 is a Rambus document discussing, *inter alia*, how "cost-sensitive" their industry is, a point that may have some bearing on the question of what JEDEC members might have done had Rambus's patent disclosures come earlier. CX-5109 at 4. Accordingly, Exhibits CX-5100 through CX-5116 appear to be relevant to issues in this case.

However, we find that Complaint Counsel has not offered a persuasive argument regarding the probative value of CX-5117. This exhibit is a log identifying responsive documents on Rambus's back-up media which have not been produced because of privilege claims. Complaint Counsel state that some portion of those documents are no longer privileged because Rambus waived its privilege claims as to them earlier in this matter<sup>9</sup>. Footnotes found in CX-5117 contest Complaint Counsel's position regarding privilege waiver. The Commission has not been asked to rule on, and expresses no opinion regarding, this privilege waiver issue. More importantly, the Commission has not been advised what probative value should be given to this privilege log or for what purposes<sup>10</sup>. Thus, with the exception of the privilege log, CX-5117, the Commission finds Exhibits CX-5100 - 5116 and RX-2554 to be probative of the issues that need to be resolved in this proceeding.

In addition, we find these probative exhibits to be non-cumulative<sup>11</sup>. Rambus argues that CX-5100, CX-5101, and CX-5105

Complaint Counsel's Motion to Reopen at 5-6.

See Rambus Memo in Opposition at 8-9.

For the purpose of this motion, otherwise admissible evidence is cumulative, and thus excludable, when it is *unnecessarily* duplicative of other evidence already in the record. *See*, Rule 3.43(b), 16 C.F.R. § 3.43(b); FED. R. EVIDENCE 403;

are cumulative of record evidence such as CX-837<sup>12</sup>. We disagree. CX-837 is an email from Crisp reflecting, among other things, his recommendation that Rambus "tell the world what patents have issued . . . to be clean on this." CX-837 at 2. CX-5105, by contrast, is an email that reflects Crisp's question about what Rambus should do "if we are required to disclose in order to remain members in good standing." While both offer some evidence about what Crisp thought about the import of the JEDEC policies, the observations they contain are distinct. The argument that CX-837 and CX-5100-01 are cumulative is weaker. CX-837 contains Crisp's views on the advisability of coming "clean"; CX-5100 and CX-5101 contain the views of Rambus's CEO, Geoff Tate, as communicated to Crisp and others, regarding the need for a "strategy" regarding patent disclosure within JEDEC.

Rambus further argues that CX-5113 is "virtually identical" to an email by Mr. Crisp that is already in the record, CX-711<sup>13</sup>. We again disagree. CX-5113 gives Mr. Crisp's view of the point of the JEDEC policy: "the major reason for the policy [JEDEC has] in place is that if they were to standardize something that has a patent on it and the patent is necessary to build the device and the patent holder decides to not license certain companies, then they potentially have an antitrust situation on their hands." CX711 is an email stating that "Micron says the policy exists due to antitrust concerns. That if a group of companies wanted to keep out competition they could agree amongst themselves to standardize something that is patented and not license those that they do not want to compete with." These seem to be distinct antitrust concerns attributed to different people. The probative documents, CX-5100 - 5116, are not cumulative.

Third, the Commission finds that these exhibits can be admitted into evidence without undue prejudice to any party. Indeed, Rambus

and Joseph W. Cotchett, FEDERAL COURTROOM EVIDENCE § 403.5 (G. Richard Poehner ed., 5<sup>th</sup> ed. 2004).

Rambus Memo in Opposition at 5-6.

Rambus Memo in Opposition at 7-8.

does not argue that it would be prejudiced by the admission of these documents.

# Rambus's Motion to Reopen

Rambus has moved to reopen the record to admit up to 250 pages of the one million pages of documents that it received in May 2005 in private litigation <sup>14</sup>. Rambus asserts that the documents will show a price-fixing conspiracy among DRAM manufacturers directed against Rambus's RDRAM architecture. This, Rambus states, will undercut Complaint Counsel's contentions that the DRAM market was highly competitive; that technical problems, high royalty rates, and high manufacturing costs led to RDRAM's decline; that DRAM manufacturers would have chosen other technologies for their standard if Rambus had made certain disclosures; and that compulsory royalty-free licensing is appropriate here<sup>15</sup>.

However, Rambus states that a protective order in that private action prevents it from providing that evidence to Complaint Counsel or the Commission, or from discussing the "specific contents" of that evidence 16 and that a hearing on its motion to amend the protective order is scheduled by the trial judge in that matter for February 23, 2006. In light of this, Rambus requests that the Commission either grant its motion to reopen the record "on a conditional basis, pending the ruling on Rambus's motion to amend the protective order," or "defer ruling on this motion to reopen until [the judge presiding over the private action] determines whether to allow the documents to be

Rambus's Motion to Reopen the Record to Admit Newly Obtained Evidence Rebutting Complaint Counsel's Proposed Findings and Undermining Complaint Counsel's Proposed Remedy ("Rambus's Motion to Reopen") at 4-5.

Rambus's Motion to Reopen at 9-15.

Rambus's Motion to Reopen at 7.

submitted to the Commission."<sup>17</sup> Complaint Counsel argue that the evidence is likely to be irrelevant and that the case should not be delayed for its entry.<sup>18</sup>

Rambus's alternative request is the most appropriate course at this time. The protective order makes the documents unavailable for our review. The Commission cannot easily evaluate the propriety of admitting evidence which is not available to it. Similarly, Complaint Counsel are correct in claiming that it would be prejudicial to admit documents into evidence without providing them a meaningful opportunity for opposition based on actual knowledge of the contents of the proffered evidence<sup>19</sup>. Therefore, we will deny Rambus's motion to reopen without prejudice<sup>20</sup>.

# Accordingly,

It is ordered that Complaint Counsel's Motion to Reopen the Record to Admit Documents from Rambus's Newly-Found Back-Up Tapes Pertaining to Rambus's Spoliation of the Evidence shall be, and

Supplemental Brief in Support of Motion by Rambus to Reopen Record to Admit Newly Obtained Evidence Rebutting Complaint Counsel's Proposed Findings and Undermining Complaint Counsel's Proposed Remedy at 1.

Complaint Counsel's Opposition to Rambus's Motion to Reopen the Record at 2; Complaint Counsel's Response to Rambus's Supplemental Brief in Support of Motion to Reopen Record at 2-3.

Complaint Counsel's Opposition to Rambus's Motion to Reopen the Record at 3.

Rambus may refile its motion to reopen when and if the documents become available to it for use in this matter. This disposition should not be construed as expressing any view on the merits of Rambus's motion to reopen the record to admit these documents.

it hereby is, *granted* as to Exhibits CX-5100 through CX-5116, and *denied* without prejudice as to Exhibit CX 5117;

It is further ordered that Rambus's motion to admit into evidence Exhibit RX-2554 shall be, and it hereby is, granted;

It is further ordered that Complaint Counsel's Motion for Leave to File Complaint Counsel's Response to Rambus's Supplemental Brief in Support of Motion to Reopen Record shall be, and it hereby is, granted; and

It is further ordered that Rambus's Motion to Reopen the Record to Admit Newly Obtained Evidence Rebutting Complaint Counsel's Proposed Findings and Undermining Complaint Counsel's Proposed Remedy shall be, and it hereby is, denied without prejudice.

By the Commission.

# EVANSTON NORTHWESTERN HEALTHCARE CORPORATION

Docket No. 9315 Order, April 12, 2006

Order placing previously designated in camera material on the public record.

ORDER GRANTING CONSENT MOTION TO WAIVE IN CAMERA PROTECTION OF SELECTED PLEADINGS AND EXHIBITS

On October 7, 2005, Respondent Evanston Northwestern Healthcare Corporation ("Respondent"), with the consent of Complaint Counsel, filed a motion (hereinafter "Consent Motion") (1) seeking to waive *in camera* treatment for certain pleadings filed and certain documents admitted into evidence during the trial of this matter, and (2) seeking to correct the *in camera* formatting of one of

Respondent's replies to Complaint Counsel's findings of fact. On January 24, 2006, the parties filed a set of four tables summarizing the proposed changes. The Initial Decision in this case was filed on October 17, 2005, and the jurisdiction of Chief Administrative Law Judge McGuire terminated at that point. Commission Rule 3.51(e)(2), 16 C.F.R. § 3.51(e)(2) (2006). Pursuant to Commission Rule 3.22(a), 16 C.F.R. § 3.22(a), Chief Judge McGuire has therefore certified the Consent Motion to the Commission, with the recommendation that it be granted.

The Commission "strongly favors making available to the public the full record of its adjudicative proceedings to permit public evaluation of the fairness of the Commission's work and to provide guidance to persons affected by its actions." In re Crown Cork & Seal Co., Inc., 71 F.T.C. 1714-15 (June 26, 1967); accord, In re Hood, 58 F.T.C. 1184, 1186 (March 14, 1961). As Chief Judge McGuire notes, the parties have reviewed their respective post-trial filings, including post-trial briefs, proposed findings of fact, and responses to proposed findings of fact, and have identified discussions of trial testimony elicited during in camera sessions and trial exhibits granted in camera treatment that, in the parties' view, no longer warrant in camera protection. Consent Motion at 1-2. The parties also state that they are not requesting removal of in camera protection for any in camera testimony elicited from a third party or any trial exhibit granted in camera protection at the request of a third party. Consent Motion at 2.

The Commission has determined to grant the Consent Motion, as recommended by Chief Judge McGuire. Accordingly,

It is ordered that the Consent Motion be, and it hereby is, granted. The Secretary is directed to place on the public record of this proceeding the January 24, 2006 filing by Counsel for Respondent and Counsel for the Complaint -- a copy of which is appended to this Order -- including the following four Attachments:

- Attachment 1: Proposed Removals of *In Camera* Treatment Respondent's Post-Trial Brief and Post-Trial Reply Brief
- Attachment 2: Index of Re-Designated Text in Complaint Counsel's Post-Trial Brief
- Attachment 3: Proposed Removals of *In Camera* Treatment Paragraphs in Complaint Counsel's Proposed
  Findings of Fact and Respondent's Reply Findings of
  Fact
- <u>Attachment 4</u>: Paragraphs Changed of Complaint Counsel's Replies to Respondent's Proposed Findings of Facts;

It is further ordered that Respondent and Complaint Counsel shall by June 5, 2006, file a paper original, one paper copy, and an electronic copy of the amended version of each of the public filings modified pursuant to this Order, in the manner prescribed by Commission Rule 4.2(c), 16 C.F.R. § 4.2(c);

It is further ordered that the original versions of each such public filing shall be retained in the public record of this proceeding; and

*It is further ordered that* page 15 of Section I of Respondent's Reply to Complaint Counsel's Findings, Response to Finding No. 2, shall be marked *in camera*.

By the Commission.

### JOHNSON & JOHNSON

Docket No. C-4154 Order, May 31, 2006

Order reopening and setting aside a final order where the respondent did not acquire the assets at issue.

## ORDER REOPENING AND SETTING ASIDE ORDER

On April 24, 2006, Johnson & Johnson ("J&J") filed a "Petition to Reopen and Set Aside Decision and Order" ("Petition") to set aside the Order in Docket No. C-4154 ("Order"). J&J bases the Petition on changes of fact in that the Order was premised upon its acquisition of Guidant Corporation ("Guidant"), but it did not in fact acquire Guidant. For the reasons stated below, the Commission has determined to grant the Petition and has reopened and set aside the Order.<sup>1</sup>

### I. BACKGROUND

This matter arose from J&J's proposed acquisition of Guidant. On or about December 14, 2004, J&J entered into an agreement to acquire Guidant. The Commission determined that the proposed acquisition raised competitive concerns in the drug eluting stent ("DES"), endoscopic vessel harvesting ("EVH"), and proximal anastomotic assist devices markets.

J&J agreed to settle the matter, and on November 2, 2005, the Commission accepted an agreement containing consent order. On December 27, 2005, the Commission issued the final Order, which

In connection with the Petition, J&J requested that the Commission eliminate the public comment period on the Petition. A press release was issued on the Petition on April 28, 2006, starting the comment period and noting J&J's request to eliminate it. The Commission has determined to end the comment period on the Petition prior to its normal 30-day expiration.

required J&J to license DES intellectual property to Abbott Laboratories, to divest its EVH Business to Datascope Corp. ("Datascope"), and to end its distribution agreement with Novare Surgical Systems, Inc., all within 15 business days of acquiring Guidant. In addition to divesting the EVH Business to Datascope, J&J was also required to provide transitional services to Datascope and enter into a supply agreement with Datascope. On November 2, 2005, the Commission appointed KPMG, LLP ("KPMG") as Interim Monitor pursuant to Paragraph V. of the Order to monitor J&J's compliance with the provisions of the Order related to the divestiture of the EVH Business.

Before J&J could complete its acquisition of Guidant, however, Boston Scientific Corporation ("BSC") made a competing bid for Guidant. Eventually, Guidant agreed to be acquired by BSC, and on January 25, 2006, Guidant terminated its agreement with J&J. Petition at 3. On April 20, 2006, the Commission accepted for public comment an agreement containing consent order with BSC, and on April 21, 2006, BSC closed on its acquisition of Guidant.

Although J&J was not required to divest the EVH Business until after it acquired Guidant, J&J made the decision to go ahead with the divestiture even though it had not completed the acquisition of Guidant. Accordingly, on January 3, 2006, J&J divested the EVH Business to Datascope and has provided transitional services and a supply of product to Datascope. Petition at 3. KPMG has been monitoring J&J's compliance with its obligations under the Order and the agreement with Datascope. Petition at 3.

## II. THE PETITION

On April 24, 2006, J&J filed the Petition. The impetus for the Petition was the desire of J&J to end the role of the Interim Monitor, and the expense of paying for the Monitor's services, now that it no longer is going to acquire Guidant. J&J asserts that the termination of its agreement to acquire Guidant is a change of fact that eliminates the need for the Order. Petition at 5. Although J&J did

divest the EVH Business to Datascope, it no longer has any incentive to undercut the viability of the EVH Business because it is not acquiring the competing business of Guidant. Petition at 5. Included in the Petition is an affidavit of Eric Harris, Assistant General Counsel of J&J.

# III. STANDARD FOR REOPENING AND MODIFYING A FINAL ORDER

The Order may be reopened and modified on the grounds set forth in § 5(b) of the Federal Trade Commission Act, 15 U.S.C. § 45(b). First, Section 5(b) provides that the Commission shall reopen an order to consider whether it should be modified if the respondent "makes a satisfactory showing that changed conditions of law or fact" so require<sup>2</sup>. A satisfactory showing sufficient to require reopening is made when a request to reopen identifies significant changes in circumstances and shows that the changes eliminate the need for the order or make continued application of it inequitable or harmful to competition.<sup>3</sup>

Second, Section 5(b) provides that the Commission may also reopen and modify an order when, although changed circumstances would not require reopening, the Commission determines that the public interest so requires. Respondents are therefore invited in petitions to reopen to show how the public interest warrants the

<sup>&</sup>lt;sup>2</sup> See Supplementary Information, Amendment to 16 CFR 2.51(b), announced August 15, 2001, ("Amendment").

S. Rep. No. 96-500, 96th Cong., 2d Sess. 9 (1979) (significant changes or changes causing unfair disadvantage); *Louisiana-Pacific Corp.*, Docket No. C-2956, Letter to John C. Hart (June 5, 1986), at 4 (unpublished) ("Hart Letter"). *See also United States v. Louisiana-Pacific Corp.*, 967 F.2d 1372, 1376-77 (9th Cir. 1992) ("A decision to reopen does not necessarily entail a decision to modify the Order. Reopening may occur even where the petition itself does not plead facts requiring modification.").

requested modification.<sup>4</sup> In the case of "public interest" requests, FTC Rule of Practice 2.51(b) requires an initial "satisfactory showing" of how modification would serve the public interest before the Commission determines whether to reopen an order and consider all of the reasons for and against its modification.

A "satisfactory showing" requires, with respect to public interest requests, that the requester make a *prima facie* showing of a legitimate public interest reason or reasons justifying relief. A request to reopen and modify will not contain a "satisfactory showing" if it is merely conclusory or otherwise fails to set forth by affidavit(s) specific facts demonstrating in detail the reasons why the public interest would be served by the modification.<sup>5</sup> This showing requires the requester to demonstrate, for example, that there is a more effective or efficient way of achieving the purposes of the order, that the order in whole or part is no longer needed, or that there is some other clear public interest that would be served if the Commission were to grant the requested relief. In addition, this showing must be supported by evidence that is credible and reliable.

If, after determining that the requester has made the required showing, the Commission decides to reopen the order, the Commission will then consider and balance all of the reasons for and against modification. In no instance does a decision to reopen an order oblige the Commission to modify it,<sup>6</sup> and the burden remains on the requester in all cases to demonstrate why the order should be reopened and modified. The petitioner's burden is not a light one in view of the public interest in repose and the finality of

<sup>4</sup> Hart Letter at 5; 16 C.F.R. § 2.51.

<sup>&</sup>lt;sup>5</sup> 16 C.F.R. § 2.51.

See United States v. Louisiana-Pacific Corp., 967
 F.2d 1372, 1376-77 (9<sup>th</sup> Cir. 1992) (reopening and modification are independent determinations).

Commission orders. All information and material that the requester wishes the Commission to consider shall be contained in the request at the time of filing. 8

## IV. THE ORDER WILL BE REOPENED AND SET ASIDE

The Commission has determined to reopen and set aside the Order as requested by J&J. The Order was premised on the assumption that J&J would acquire Guidant. The Order explicitly states that the purpose of the Order is "to remedy the lessening of competition alleged in the Commission's complaint." Order ¶ II.G., III.K., IV.D. The complaint alleges that the agreement between J&J and Guidant violates Section 5 of the FTC Act, Complaint ¶ 22, and "the [acquisition of Guidant by J&J], if consummated, would constitute a violation of Section 7 of the Clayton Act... and Section 5 of the FTC Act...." Complaint ¶ 23. The acquisition agreement between J&J and Guidant has been terminated, and the acquisition was never consummated. Accordingly, the basic premise of the Order, the unlawful acquisition that it was designed to remedy, did not come to pass. Therefore there is no reason to keep the Order in place. This conclusion is not changed by the fact that J&J divested the EVH Business to Datascope, even though it was not required to do so.<sup>9</sup> Absent the competitive concerns tied to the proposed acquisition of Guidant, the Commission has no reason to be concerned about J&J's conduct in connection with the sale of the EVH Business. The Commission does not routinely enter orders in connection with the sale of a business from one company to another, but does so only

See Federated Department Stores, Inc. v. Moitie,
 425 U.S. 394 (1981) (strong public interest considerations support repose and finality).

<sup>&</sup>lt;sup>8</sup> 16 C.F.R. § 2.51(b).

J&J was required to divest the EVH Business no later than 15 business days after it acquired Guidant. Because it never acquired Guidant, that deadline would never arrive.

when there is reason to be concerned about the continued viability of the business being sold. As noted in the Petition, J&J no longer has any incentive to take any action under the transitional services or supply agreements that might reduce Datascope's viability, because it no longer will be acquiring a business (as part of Guidant) that will compete with the EVH Business<sup>10</sup>. Therefore, there is no need to retain the services of the Interim Monitor.

Accordingly,

*It is ordered* that this matter be, and it hereby is, reopened and set aside.

By the Commission, Commissioner Harbour and Commissioner Kovacic recused.

# TIME WARNER INC.; TURNER BROADCASTING SYSTEM, INC.; TELE-COMMUNICATIONS, INC.; AND LIBERTY MEDIA CORPORATION

Docket No. C-3709 Order, June 14, 2006

Order terminating applicability of a consent order with respect to Liberty Media Corporation ("Liberty"), where Liberty has demonstrated that it is exiting the relevant market and has no intention to return.

### ORDER REOPENING AND MODIFYING ORDER

On February 16, 2006, Liberty Media Corporation ("Liberty"), one of the respondents named in the consent order issued by the Commission on February 3, 1997, in Docket No. C-3709 ("Order"), filed a Motion requesting the Commission to reopen and terminate

J&J will still be subject to a breach of contract claim by Datascope if it does not comply with the agreements.

the Order insofar as it applies to Liberty. Liberty's Motion was filed pursuant Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. § 45(b) and Section 2.51 of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.51. On February 27, 2006, the Commission placed on the public record Liberty's Motion and invited the public, for a period of 30 days, to submit comments on the Motion. No comments have been received. The Commission has reviewed the Motion and has determined to grant Liberty's Motion.

The Order that Liberty seeks to modify resulted from Time Warner Inc.'s ("Time Warner") 1996 acquisition of Turner Broadcasting, Inc. ("Turner"). Respondent Tele-Communications, Inc. ("TCI"), and its then wholly-owned subsidiary, Liberty, had a minority interest in Turner. As a result of the acquisition TCI and Liberty acquired approximately a 7.5 percent ownership interest in Time Warner. The transaction raised competitive concerns relating to the integration of Time Warner's programming services and cable systems with other cable systems. <sup>1</sup>

According to the Complaint, the effects of the acquisition would have been to reduce competition in the cable television programming and cable television system markets. Time Warner's control of so much of the cable programming in general, and of marquee or crown jewel programming in particular, would have enabled Time Warner to raise prices on its programming or condition access to some of its marquee programming on the purchase of unwanted programming, and would have limited the ability of cable television systems that buy such programming to take responsive action to avoid such price increases. The vertical integration of Time Warner's and TCI's cable systems with Time Warner's, Turner's and TCI's programming would also have allowed Time Warner to limit competition with its programming by denying rival programmers access to TCI's and Time Warner's cable systems, thereby preventing them from gaining access to sufficient distribution to realize economies of scale. At the same time, TCI's ownership interest in Time Warner and concurrent long-term contractual obligations to carry Turner programming would have undermined TCI's incentive to sign up better or less expensive non-Time Warner programming. Complaint ¶ 38. See also Analysis to Aid Public Comment, 61 Fed. Reg. 50301, 50309-10 (September 25, 1996) ("Analysis to Aid Public Comment").

The Order, among other things, requires that the Liberty shares of Time Warner be nonvoting unless and until the shares are sold to an independent third party<sup>2</sup>. In addition there are further restrictions on Liberty's ability to increase its overall position in Time Warner<sup>3</sup>. The Order will terminate on February 3, 2007.<sup>4</sup>

Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. § 45(b), provides that the Commission shall reopen an order to consider whether it should be modified if the respondent "makes a satisfactory showing that changed conditions of law or fact" so require. A satisfactory showing sufficient to require reopening is made when a request to reopen identifies significant changes in circumstances and shows that the changes eliminate the need for the order or make continued application of it inequitable or harmful to competition.<sup>5</sup>

<sup>&</sup>lt;sup>2</sup> *Id.* at II.D.(2).

<sup>&</sup>lt;sup>3</sup> *Id.* at II.D.(1). The remaining substantive Order provisions (Paragraphs IV. through IX.) apply only to TCI and Time Warner.

<sup>4</sup> Order ¶ XIII.

<sup>&</sup>lt;sup>5</sup> See Louisiana Pacific Corp., Docket No. C-2956, Letter to John C. Hart (June 5, 1986), at 4 (unpublished); S. Rep. No. 96-500, 96th Cong., 2nd Sess. 9 (1979) (significant changes or changes causing unfair disadvantage); see Phillips Petroleum Co.,

<sup>78</sup> F.T.C. 1573 (1971) (modification not required for changes reasonably foreseeable at time of consent negotiations); *Pay Less Drugstores Northwest, Inc.*, Docket No. C-3039, Letter to H.B. Hummelt (January 22, 1982) (changed conditions must be unforeseeable, create severe competitive hardship and eliminate dangers order sought to remedy) (unpublished); *see also United States v. Louisiana-Pacific Corp.*, 967 F.2d 1372, 1376-77 (9th Cir. 1992) ("A decision to reopen does not necessarily entail a decision to modify the order. Reopening may occur even where the petition itself does not plead facts requiring modification."); *United States v. Swift & Co.*, 286 U.S. 106, 119 (1932) ("clear showing" of changes that have eliminated reasons for order or such that the order causes unanticipated hardship).

The language of Section 5(b) plainly anticipates that the burden is on the petitioner to make a "satisfactory showing" of changed conditions to obtain reopening of the order. The legislative history also makes clear that the petitioner has the burden of showing, other than by conclusory statements, why an order should be modified. The Commission "may properly decline to reopen an order if a request is merely conclusory or otherwise fails to set forth specific facts demonstrating in detail the nature of the changed conditions and the reasons why these changed conditions require the requested modification of the order." If the Commission determines that the petitioner has made the necessary showing, the Commission must reopen the order to consider whether modification is required and, if so, the nature and extent of the modification. The Commission is not required to reopen the order, however, if the petitioner fails to meet its burden of making the satisfactory showing required by the statute. The petitioner's burden is not a light one in view of the public interest in repose and the finality of Commission orders<sup>7</sup>.

Where a request to reopen based on a change of fact alleges that respondent has exited the market that was subject of the order, the respondent must show *both* that it has in fact exited and that it has a present intention not to reenter that market<sup>8</sup>. In all cases, the

See S. Rep. No. 96-500, 96th Cong., 1st Sess. 9-10 (1979); see also Rule 2.51(b) (requiring affidavits in support of petitions to reopen and modify).

See Federated Department Stores, Inc. v. Moitie,
 425 U.S. 394 (1981) (strong public interest considerations support repose and finality).

See KKR Associates, L.P., 116 F.T.C. 335 at 341 (1993) (request to modify denied where the "exit from the two relevant markets may be temporary." Also "KKR, in contrast, has not definitively stated an intention to remain out of these markets") (The Order was subsequently set aside in 1995 pursuant to the Statement of the Federal Trade Commission Concerning Prior Approval and Prior Notice Provisions, 120 F.T.C. 879 (1995)); and Letter to Abbott B. Lipsky, Jr. (January 26, 1996) concerning The Coca-Cola Company, 121 F.T.C. 958, 960 (1996) (request to reopen denied because "Coca-Cola has to this day never disavowed an interest in acquiring Dr Pepper in the future."). Contrast Union Carbide, 108 F.T.C. 184, 188 (1986)

petitioner must provide all relevant information and material for the Commission to review at the time of the filing<sup>9</sup>. As required by Section 2.51(b) of the Commission's Rules, Liberty has submitted an affidavit affirming that it has exited the relevant market *and* that it has no current intention to reenter that market.<sup>10</sup>

Liberty's Motion seeks to terminate the Order insofar as it applies to Liberty based on "materially changed facts [which] mean that the Order's provisions relating to Liberty are no longer in the public interest or required to preserve competition." Liberty notes that since the Order was issued, there have been significant changes in the corporate structure of Liberty and TCI, particularly as it relates to any ownership interest in United States cable systems.

(granting a modification where "Carbide states its intention not to reenter that line of business."); and *Allied Corporation*, 109 F.T.C. 83, 84 (1987) (granting a modification where "Allied states that it does not intend now to reenter that market.").

that any changed condition of law requires reopening the Order, and the Commission, therefore, does not need to consider that issue. Additionally, where changed circumstances do not require reopening, Section 5(b) further provides that the Commission may reopen and set aside an order when it determines that the public interest so requires. Liberty's Motion also addresses the public interest standard, which requires that the requester make a *prima facie* showing of a legitimate public interest reason or reasons justifying relief. In this instance, however, we do not need to assess the sufficiency of Liberty's public interest showing, because Liberty has made the requisite satisfactory showing that changed conditions of fact require the Order to be set aside as to Liberty.

In 2002, the Commission denied a motion by Liberty to reopen and modify the Order that was similar to Liberty's February 16, 2006, Motion. Among other things, the Commission based its denial on the fact that Liberty's Motion failed to address the issue of whether its exit from the relevant market was temporary or permanent. *Time Warner Inc.*, *et al.*, Docket C-3709, Letter to Kathryn M. Fenton (July 17, 2002) at 3, accessible at <a href="http://www.ftc.gov/opa/2002/07/fyi0240.htm">http://www.ftc.gov/opa/2002/07/fyi0240.htm</a>.

<sup>11</sup> Motion at 2.

Specifically, in 1999, TCI merged with AT&T Corporation ("AT&T"). In 2001, Liberty was split off from AT&T to the holders of AT&T's Liberty Media Group Tracking Stock, making Liberty a separate publicly traded company with no further relationship with the former TCI cable systems that were the focus of the Turner merger review. Liberty also asserts that it "has no current intention to acquire or to invest in any other cable television systems in the United States [including] both specific acquisitions of or investments in particular cable television systems as well as any more generalized intent to acquire or invest in any such cable television systems as a current goal or direction of Liberty's overall business plan." 12

Upon consideration of Liberty's Motion and other information, the Commission finds, pursuant to Section 2.51 of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.51, that changed conditions of fact warrant reopening and setting aside the Order as to Liberty. Liberty has shown that it has exited the relevant market and that it does not have the current intention of reentering that market. The Order provisions relating to Liberty were designed to ensure that Time Warner's acquisition of Turner will not leave TCI/Liberty, or their management in a position to influence Time Warner to alter its own conduct in order to benefit TCI's/Liberty's, interests<sup>13</sup>. Consequently, Liberty severing its ties with TCI and becoming an independent company with no ties to United States cable systems together with its intention not to reenter that market, warrants relieving Liberty from the Order's proscriptions.

# Accordingly,

It is ordered that this matter be, and it hereby is, reopened; and that the Commission's Order issued on February 3, 1997, as modified on December 21, 2004, be, and it hereby is, set aside as to respondent Liberty Media Corporation as of the effective date of this Order.

By the Commission, Commissioner Kovacic recused.

Motion, Affidavit of Charles Y. Tanabe, Senior Vice President, General Counsel and Secretary of Liberty Media Corporation (February 16, 2006) ("Tanabe Affidavit") ¶ 5.

Analysis to Aid Public Comment.

# RESPONSES TO PETITIONS TO QUASH OR LIMIT COMPULSORY PROCESS

## GASOLINE PRICING INVESTIGATION

FTC File No. 051 0243 Decision, January 10, 2006

RESPONSE TO EXXON MOBIL CORPORATION'S PETITION TO LIMIT CIVIL INVESTIGATIVE DEMAND

Dear Mr. Muris:

This letter advises you of the disposition of Exxon Mobil Corporation's ("Exxon Mobil" or "the Company") Petition to Limit Specification 26 of the Civil Investigative Demand ("CID") issued to it on November 23, 2005. For the reasons stated herein, the Commission denies the Petition to Limit. Pursuant to 16 C.F.R. § 2.7(e), Exxon Mobil is ordered to comply with Specification 26 of the CID on or before January 20, 2006 at 5:00 p.m. E.S.T.

This ruling was made by Commissioner Pamela Jones Harbour, acting as the Commission's delegate. *See* 16 C.F.R. § 2.7(d)(4). Petitioner has the right to request review of this matter by the full Commission. Such a request must be filed with the Secretary of the Commission within three days after service of this letter.<sup>1</sup>

This letter decision is being delivered by email and express mail. The email copy is being provided as a courtesy. Computation of the time for appeal, therefore, should be calculated from the date you received the original by express mail. In accordance with the provisions of 16 C.F.R. § 2.7(f), the timely filing of a request for review of this matter by the full Commission shall not stay the return date established by this decision.

## I. Background and Summary

Section 1809 of the Energy Policy Act of 2005 ("Energy Act") directs the Commission to "conduct an investigation to determine if the price of gasoline is being artificially manipulated by reducing refiner capacity or by any other form of market manipulation or price gouging practices." Accordingly, the Commission is conducting an investigation to "determine whether certain oil refiners, marketers, or others have adopted or engaged in practices that have lessened competition in the refining, distribution, and supply of gasoline in the United States, and whether these practices are in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, as amended." On November 8, 2005, the Commission issued CIDs to a number of companies, including Exxon Mobil, containing 25 separate specifications. Petition to Limit at 2. Exxon Mobil did not object to the first CID.

On November 22, 2005, the President signed the fiscal 2006 appropriations bill for the Departments of State, Justice, Commerce, and related federal agencies, including the Commission. Section 632 of the act ("Pryor Amendment") requires the Commission to investigate post-Hurricane Katrina gasoline prices and to report on industry profits, tax incentives, and the overall effects of increased gasoline prices on the economy<sup>4</sup>. Subsequent to this legislation, the

<sup>&</sup>lt;sup>2</sup> Energy Policy Act of 2005, Pub. L. No. 109-058 § 1809, 119 Stat. 594 (2005).

Resolution Authorizing Use of Compulsory Process in Nonpublic Investigation, File No. 051-0243 (Sept. 30, 2005).

Petition to Limit at 7; and Science, State, Justice, Commerce, and Related Agencies Appropriations Act, 2006,

Commission issued a second set of CIDs to a number of companies, including Exxon Mobil, containing an additional three specifications (Specifications 26-28)<sup>5</sup>. The Petition to Limit only challenges Specification 26 of the second CID. Specification 26 requires Exxon Mobil to provide the Commission with its "claimed Tax Expenditures for tax years 2003 and 2004[.]" *Id*.

Exxon Mobil timely filed its Petition to Limit on December 19, 2005. Exxon Mobil claims that Specification 26 should be limited for three reasons: (1) the tax information sought by Specification 26 is not relevant to the Commission investigation, and therefore the

Pub.L. No.109-108 § 632, 119 Stat. 2290 (2005). The so-called "Pryor Amendment" to this act directs that not less than \$1 million of funds appropriated to the Commission must be used "to conduct an immediate investigation into nationwide gasoline prices in the aftermath of Hurricane Katrina: Provided, That the investigation shall include: (1) any evidence of price-gouging by companies with total United States wholesale sales of gasoline and petroleum distillates for calendar 2004 in excess of \$500,000,000 and by any retail distributor of gasoline and petroleum distillates against which multiple formal complaints . . . of price-gouging were filed in August or September, 2005, with a Federal or State consumer protection agency; (2) a comparison of, and an explanation of the reasons for changes in, profit levels of such companies during the 12-month period ending on August 31, 2005, and their profit levels for the month of September, 2005 . . . ; [and] (3) a summary of tax expenditures (as defined in section 3(3) of the Congressional Budget and Impoundment Control Act of 1974 (2 U.S.C. 622(3)) for such companies...."

<sup>&</sup>lt;sup>5</sup> *Id.* The second CID was served on Exxon Mobil on November 28, 2005.

Commission lacks authority under the FTC Act to seek this information;<sup>6</sup> (2) "Exxon Mobil cannot respond accurately to the Specification" because the Company does not compile this information in the ordinary course of business;<sup>7</sup> and (3) the Commission should seek tax expenditure information from the IRS and other federal agencies, rather than demand it from Exxon Mobil, in order to afford the Company greater confidentiality protection.<sup>8</sup>

# II. The Information Requested Is Relevant to the Commission's Investigation

Exxon Mobil claims in essence that there is no nexus between the information requested in Specification 26 and the law enforcement purpose of the investigation as stated in the Resolution authorizing the use of compulsory process<sup>9</sup>. We disagree. The information sought by Specification 26 is sufficiently related to the investigation. In any event, this argument has been rendered moot by the

<sup>6</sup> *Id.* at 3 and 9.

<sup>&</sup>lt;sup>7</sup> *Id.* at 3.

Id. at 1819 ("Therefore, the FTC would be required to provide the taxpayer information to Congress upon request, and that information could identify Exxon Mobil. Congress would have no statutory limitation on the use of that information, and courts are unlikely to provide any tangible limitation on any such use in deference to the separation of powers.... As a practical matter, therefore, there would be nothing to prevent Congress from disclosing Exxon Mobil's tax information, inadvertently or otherwise.").

<sup>&</sup>lt;sup>9</sup> Note 3, *supra*.

Commission's issuance of an Order Requiring the Filing of a Special Report pursuant to Section 6(b) of the FTC Act, 15 U.S.C. § 46(b).

The Commission is entitled to require respondents to provide any information that is "not plainly incompetent or irrelevant to any lawful purpose of the [agency]...and not unduly burdensome to produce[.]" Federal Trade Commission v. Invention Submission Corp., 965 F.2d 1086, 1089 (D.C. Cir. 1992) (internal quotations and citations omitted). Moreover, "the agency's own appraisal of relevancy must be accepted so long as it is not obviously wrong." Id. (internal quotations and citations omitted). Furthermore, "the Commission has no obligation to establish precisely the relevance of the material it seeks in an investigative subpoena by tying that material to a particular theory of violation." Id. at 1090 (citing Federal Trade Commission v. Texaco, Inc., 555 F.2d 862, 872 (D.C. Cir. 1977). Determination of relevancy in an investigation is "more relaxed than in an adjudicat[ion]." Id. The material requested "need only be relevant to the *investigation* – the boundary of which may be defined quite generally,...as it was in the Commission's resolution here." Id.

The Resolution authorizing the CID implements an investigation to determine whether a violation of Section 5 of the FTC Act may have occurred. Note 3, *supra*. Accordingly, the information sought by Specification 26 is relevant to that purpose if it is of some assistance to the Commission in deciding whether there is reason to believe that Section 5 has been violated and whether an enforcement action should be commenced. *Invention Submission Corp.*, 965 F.2d at 1090. Exxon Mobil's assertion that there can be no relevance is mistaken. The material required by Specification 26 will permit the Commission to make a more accurate assessment of whether Exxon Mobil's profits were the product of tax expenditures or whether those profits were the result of other market-based forces. Thus, the information requested by Specification 26 clearly falls within the

"more relaxed" standard of relevance applicable to investigative subpoenas. *Id.* Indeed, Exxon Mobil has tacitly recognized that profitability information is relevant to this investigation because it has responded without objection to Specification 21 of the November 8 CID.<sup>10</sup>

Exxon Mobil correctly observes that the Commission's antitrust investigations do not routinely request information regarding tax expenditures. Petition to Limit at 9. However, this investigation is somewhat different from most Commission antitrust investigations. In the ordinary investigation, the Commission would identify a suspicious practice and inquire whether it contributed to higher consumer prices. In this investigation, by contrast, the inquiry begins, as directed by Congress, with the existence of higher prices and the Commission is investigating whether specific company practices have led to artificially maintained higher prices, or whether those prices are part of a properly functioning long-term competitive landscape.

Because this investigation begins, as directed by Congress, with the premise that prices and profits are high, the Commission must guard against mistakenly or reflexively ascribing high profits to the illegal exercise of market power. The information requested by Specification 26 will allow the Commission to gauge the portion of profitability attributable to Exxon Mobil's business efforts and the portion attributable to tax expenditures. Ultimately this information will allow the Commission to make a more accurate assessment of whether or not Exxon Mobil's profits are the product of market-based forces. We therefore find that the information requested by Specification 26 is sufficiently relevant to the law enforcement purposes of the Commission's investigation.

Specification 21 requested monthly revenue and cost data for Exxon Mobil's wholesale motor fuels sales.

In any event, even if there were merit to Exxon Mobil's relevance argument, that argument is moot. As Exxon Mobil recognizes, Section 6(b) of the FTC Act, 15 U.S.C. § 46(b), provides a means whereby the Commission may obtain information even if that information is not related to a law enforcement investigation. *See* Petition to Limit at 10. Pursuant to Section 6(b), the Commission has now served Exxon Mobil with an Order Requiring the Filing of a Special Report. That Order seeks the same information sought by Specification 26 of the CID. Exxon Mobil's compliance with that Order, to which its relevance argument does not apply, will obviate its compliance with Specification 26.<sup>11</sup>

# III. Exxon Mobil Has Not Established That Compliance with Specification 26 Is Unduly Burdensome

Exxon Mobil does not claim that it would be unable to prepare a response to Specification 26 or that the preparation is "burdensome," as that term is ordinarily understood. *See, e.g., Federal Trade Commission v. Rockefeller*, 591 F.2d 182, 190 (2<sup>nd</sup> Cir. 1979) (target of compulsory process must show that compliance threatens to unduly disrupt or seriously hinder operation of its business). Rather, Exxon Mobil claims that it does not prepare the information requested in its ordinary course of business and would have to make assumptions and calculations in responding and that such assumptions and calculations might differ from those made by other respondents to similar CIDs. Petition to Limit at 4.

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Although compliance with the Order Requiring the Filing of a Special Report obviates compliance with Specification 26, thus mooting Exxon Mobil's Petition to Limit, this letter nonetheless responds to all the arguments raised in the Petition lest Exxon Mobil seek to quash the Order.

The Commission regularly anticipates that CID recipients may need to provide estimates, or make assumptions and calculations in responding to a CID. Instruction K of the CID and the Certification language clearly state that CID responses be accompanied by adequate explanations of the methods used in preparing the responses.<sup>12</sup>

Nor does Exxon Mobil establish undue burden with its contention that other federal agencies could provide the Commission with the information it seeks. The Commission is not obligated to exhaust all other potential sources for information before issuing a CID to a respondent.

The Pryor Amendment requires both a company-specific comparison of profitability and an aggregate summary of tax expenditures, for a group of firms with gasoline and distillate sales above a dollar threshold, or that have been the subject of recent price-gouging complaints. Exxon Mobil has not shown that other federal agencies could, in fact, provide equally probative

Whenever a Specification requests the submission of data: (i) provide documents sufficient to show the data used and all sources for such data; (ii) explain each step in the Company's calculations in sufficient detail to permit replication of the Company's calculations from the source documents submitted; and (iii) explain why the methodology used represents the most accurate estimate the Company can make.

CID at 4.

Instruction K of the CID expressly directs Exxon Mobil that:

information to the Commission<sup>13</sup>. More importantly, even if responsive information were available from alternative sources, Exxon Mobil cannot be permitted to determine the course of the Commission's investigation. Rather, the Commission must remain free to structure its investigations, including the selection of the sources from which it seeks information, in the manner it deems most appropriate. Accordingly, Exxon Mobil's second argument provides no grounds for relief.

# IV. Exxon Mobil's Concern about Congressional Disclosure Does Not Raise a Valid Claim of Privilege

The Commission appreciates Exxon Mobil's confidentiality concerns, but Congress has the prerogative to request trade secret and other business confidences that the Commission acquires during the course of an investigation. Further, the Commission cannot restrict Congress's ultimate uses of such information. Under the

that other federal agencies could provide the Commission with the information required of Exxon Mobil by Specification 26. Even if that were a sufficient ground for relief, Exxon Mobil has not provided the Commission with either a factual or legal basis to believe that such agencies could or would provide the information. Indeed, the Commission believes that such agencies could not provide the Commission with information of comparable probative value to that which can be provided by Exxon Mobil. That being the case, Exxon Mobil has not satisfied its burden of demonstrating that it is entitled to relief. *Rockefeller*, 591 F.2d at 190 ("the burden of showing that an agency subpoena is unreasonable remains with the respondent . . .").

Commission's rules, if Congress requests confidential information from the Commission, notice will be given to the person who provided such information to the Commission and the Commission will advise Congress that the person who provided the information to the Commission considers it to be confidential. 16 C.F.R. § 4.11(b). If fear of Congressional use or disclosure of information provided a legitimate ground for limiting a CID, however, the Commission would be deprived of its ability to acquire the confidential business information that often is central to its investigations, especially given that Congress often requests the initiation of agency investigations in the first instance. Therefore, Exxon Mobil's concern about Congress's possible use or disclosure of the Company's confidential business records does not create a legitimate basis for limiting the CID.

### V. Conclusion and Order

Accordingly, no grounds having been established by Exxon Mobil to warrant limiting Specification 26 of the CID, *it is ordered that* Exxon Mobil's Petition to Limit should be, and it hereby is, *denied*.

It is further ordered that Exxon Mobil shall respond to Specification 26 of the CID on or before January 20, 2006 at 5:00 p.m. E.S.T.

By direction of the Commission.