Complaint

IN THE MATTER OF

THE WISCONSIN CHIROPRACTIC ASSOCIATION

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

Docket C-3943; File No. 9710117
Complaint, May 18, 2000--Decision, May 18, 2000

This consent order addresses practices used by Respondents, Wisconsin Chiropractic Association and Russell A. Leonard. The order prohibits Respondents from fixing prices for any chiropractic services or other health care goods or services. Respondents are also prohibited from creating, suggesting, or endorsing any proposed fees or conversion factors for any health care goods or services, from engaging in negotiations on behalf of any chiropractor or group of chiropractors or other health care providers, from urging or recommending that any chiropractor or any provider accept or not accept any term or condition of any participation agreement, or from organizing or participating in any meeting or discussion where they expect chiropractors will discuss intentions concerning participation in any health plans and terminating any meeting in which two or more persons make such communications. The order also bans Respondents from initiating, originating, developing, publishing, or circulating any fee survey for any health care goods or services for a period of two years and from conducting or distributing any fee survey unless (1) the data collection and analysis are managed by a third party; (2) the raw fee survey data is retained by the third party and not made available to the respondents; (3) any information that is shared among or is available to providers is more than three months old; and (4) there are at least five providers reporting data upon which each disseminated statistic is based, no individual provider's data represents more than 25 percent on a weighted basis of that statistic, and any information disseminated is sufficiently aggregated that it would not allow respondents or any other recipients to identify the prices charged or compensation paid by any particular provider.

Participants

For the Commission: *Nicholas J. Franczyk, David A. O'Toole, Evan Siegel, Daniel P. Ducore, Elizabeth Schneirov,* and *Gregory S. Vistnes.*

For the Respondents: *Roxane C. Busey, Gardner, Carton & Douglas,* and *Steven P. Hurley, Hurley, Burish & Milliken.*

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, having reason to believe that the Wisconsin Chiropractic Association ("WCA") and Russell A. Leonard ("Leonard") have 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 as follows:

RESPONDENTS

PARAGRAPH ONE: Respondent WCA is a nonprofit corporation organized, existing, and doing business under and by virtue of the laws of the State of Wisconsin, with its principal office and place of business located at 521 E. Washington Avenue, Madison, Wisconsin 53703.

PARAGRAPH TWO: Respondent Leonard is, and at all times relevant to this complaint was, the executive director of respondent WCA. His principal office or place of business is the same as that of respondent WCA.

JURISDICTION

PARAGRAPH THREE: Respondent WCA exists and operates, and at all times relevant to this complaint existed and operated, in substantial part for the pecuniary benefit of its members. By virtue of its purposes and activities, respondent WCA is a "corporation" within the meaning of Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

PARAGRAPH FOUR: The acts or practices of respondents WCA and Leonard, and WCA's members, including those herein alleged, are in or affecting commerce within the meaning of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

WCA'S MEMBERSHIP

PARAGRAPH FIVE: Approximately 900 chiropractors are members of respondent WCA, constituting a substantial majority of the chiropractors licensed to practice in Wisconsin. Its members are generally engaged in the business of providing chiropractic services to patients for a fee.

PARAGRAPH SIX: Except to the extent that competition has been restrained as herein alleged, some or all of the members of respondent WCA have been, and are now, in competition among themselves and with other chiropractors in Wisconsin.

CHIROPRACTIC MANIPULATION SERVICES

PARAGRAPH SEVEN: Professional services performed by chiropractors include, among other things, spinal and extra spinal manipulations. Prior to January 1, 1997, chiropractors generally billed for these services using a single billing code (A2000 for Medicare and 97260 for most private insurance) regardless of the

number of spinal or extra spinal regions adjusted. Beginning on January 1, 1997, the Health Care Financing Administration and many private insurance companies began accepting four new chiropractic manipulative treatment ("CMT") codes (98940, 98941, 98942, and 98943) in place of the old single billing code. The new CMT codes reflected more detailed or precise descriptions of the manipulation services: 98940 (adjustment of 1-2 regions); 98941 (adjustment of 3-4 regions); 98942 (adjustment of 5 regions); and 98943 (adjustment of at least one extra spinal region).

PARAGRAPH EIGHT: Wisconsin law provides that a health care insurer (other than a health maintenance organization) must provide a specific methodology, including but not limited to the usual, customary, and reasonable ("UCR") charges by which it will determine the eligible amount of a provider's charge. The methodology must be predicated on a database that, among other things, accurately reflects the amounts charged by providers for the procedure, is updated at least every six months, and contains no data that is more than 18 months old at the time of an update. Each health care insurer selects a certain percentile (*e.g.*, 80%) of the charges in the database as its UCR amount. In many instances, health care insurers will provide their insured members an explanation of benefits form notifying the insured members if their health care provider has charged more than the UCR amount for services.

ANTICOMPETITIVE CONDUCT

PARAGRAPH NINE: Respondent Leonard, acting in his capacity as executive director of respondent WCA, and respondent WCA, acting as a combination of its members, and in conspiracy with at least some of its members, and others, have acted to restrain competition by, among other things, encouraging, facilitating, entering into, and implementing agreements, express or implied, among WCA's members to fix and/or increase the prices paid for chiropractic services and to boycott third-party payers to obtain higher reimbursement for chiropractic services.

PARAGRAPH TEN: Respondents WCA and Leonard have engaged in acts and practices in furtherance of the combination and conspiracy, including, among other things:

Training Seminars

A. Respondents WCA and Leonard have organized and conducted seminars at eight different locations throughout the State of Wisconsin to train chiropractors and their staffs on the new CMT codes (the "CMT Seminars "), including how to price the codes, and have urged chiropractors to make no decisions on their fees for the new CMT codes before attending one of the training seminars.

B. During the CMT Seminars respondent Leonard, the principal or sole speaker at the seminars:

1. told the approximately 1300 attendees that the new CMT codes had the same values as osteopathic manipulative treatment ("OMT ") codes;

2. represented that the marketplace expected the average prices for the new CMT codes to be about the same as the average prices for the OMT codes, which were significantly higher than the average prices then charged by chiropractors for manipulation services;

3. provided data which showed the average charges for the current chiropractic code (97260) were: $30.28 (Northeast District); $28.23 (Northcentral District); $27.58 (Northwest District); $31.03 (Southeast District); $32.20 (Southcentral District); and $28.96 (Southwest District);

4. provided data which showed that the current average statewide charges for osteopathic manipulations were: $40.30 (manipulation of 1-2 regions); $57.40 (manipulation of 3-4 regions); and $91.68 (manipulation of 5 or more regions);

5. suggested that the chiropractors call osteopaths in their own areas to determine their local charges;

6. urged chiropractors to question any third-party payer that reimbursed a lesser amount for the CMT codes than for the OMT codes;

7. during at least some of the seminars, represented that the WCA had surveyed numerous chiropractors and determined that private insurance companies were paying CMT code claims at the prices the chiropractors chose to charge;

8. told chiropractors that with the introduction of the new CMT codes, chiropractors could increase their fees without any risk that third-party payers would refuse to pay their new fees, because there was no current database from which to calculate UCR fees; and

9. told chiropractors to increase their fees because their new fees would determine the new UCRs.

Negotiations with Third-Party Payers

C. Respondent Leonard told third-party payers that as a result of the new CMT codes, chiropractors should be paid the same amount that osteopaths are paid by third-party payers for manipulation services; encouraged third-party payers to agree to pay specific sums certain and/or to calculate UCRs in a manner or using a methodology proposed by respondent WCA; and threatened to take legal action against third-party payers in the absence of such agreements.

Fee Surveys

D. Respondents WCA and Leonard have frequently collected, analyzed, and provided to respondent WCA's members and others current charge data for the new CMT codes, including, but not limited to, the following:

1. Respondent Leonard, during a meeting of respondent WCA's board of directors in late March 1997, and during a series of WCA-sponsored seminars entitled, "Getting Paid For Your CMT Codes," held throughout the State of Wisconsin in early April 1997, provided data which showed current average charges for each of the new CMT codes within each of respondent WCA's six districts as follows:

District	98940 (1-2 Regions)	98941 (3-4 Regions)	98942 (5 Regions)
Northeast	$38.45	$54.51	$74.46
Northcentral	$32.72	$42.87	$54.51
Northwest	$33.63	$46.55	$62.17
Southeast	$38.34	$53.56	$70.54
Southcentral	$37.46	$50.57	$64.74
Southwest	$37.25	$50.77	$65.56

The data was obtained from a statewide fee survey conducted by respondent WCA during the last week of February 1997.

2. In June 1997, respondent Leonard furnished to a board member of respondent WCA, and other members of respondent WCA's Southwest District, data from a survey which was conducted by respondent WCA less than one month earlier and listed actual current

charges in nine digit zip code order for the entire Southwest District.

Review of Managed Care Contracts

E. Respondent Leonard reviewed individual contract offers to WCA's members by third-party payers and circulated to respondent WCA's membership memoranda containing adverse comments about the payers' proposed fee schedules for the new CMT codes, encouraged chiropractors to negotiate higher fees, and advised them to exchange and discuss all information they receive with other chiropractors in their area to improve their bargaining position with the third-party payers.

Boycott of Managed Care Plans

F. Respondents WCA and Leonard encouraged, recommended and assisted in the boycott of managed care plans by respondent WCA's members and others, including, but not necessarily limited to, MultiPlan and Gundersen Lutheran Health Plan, to obtain higher reimbursement for chiropractic services.

G. Respondent Leonard, during a meeting of respondent WCA's board of directors in late March 1997: (1) discussed MultiPlan's proposed contract terms, including the fee schedule and a provision that network chiropractors treat worker compensation and auto insurance patients on the same terms as they treat other patients covered by the network arrangement; (2) recommended that chiropractors reject the entire contract and disrupt the MultiPlan network; (3) recommended that chiropractors hold out for a fee schedule based on 85% of the market price; (4) provided data which showed current average charges for the new CMT codes; and (5) encouraged chiropractors to communicate this information to all the other chiropractors.

H. Respondent Leonard, during at least some of the WCA-sponsored seminars entitled, "Getting Paid For Your CMT Codes," held throughout the State of Wisconsin in April 1997: (1)

discussed MultiPlan's proposed contract terms, including the fee schedule and a provision that network chiropractors treat worker compensation and auto insurance patients on the same terms as they treat other patients covered by the network arrangement; (2) recommended that chiropractors reject the workers compensation and personal injury provisions of the contract; (3) suggested that if enough chiropractors rejected the contract, MultiPlan would be forced to renegotiate the terms; and (4) encouraged chiropractors to discuss the MultiPlan contract with other chiropractors in their area.

I. In April 1997, after MultiPlan revised its fee schedule, respondent Leonard communicated to the chiropractors that the revised fee schedule reflected fair market prices for chiropractic services.

J. In June 1997, respondent Leonard furnished to a board member of respondent WCA, and other members of respondent WCA's Southwest District who were actively engaged in a collective effort to induce Gundersen Lutheran Health Plan to increase its reimbursement rates, a copy of respondent WCA's most current fee survey which was concluded on May 31, 1997, and listed actual current charges in nine digit zip code order for the entire Southwest District.

PARAGRAPH ELEVEN: The members of respondent WCA have not integrated their practices in any economically significant way, nor have they created any efficiencies that might justify the acts or practices described in Paragraphs Nine and Ten.

ANTICOMPETITIVE EFFECTS

PARAGRAPH TWELVE: The acts or practices of the respondents as described in this complaint have had the purpose, tendency, effects, and capacity to restrain trade unreasonably and

hinder competition in the provision of chiropractic goods and services in Wisconsin in the following ways, among others:

A. to restrain competition among chiropractors;

B. to deprive consumers of the benefits of competition among chiropractors;

C. to fix or increase the prices that consumers pay for chiropractic services;

D. to fix the terms and conditions upon which chiropractors would deal with third- party payers, including terms of chiropractic compensation, thereby raising the price to consumers of medical insurance coverage issued by third-party payers; and

E. to deprive consumers of the benefits of managed care.

PARAGRAPH THIRTEEN: The aforesaid acts and practices of the respondents are to the prejudice and injury of the public and 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. The acts or practices of the respondents, as herein alleged, are continuing and will continue or recur in the absence of the relief requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this eighteenth day of May, 2000, issues its complaint against said 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 of complaint which the Midwest Region proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violations of the Federal Trade Commission Act; and

The respondents, their attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of 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, 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 the respondents have 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 agreement on the public record for a period of thirty (30) days, and having duly considered the comment filed thereafter by an interested person pursuant to §2.34 of its Rules, now in further conformity with the procedures prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Wisconsin Chiropractic Association is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Wisconsin, with its principal

office and place of business located at 521 E. Washington Avenue, Madison, Wisconsin 53703.

2. Respondent Russell A. Leonard is the Executive Director of the WCA. His principal office or place of business is the same as that of respondent WCA.

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

ORDER

I.

IT IS ORDERED that, for the purposes of this order, the following definitions shall apply:

A. "Wisconsin Chiropractic Association" or "WCA" means Wisconsin Chiropractic Association, its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups, and affiliates, controlled by WCA, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

B. "Russell A. Leonard" or "Leonard" means Russell A. Leonard, his representatives, agents, and employees.

C. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, partnerships, and governments.

D. "Payer" means any person that purchases, reimburses for, or otherwise pays for all or part of any health care services, including, but not limited to, chiropractic services, for itself or for any other person. "Payer" includes, but is not limited to, any health insurance

company; preferred provider organization; prepaid hospital, medical, or other health service plan; health maintenance organization; government health benefits program; employer or other person providing or administering self-insured health benefits programs; and patients who purchase health care for themselves.

E. "Provider" means any person that supplies health care services to any other person, including, but not limited to, chiropractors, physicians, hospitals, and clinics.

F. "Reimbursement" means any payment, whether cash or non-cash, or other benefit received for the provision of chiropractic goods and services.

G. "Chiropractor" means a person licensed to engage in the practice of chiropractic.

H. "Participation agreement" means any agreement between a payer and a provider in which the payer agrees to pay the provider for the provision of health care services, and in which the provider agrees to accept payment from the payer for the provision of health care services.

II.

IT IS FURTHER ORDERED that respondent WCA, directly or indirectly, or through any corporation or other device, in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, forthwith cease and desist from:

A. Requesting, proposing, urging, advising, recommending, advocating, or attempting to persuade in any way any person to fix, establish, raise, stabilize, maintain, adjust, or

tamper with any fee, fee schedule, price, pricing formula, discount, conversion factor, or other aspect or term or condition of the fees charged or to be charged for any chiropractic goods or services.

B. Creating, formulating, suggesting, encouraging adherence to, endorsing, or authorizing any list or schedule of fees for any health care goods or services, including, but not limited to, suggested fees, proposed fees, fee guidelines, discounts, discounted fees, standard fees, recommended fees, or conversion factors.

C. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding:

1. To negotiate on behalf of any chiropractor or group of chiropractors regarding any term, condition, or requirement of dealing with any payer or provider; or

2. To deal or refuse to deal with, boycott or threaten to boycott, any payer or provider.

D. Requesting, proposing, urging, advising, recommending, advocating, or attempting to persuade in any way any chiropractor to accept or not accept any aspect, term, or condition of any existing or proposed participation agreement, including, but not limited to, the price to be paid for chiropractic goods or services.

E. Soliciting from, or communicating to, any chiropractor any information concerning any other chiropractor's intention or decision with respect to entering into, refusing to enter into, threatening to refuse to enter into, participating in, threatening to withdraw from, or withdrawing from any existing or proposed participation agreement.

F. 1. Organizing, sponsoring, facilitating or participating in any meeting or discussion that respondent WCA expects or reasonably should expect will facilitate communications concerning one or more chiropractors' intentions or decisions with respect to entering into, refusing to enter into, threatening to refuse to enter into, participating in, threatening to withdraw from, or withdrawing from any existing or proposed participation agreement; or

2. Continuing a meeting or discussion where respondent WCA knows or reasonably should know that a person makes communications concerning one or more chiropractors' intentions or decisions with respect to entering into, refusing to enter into, threatening to refuse to enter into, participating in, threatening to withdraw from, or withdrawing from any existing or proposed participation agreement, and respondent WCA fails to eject such person from the meeting or discussion; or

3. Continuing a meeting or discussion where respondent WCA knows or reasonably should know that two or more persons make communications concerning one or more chiropractors' intentions or decisions with respect to entering into, refusing to enter into, threatening to refuse to enter into, participating in, threatening to withdraw from, or withdrawing from any existing or proposed participation agreement.

G. For a period of two (2) years after the date that this order becomes final, or until December 31, 2001, whichever is earlier, initiating, originating, developing, publishing, or

circulating the whole or any part of any proposed or existing fee survey for any health care goods or services.

H. For a period of five (5) years beginning at the expiration of the period in Paragraph II G of this order, initiating, originating, developing, publishing, or circulating the whole or any part of any proposed or existing fee survey for any health care goods or services unless (1) the data collection and analysis are managed by a third party; (2) the raw fee survey data is retained by the third party and not made available to respondent WCA; (3) any information that is shared among or is available to providers is more than three months old; and (4) there are at least five providers reporting data upon which each disseminated statistic is based, no individual provider's data represents more than 25 percent on a weighted basis of that statistic, and any information disseminated is sufficiently aggregated such that it would not allow respondent or any other recipients to identify the prices charged or compensation paid by any particular provider.

I. Inducing, suggesting, urging, encouraging, or assisting any person to take any action that, if taken by respondent WCA, would violate this order.

Provided, however, that nothing contained in this order shall be construed to prohibit respondent WCA from petitioning any federal or state government executive agency or legislative body concerning legislation, rules, or procedures, or to participate in any federal or state administrative or judicial proceeding, in so far as such activity is protected by the Noerr-Pennington doctrine.

III.

IT IS FURTHER ORDERED that respondent Leonard, directly or indirectly, or through any corporation or other device, in or affecting commerce, as “commerce” is defined in Section 4

of the Federal Trade Commission Act, 15 U.S.C. § 44, forthwith cease and desist from:

A. Requesting, proposing, urging, advising, recommending, advocating, or attempting to persuade in any way any person to fix, establish, raise, stabilize, maintain, adjust, or tamper with any fee, fee schedule, price, pricing formula, discount, conversion factor, or other aspect or term or condition of the fees charged or to be charged for any health care goods or services.

B. Creating, formulating, suggesting, encouraging adherence to, endorsing, or authorizing any list or schedule of fees for any health care goods or services, including, but not limited to, suggested fees, proposed fees, fee guidelines, discounts, discounted fees, standard fees, recommended fees or conversion factors.

C. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding:

    1. To negotiate on behalf of any health care provider or group of health care providers regarding any term, condition, or requirement of dealing with any payer or provider; or

    2. To deal or refuse to deal with, boycott or threaten to boycott, any payer or provider.

D. Requesting, proposing, urging, advising, recommending, advocating, or attempting to persuade in any way any health care provider to accept or not accept any aspect, term, or condition of any existing or proposed

participation agreement, including, but not limited to, the price to be paid for any health care goods or services.

E. Soliciting from, or communicating to, any health care provider any information concerning any other health care provider's intention or decision with respect to entering into, refusing to enter into, threatening to refuse to enter into, participating in, threatening to withdraw from, or withdrawing from any existing or proposed participation agreement.

F. 1. Organizing, sponsoring, facilitating or participating in any meeting or discussion that respondent Leonard expects or reasonably should expect will facilitate communications concerning one or more health care providers' intentions or decisions with respect to entering into, refusing to enter into, threatening to refuse to enter into, participating in, threatening to withdraw from, or withdrawing from any existing or proposed participation agreement; or

2. Continuing a meeting or discussion where respondent Leonard knows or reasonably should know that a person makes communications concerning one or more health care providers' intentions or decisions with respect to entering into, refusing to enter into, threatening to refuse to enter into, participating in, threatening to withdraw from, or withdrawing from any existing or proposed participation agreement, and respondent Leonard fails to eject such person from the meeting or discussion; or

3. Continuing a meeting or discussion where respondent Leonard knows or reasonably should know that two or more persons make communications concerning one or more health care providers' intentions or decisions with respect to entering into, refusing to enter into, threatening to refuse to enter into, participating in,

threatening to withdraw from, or withdrawing from any existing or proposed participation agreement.

G. For a period of two (2) years after the date that this order becomes final, or until December 31, 2001, whichever is earlier, initiating, originating, developing, publishing, or circulating the whole or any part of any proposed or existing fee survey for any health care goods or services.

H. For a period of five (5) years beginning at the expiration of the period in Paragraph III G of this order, initiating, originating, developing, publishing, or circulating the whole or any part of any proposed or existing fee survey for any health care goods or services unless (1) the data collection and analysis are managed by a third party; (2) the raw fee survey data is retained by the third party and not made available to respondent Leonard; (3) any information that is shared among or is available to providers is more than three months old; and (4) there are at least five providers reporting data upon which each disseminated statistic is based, no individual provider's data represents more than 25 percent on a weighted basis of that statistic, and any information disseminated is sufficiently aggregated such that it would not allow respondent or any other recipients to identify the prices charged or compensation paid by any particular provider.

I. Inducing, suggesting, urging, encouraging, or assisting any person to take any action that, if taken by respondent Leonard, would violate this order.

Provided, however, that nothing contained in this order shall be construed to prohibit respondent Leonard from petitioning any federal or state government executive agency or legislative body concerning legislation, rules, or procedures, or to participate in

any federal or state administrative or judicial proceeding, in so far as such activity is protected by the Noerr-Pennington doctrine.

Provided further that nothing contained in Paragraph III of this order shall prohibit respondent Leonard, acting as an agent, employee or representative exclusively for a single provider or payer, from providing comments or advice on any matter to such single provider or payer, or determining or negotiating any terms, conditions, or requirements, including the price to be paid for any health care goods or services, upon which such single provider or payer will deal with any person.

IV.

IT IS FURTHER ORDERED that for a period of five (5) years from the date that this order becomes final, respondent WCA shall:

A. Maintain a copy of each document distributed at each meeting of the WCA's board of directors, WCA district meeting, or seminar or training session sponsored in whole or in part by the WCA for a period of five (5) years from the date of distribution, along with records showing the date of the meeting or seminar at which the document was distributed.

B. Maintain a copy of each fee survey, or part thereof, distributed to any WCA member or members for a period of five (5) years from the last date of its distribution, along with records showing the date(s) of distribution and each person to whom the fee survey, or part thereof, was distributed.

C. Maintain a copy of each document relating to any subject that is covered by any provision of this order and which is distributed to any WCA member or members for a period of five (5) years from the last date of its distribution, along

with records showing the date(s) of distribution and each person to whom the document was distributed.

V.

IT IS FURTHER ORDERED that respondent WCA shall:

A. Within thirty (30) days after the date that this order becomes final, distribute a dated and signed notification letter in the form set forth in Appendix A of this order along with a copy of the complaint and order in this matter: (1) to each of its current officers and directors, and to each other agent, representative, or employee of the WCA whose activities are affected by this order, or who has responsibilities with respect to the subject matter of this order; (2) to each of its current members; and (3) to the designated registered agent on file with the Wisconsin Office of the Commissioner of Insurance for each payer set forth in Appendix B of this order. The notification letter, complaint and order shall be delivered in a format that does not include any additional communication from respondent WCA or any other person.

B. For a period of five (5) years after the date that this order becomes final, and within thirty (30) days of the date that the person assumes such position, distribute a dated and signed notification letter in the form set forth in Appendix A of this order, along with a copy of the complaint and order in this matter, to each new officer and director of the WCA, and to each other new agent, representative, or employee of the WCA whose activities are affected by this order, or who has responsibilities with respect to the subject matter of this order. The notification letter, complaint and order shall be delivered in a format that

does not include any additional communication from respondent WCA or any other person.

C. For a period of five (5) years after the date that this order becomes final, provide each new member with a dated and signed notification letter in the form set forth in Appendix A of this order, along with a copy of the complaint and order in this matter, within thirty (30) days of the new member's admission to the WCA. The notification letter, complaint and order shall be delivered in a format that does not include any additional communication from respondent WCA or any other person.

D. Publish a notification letter in the form set forth in Appendix A of this order, along with a copy of this order and the complaint, in an issue of *The Wisconsin Chiropractor* published no later than 60 days after the date that this order becomes final, and annually each year thereafter for a period of five (5) years. The notification letter, order and the complaint shall be published with such prominence as is given to regularly featured articles in *The Wisconsin Chiropractor*.

VI.

IT IS FURTHER ORDERED that respondent WCA shall notify the Commission at least thirty (30) days prior to any proposed change in the respondent, such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the respondent that may affect compliance obligations arising under this order.

VII.

IT IS FURTHER ORDERED that respondent Leonard shall, for a period of five (5) years after the date that this order becomes final:

A. Notify the Commission within thirty (30) days of the discontinuance of his present business or employment and of each affiliation with a new business or employment where the duties and responsibilities of such employment are subject to the provisions of this order. Each such notice of affiliation with any new business or employment shall include his new business address and telephone number, current home address, and a statement describing the nature of the business or employment and the duties and responsibilities.

B. Provide a copy of the complaint and order in this matter to each new employer within seven (7) days of his employment where the duties and responsibilities of such employment are subject to the provisions of this order.

VIII.

IT IS FURTHER ORDERED that:

A. Within sixty (60) days after the date that this order becomes final, each respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which the respondent intends to comply, is complying, and has complied with Paragraphs II through VII of this order.

B. One (1) year from the date that this order becomes final, annually for the next five (5) years on the anniversary of the date that this order becomes final, and at other times as the Commission may require, each respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which the respondent has

complied and is complying with Paragraphs II through VII of this order.

IX.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this order, upon five business days' written notice, each respondent shall permit any duly authorized representative of the Commission:

A. To obtain access, during normal 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 the possession or under the control of respondent relating to any matter contained in this order; and

B. To interview that respondent or any employee or representative of that respondent in the presence of counsel and without restraint or interference from that respondent.

X.

IT IS FURTHER ORDERED that this order shall terminate on May 18, 2020.

By the Commission.

APPENDIX A

[Wisconsin Chiropractic Association Letterhead]

Dear Officer, Director, Agent, Representative, Employee, Member or Third Party Payer:

The Wisconsin Chiropractic Association ("WCA") and its executive director, Russell A. Leonard, have entered into an agreement with the Federal Trade Commission to settle charges that the WCA, acting through its executive director, violated the antitrust laws by, among other things, conspiring with at least some of the WCA's members and others to fix or to increase prices paid for chiropractic manipulation services and to boycott third-party payers to raise reimbursement rates for chiropractic manipulation services. As part of the settlement agreement, the WCA is required to send this notification letter and a copy of the complaint and order to each of its officers and directors, its agents, representatives, and employees who have responsibilities with respect to the subject matter of the order, its members, and third-party payers.

Under the terms of the order, the WCA and Russell A. Leonard are prohibited from:

Fixing prices or encouraging others to fix prices for any chiropractic good or service (or, in the case of Mr. Leonard, any health care goods or services);

Creating, suggesting, or endorsing any list or schedule of fees to be charged for any health care good or service;

Organizing, participating in, or enforcing any agreement (1) to negotiate on behalf of any chiropractor or group of chiropractors (or, in the case of Mr. Leonard, any health care provider or group

of health care providers) regarding any term, condition, or requirement of dealing with any payer or provider; or (2) to deal or refuse to deal with, boycott or threaten to boycott, any payer or provider;

Advising, recommending, advocating, or attempting to persuade in any way any chiropractor (or, in the case of Mr. Leonard, any health care provider) to accept or not accept any aspect, term or condition of any existing or proposed participation agreement;

Soliciting or communicating any chiropractor's (or, in the case of Mr. Leonard, any health care provider's) views, decisions or intentions concerning any participation agreement;

Organizing, sponsoring, facilitating or participating in any meeting or discussion that the WCA or Mr. Leonard expects or reasonably should expect will facilitate communications concerning any chiropractor's intentions pertaining to any participation agreement;

Conducting or distributing any fee survey for any health care good or service for a period of two (2) years after the date the order becomes final, or before December 31, 2001, whichever is earlier. For an additional five (5) year period thereafter, the WCA and Mr. Leonard are permitted to conduct and distribute fee surveys, provided that (a) the data collection and analysis are managed by a third party; (b) the raw fee survey data is retained by the third party and not made available to the WCA or Mr. Leonard; (c) any information that is shared among or is available to providers is more than three months old; and (d) there are at least five providers reporting data upon which each disseminated statistic is based, no individual provider's data represents more than 25 percent on a weighted basis of that statistic, and any information disseminated is sufficiently aggregated that it would not allow respondents or any other recipients to identify the prices charged or compensation paid by any particular provider; and

Encouraging or assisting any person to take any action that, if taken by the WCA or Mr. Leonard, would violate the order.

In addition, the WCA is required, under the terms of the order, to maintain better records, including, but not limited to, retaining copies of all materials distributed at WCA meetings and seminars. The WCA must also maintain a copy of each fee survey distributed to any WCA member, along with a record of its distribution. Finally, the WCA is required to maintain a copy of each other document relating to any subject that is covered by any provision of the order, along with a record of its distribution.

Nothing in the order prohibits either the WCA or Mr. Leonard from petitioning any federal or state government executive agency or legislative body concerning legislation, rules, or procedures, or from participating in any federal or state administrative or judicial proceeding, in so far as such activity is protected by the Noerr-Pennington doctrine. In addition, the order does not prohibit Mr. Leonard, acting as an agent, employee or representative exclusively for a single provider or payer, from providing comments or advice on any matter to such single provider or payer, or from determining or negotiating any terms, conditions, or requirements, including prices to be paid for any health care goods or services, upon which such single provider or payer will deal with any person.

Copies of the complaint and order are enclosed.

/s/
Michael McMahon, D.C.
President
Wisconsin Chiropractic Association

APPENDIX B

Aetna Insurance Company of America

American Medical Security

Atrium Health Plan, Inc.

Blue Cross & Blue Shield United of Wisconsin

CNA Insurance

Compcare Health Services Insurance Corp.

Coordinated Care Health Plan of WI

The Dean Health Plan, Inc.

EMPHESYS Wisconsin Insurance Company

Employers Health Insurance Company

Equitable Insurance

Family Health Plan Cooperative

Farmers Insurance Group

Federated Mutual Insurance

Greater La Crosse Health Plan, Inc

Group Health Cooperative of Eau Claire

Group Health Cooperative of South Central Wisconsin

Gundersen Lutheran Health Plan, Inc.

Heritage Mutual Insurance Company

Humana Wisconsin Health Org. Ins. Corp.

Liberty Insurance Corporation

Lutheran Brotherhood

Managed Health Services Ins. Corp.

Medica Health Plans of Wisconsin

The Medical Associates Clinic Health Plan of WI

MercyCare Insurance Company

Mutual of Omaha Insurance Company

Nationwide Mutual Insurance Company

Network Health Plan of WI, Inc.

North Central Health Protection Plan

Physicians Plus Insurance Corp.

Prevea Health Insurance Plan, Inc.

Primerica Insurance Company

PrimeCare Health Plan, Inc.

Rural Mutual Insurance Company

Security Health Plan of WI, Inc.

Sentry Insurance

Touchpoint Health Plan, Inc.

Travelers Insurance Company

Unity Health Plans Insurance Corp.

Valley Health Plan, Inc.

Wausau Insurance Company

Wisconsin Mutual Insurance Company

Wisconsin Physician Services Insurance Company

WPPN/MultiPlan

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement from the Wisconsin Chiropractic Association ("WCA") and its executive director, Russell A. Leonard, to a proposed consent order. The agreement settles charges by the Federal Trade Commission that the WCA and Mr. Leonard have violated Section 5 of the Federal Trade Commission Act by conspiring with some of the WCA's members and others to fix prices for chiropractic services and to boycott third-party payers to obtain higher reimbursement rates for services. The proposed consent order has been placed on the public record for thirty days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will review the

agreement and the comments received, and will decide whether it should withdraw from the agreement or make the agreement and 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 in any way their terms. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by the WCA or Mr. Leonard that the law has been violated as alleged in the complaint.

The Complaint

The WCA is a professional trade association of chiropractors with its principal place of business in Madison, Wisconsin. The WCA has approximately 900 chiropractor members. A substantial majority of the chiropractors licensed to practice in the state of Wisconsin are members of the WCA. The WCA exists and operates in substantial part for the pecuniary benefit of its members. Mr. Leonard is, and during the time period addressed by the allegations of the complaint was, the executive director of the WCA.

Professional services performed by chiropractors include, among other things, spinal and extra spinal manipulations. Prior to January 1, 1997, chiropractors generally billed for these services using a single billing code regardless of the number of regions adjusted. Osteopathic physicians performing manipulation treatments, by contrast, had been using multiple codes to bill based on the number of regions of the body adjusted. Beginning in January 1997, the federal government and private insurance companies began accepting four new codes for chiropractic manipulations. The new chiropractic manipulative treatment ("CMT") codes reflected more detailed or precise

descriptions of the manipulation services and allowed chiropractors, like osteopathic physicians, to bill based on the number of regions adjusted.

Beginning in late 1996, shortly after the new CMT codes were announced, the WCA, acting through its executive director Mr. Leonard, orchestrated an agreement among its members to raise fees for chiropractic manipulation services. In late 1996 and continuing into early 1997, the WCA conducted training seminars on the new codes for members in localities throughout the state. The WCA urged chiropractors not to make any decisions on their fees under the new codes before attending one of these meetings. During the meetings, Mr. Leonard told the chiropractors that the new CMT codes provided them with a unique opportunity to increase their fees. Mr. Leonard advised members that it was important that the new codes for chiropractic manipulation were priced properly, and that the WCA's view was that proper pricing was at the same level that osteopathic physicians billed for spinal manipulation services. He provided detailed data on current osteopathic pricing, and encouraged chiropractors to raise their prices to the osteopathic levels.

At the meetings Mr. Leonard assured members that if they all raised their rates, third-party payers would not reject or reduce these higher charges for the new codes. Under the "UCR" ("usual, customary, and reasonable rate") system of reimbursement that was in general use in Wisconsin's health care industry, price increases by a significant number of chiropractors would raise the UCR level and thereby result in higher reimbursement for chiropractic services. On the other hand, if other members did not raise their prices, UCR levels would not rise, the chiropractor would not receive higher reimbursement, and he or she would be identified to patients as an "outlier" whose fees were far higher than other chiropractors. Each chiropractor's action in conformity with the WCA's pronouncements would be aided by knowledge that other members were taking similar action. Many members left the WCA local meetings with the understanding that they and others at the meeting would raise their prices in accordance with

the WCA's request. After the new codes took effect, Mr. Leonard surveyed member pricing in certain localities, and reported back to members that chiropractors in these areas had succeeded in raising reimbursement levels.

As a result of these actions by the WCA and Mr. Leonard, many chiropractors raised their fees to the osteopathic levels. Other chiropractors increased their fees substantially more than they had in previous years. Overall, the effect of these actions was to raise the prices that consumers pay for chiropractic services.

In furtherance of the WCA's efforts to raise chiropractic fees, the WCA and Mr. Leonard regularly provided fee surveys to the WCA's members. At times, these fee surveys reflected insufficiently aggregated data, thus effectively identifying current prices by individual chiropractic offices. Fee survey data were also furnished in connection with boycotts of managed care plans.

In March 1997, the WCA and Mr. Leonard organized a boycott by WCA members of MultiPlan, a preferred provider network. At a board meeting, the WCA directors on Mr. Leonard's recommendation agreed to reject, and to encourage their fellow chiropractors to reject, MultiPlan's proposed contract amendments and new fee schedule. Mr. Leonard recommended that chiropractors demand a fee schedule reflecting 85% of market price, and provided survey data that showed current average charges throughout the state. At training seminars held in early April 1997, Mr. Leonard criticized MultiPlan's proposed amendments and fee schedule, encouraged chiropractors to discuss the contract with others in their area, and reminded them that if enough chiropractors rejected the contract, MultiPlan would be forced to renegotiate the terms. Soon thereafter many of the chiropractic members of the WCA submitted letters of termination to MultiPlan.

Mr. Leonard routinely reviewed managed care contract offers to the WCA's members and circulated to the WCA's membership memoranda containing adverse comments about these plans' fee schedules for the new CMT codes. In his comments, Mr. Leonard frequently encouraged chiropractors to negotiate higher fees with the plans, and advised them to exchange all information they received with other chiropractors in their area. In so doing, Mr. Leonard reminded the WCA's members that they would be more successful in their fee negotiations with third-party payers if the members continued to negotiate on a united front. In addition, Mr. Leonard, again acting in his capacity as executive director of the WCA, told third-party payers that they should be paying chiropractors the same amount that osteopaths are paid for manipulation services, encouraged third-party payers to agree to pay specific sums certain or to calculate fees in a manner proposed by the WCA, and called third-party payers to follow up on complaints of low reimbursement that he encouraged and received from individual WCA members.

The WCA's members have not integrated their practices in any economically significant way, nor have they created any efficiencies that might justify this conduct. The purpose of this conduct was to secure higher fees and reimbursement. The WCA's actions harmed consumers by increasing the prices for chiropractic services and depriving consumers of the benefits of competition among chiropractors.

The Proposed Consent Order

The proposed consent order is designed to prevent the illegal concerted action alleged in the complaint. Paragraphs II and III of the proposed order contain the key provisions. These two paragraphs are almost identical in their coverage, except that Paragraph II applies to the WCA and Paragraph III applies to Mr. Leonard. Paragraphs II.A and III.A prohibit the WCA and Mr. Leonard from fixing prices for any chiropractic goods or services (or, in the case of Mr. Leonard, any health care goods or services).

The broader category including "any health care goods or services" is needed should Mr. Leonard obtain employment with another health care entity outside the chiropractic field.

Paragraphs II.B and III.B prohibit the WCA and Mr. Leonard from creating, suggesting, or endorsing any proposed fees or conversion factors for any health care goods or services. Here, the WCA is also subject to the broader category of "any health care goods or services" since the allegations in the complaint include the WCA's endorsement of osteopathic fee schedules.

Paragraphs II.C and III.C prohibit the WCA and Mr. Leonard from engaging in negotiations on behalf of any chiropractor or group of chiropractors (or, in the case of Mr. Leonard, any provider or group of providers). In addition, this paragraph prohibits them from orchestrating concerted refusals to deal.

Paragraphs II.D and III.D prohibit the WCA and Mr. Leonard from urging or recommending that any chiropractor (or, in the case of Leonard, any provider) accept or not accept any term or condition of any participation agreement. Paragraphs II.E and III.E prohibit the WCA and Mr. Leonard from soliciting or communicating any chiropractor's (or, in the case of Leonard, any provider's) views, decisions or intentions concerning any participation agreement.

Pursuant to Paragraphs II.F and III.F, the WCA and Mr. Leonard are prohibited from organizing or participating in any meeting or discussion where they expect chiropractors (providers) will discuss intentions concerning participation in any health plans. In addition, these paragraphs prohibit the WCA and Mr. Leonard from continuing any meeting where any person makes such a communication unless the person is ejected from the meeting. Finally, this paragraph requires that the WCA and Mr.

Leonard terminate any meeting where two or more persons make such communications.

Paragraphs II.G and III.G ban the WCA and Mr. Leonard from initiating, originating, developing, publishing, or circulating any fee survey for any health care goods or services for a period of two years after the date that the order becomes final, or until December 31, 2001, whichever is earlier. The two-year ban on fee surveys is necessitated by the gross misuse of fee surveys alleged in the complaint. In addition, for five years thereafter, Paragraphs II.H and III.H prohibit the WCA and Mr. Leonard from conducting or distributing any fee survey unless (1) the data collection and analysis are managed by a third party; (2) the raw fee survey data is retained by the third party and not made available to the respondents; (3) any information that is shared among or is available to providers is more than three months old; and (4) there are at least five providers reporting data upon which each disseminated statistic is based, no individual provider's data represents more than 25 percent on a weighted basis of that statistic, and any information disseminated is sufficiently aggregated that it would not allow respondents or any other recipients to identify the prices charged or compensation paid by any particular provider. These requirements are identical to the requirements found in the safe harbor provisions of the *Statements of Antitrust Enforcement Policy in Health Care*, *Statement* 5 *on Providers' Collective Provision of Fee-Related Information to Purchasers of Health Care Services*, issued jointly by the FTC and the Department of Justice on August 18, 1996 (4 *Trade Reg. Rep*. (CCH) ¶ 13,153 at 20,809).

Paragraphs II.I and III.I prohibit the WCA and Mr. Leonard from encouraging, advising or pressuring any person to engage in any action that would be prohibited if the person were subject to the order.

Paragraph II and III contain provisos allowing the WCA and Mr. Leonard to exercise their First Amendment petitioning rights and to solicit competition-restricting government action where protected under the Noerr-Pennington doctrine. In addition, Paragraph III contains a proviso allowing Mr. Leonard to engage in certain acts otherwise prohibited by the order providing he is acting as an agent, employee, or representative exclusively for a single provider or payer.

Paragraph IV. requires that the WCA maintain copies of (1) all documents distributed at meetings and seminars; (2) all fee surveys and a record of their distribution; and (3) all documents relating to any subject that is covered by any provision in the order. Paragraph V. requires that the WCA provide copies of the complaint and order: (1) to all current and future officers, directors, and members; (2) to all current and future agents, representatives, and employees whose activities are affected by the order, or who have responsibilities with respect to the subject matter of the order; and (3) to the third-party payers set forth in Appendix B to the order.

Paragraph VI. requires that the WCA notify the Commission of any change in its corporate structure that may affect compliance obligations. Similarly, Paragraph VII. requires that Mr. Leonard notify the Commission of any change in his employment and would require him to provide copies of the complaint and consent order to any new employer for which his new duties and responsibilities are subject to any provisions in the order.

Paragraphs VIII. and IX. consist of standard Commission reporting and compliance procedures. Finally, Paragraph X. contains a standard twenty-year "sunset" provision under which the terms of the order terminate twenty years after the date of issuance.

IN THE MATTER OF

TEXAS SURGEONS, P.A., ET AL.

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

Docket C-3944; File No. 9810124
Complaint, May 18, 2000--Decision, May 18, 2000

This consent order addresses practices by Respondents Texas Surgeons, P.A., Austin Surgeons, P.L.L.C., Austin Surgical Clinic Association, P.A., Bruce McDonald & Associates, P.L.L.C., Capital Surgeons Group, P.L.L.C., Central Texas Surgical Associates, P.A., Surgical Associates of Austin, P.A. The order prohibits respondents from entering into or facilitating any agreement: (1) to negotiate physician services on behalf of any physicians with any payer or provider; (2) to deal, refuse to deal, or threaten to refuse to deal with any payer or provider; (3) regarding any term on which any physicians deal, or are willing to deal, with any payer or provider; (4) to restrict the ability, or facilitate the refusal, of any physician to deal with any payer or provider on an individual basis or through any other arrangement; or (5) to convey to any payer or provider, through any Austin area physician, any information concerning actual or potential dealings by any physician with any payer or provider. The order also prohibits respondents from exchanging, transferring, or facilitating the exchange or transfer of information among Austin area physicians concerning: (1) negotiation with any payer or provider regarding reimbursement terms; or (2) actual or contemplated intentions or decisions with respect to any terms, dealings or refusals to deal with any payer or provider. Respondents may participate in arrangements for the provision of physician services that are limited to physicians from the same medical practice group, engage in conduct that is approved and supervised by the State of Texas, so long as that conduct is protected from liability under the federal antitrust laws pursuant to the state action doctrine, and engage in conduct that is reasonably necessary to operate any "qualified risk-sharing joint arrangement" or "qualified clinically-integrated joint arrangement.

Participants

For the Commission: *Alan J. Friedman, George R. Bellack, Richard A. Feinstein, David R. Pender, Elizabeth A. Piotrowski, Geary A. Gessler, Louis Silvia,* and *Gregory S. Vistnes.*

For the Respondents: *David A. Ettinger, Honigman, Miller, Schwartz & Cohn,* and *David W. Hilgers, Hilgers & Watkins.*

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, having reason to believe that the Texas Surgeons, P.A. ("Texas Surgeons"), Austin Surgeons, P.L.L.C. ("AS"), Austin Surgical Clinic Association, P.A. ("ASCA"), Bruce McDonald & Associates, P.L.L.C. ("BM&A"), Capital Surgeons Group, P.L.L.C. ("CSG"), Central Texas Surgical Associates, P.A. ("CTSA"), and Surgical Associates of Austin, P.A. ("SAA"), hereinafter sometimes referred to as "respondents," have 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 as follows:

RESPONDENTS

1. Respondent Texas Surgeons is a for-profit professional association organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its office and principal place of business at 4007 Marathon Blvd., Austin, Texas 78756. At all times relevant to this Complaint, the shareholders of respondent Texas Surgeons have included 26 or more general surgeons.

2. Respondent AS is a professional limited liability corporation organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its office and principal place of business at 3901 Medical Parkway, #200, Austin, Texas 78756. At all times relevant to this Complaint, respondent AS has included at least three general surgeon

shareholders practicing general surgery in the Austin area through respondent AS.

3. Respondent ASCA is a for-profit professional association organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its office and principal place of business at 2911 Medical Arts Street, Austin, Texas 78705 At all times relevant to this Complaint, respondent ASCA has included at least four general surgeon shareholders practicing general surgery in the Austin area through respondent ASCA.

4. Respondent BM&A is a professional limited liability corporation organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its office and principal place of business at 4007 Marathon Blvd., Austin, Texas 78756. At all times relevant to this Complaint, respondent BM&A has included at least three general surgeon shareholders practicing general surgery in the Austin area through respondent BM&A.

5. Respondent CSG is a professional limited liability corporation organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its office and principal place of business at 3705 Medical Parkway, Austin, Texas 78705. At all times relevant to this Complaint, respondent CSG has included at least seven general surgeon shareholders practicing general surgery in the Austin area through respondent CSG.

6. Respondent CTSA is a for-profit professional association organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its office and principal place of business at 2300 Round Rock Avenue, Round Rock, Texas 78681. At all times relevant to this Complaint, respondent CTSA has included at least three general surgeon shareholders practicing general surgery in the Austin area through respondent CTSA.

7. Respondent SAA is a for-profit professional association organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its office and principal place of business at 1015 East 32nd Street, Austin, Texas 78705. At all times relevant to this Complaint, respondent SAA has included at least four general surgeon shareholders practicing general surgery in the Austin area through respondent SAA.

8. At all times relevant to this Complaint, the general surgeon shareholders of respondents AS, ASCA, BM&A, CSG, CTSA, and SAA ("respondent medical practice groups") have collectively comprised at least 24 of the 26 or more general surgeon shareholders of respondent Texas Surgeons. The few general surgeon shareholders of respondent Texas Surgeons who do not practice within any of the six respondent medical practice groups are solo practitioners.

9. At all times relevant to this Complaint, the shareholders of respondent Texas Surgeons have constituted the majority of general surgeon private practitioners serving the adult population in the Austin area. All such shareholders practice within the counties of Travis and Williamson. For purposes of this Complaint, the "Austin area" is no larger than the counties of Travis, Williamson, Hays, Bastrop, and Caldwell, including about 1,105,000 residents.

10. Except to the extent that competition has been unreasonably restrained as alleged herein, the six respondent medical practice groups, as well as the solo practitioner general surgeons within respondent Texas Surgeons, have been, and are now, in competition with each other and with other general surgeons and medical practice groups that include general surgeons in the Austin area.

JURISDICTION

11. Each respondent is a "corporation" within the meaning of Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

12. The acts and practices of the respondents, including those alleged herein, are in or affect commerce within the meaning of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

COMPETITION AMONG PHYSICIANS

13. General surgeons and other physicians often enter into professional service contracts with third-party payers, including health maintenance organization and preferred provider organization plans, that are designed to lower the costs of medical care for subscribers. Such professional service contracts typically establish the terms and conditions under which the physicians will render services to the subscribers of the third-party payers' health care plans, including terms and conditions of physician compensation. In order to gain contracts with third-party payers and thereby obtain access to their subscribers, physicians frequently agree to reductions in their compensation and to procedures for reviewing the utilization of medical resources. By lowering costs in this manner, third-party payers are able to reduce the cost of medical care for their subscribers.

14. Absent agreements among competing physicians or medical practice groups about the terms they will accept from third-party payers, and absent an arrangement where collective negotiations with third-party payers are reasonably necessary to obtain significant efficiencies through the arrangement, competing physicians and medical practice groups independently decide whether to enter into professional service contracts with third-party payers, and on the terms and conditions they will accept.

THE ACTS AND PRACTICES OF THE RESPONDENTS

15. Respondent Texas Surgeons, acting as a combination of its general surgeon shareholders and the six respondent medical practice groups, and in conspiracy with such general surgeon shareholders and medical practice groups, has, among other things, facilitated, created, and implemented express or implied agreements among its general surgeon shareholders and the six respondent medical practice groups to: (a) fix prices and other terms of dealing with third-party payers; (b) collectively threaten to refuse to deal with third-party payers; (c) collectively refuse to deal with third-party payers; and (d) deal with third-party payers only on collectively determined terms.

16. In or around June 1995, ten solo practitioner general surgeons in the Austin area formed an independent practice association named Capital Surgeons, P.A. (a predecessor to respondent Texas Surgeons), and, in or around September 1996, seven of these general surgeons formed respondent CSG and the other three formed respondent AS. Capital Surgeons, P.A., changed its name to Texas Surgeons, P.A., soon after Blue Cross Blue Shield of Texas ("Blue Cross") announced general surgery rate reductions in February 1997 (to become effective April 1, 1997). Soon after Blue Cross implemented its general surgery rate reductions on April 1, 1997, all fifteen of the general surgeons practicing through respondents ASCA, BM&A, CTSA, and SAA joined respondent Texas Surgeons as shareholders (two solo practitioner general surgeons joined respondent Texas Surgeons later in 1997).

17. Since the expansion of respondent Texas Surgeons, representatives of the six respondent medical practice groups collectively have comprised respondent Texas Surgeons' board of directors. As described below, respondent Texas Surgeons, including its board of directors, has served as a vehicle for the six respondent medical practice groups (as well as the few solo

practitioner shareholders of respondent Texas Surgeons) collectively to negotiate higher rates with two major third-party payers in the Austin area -- Blue Cross and United HealthCare of Texas.

18. The collective rate negotiations described below did not involve either significant financial risk sharing or the creation of other significant efficiencies through respondent Texas Surgeons, and therefore were not reasonably necessary to obtain any significant efficiencies.

RESPONDENTS' COLLECTIVE RATE NEGOTIATIONS WITH BLUE CROSS

19. In February 1997, Blue Cross notified its Austin area physician network that it was converting to a new physician reimbursement system for certain of its health plans. Blue Cross explained in this notice that, as part of this conversion and in order to help it compete for subscribers, it was reducing payment rates for certain physician categories, including general surgeons, effective April 1, 1997, and that payment rates for primary care physicians would increase.

20. In the summer of 1997, respondent Texas Surgeons' president informed Blue Cross about its general surgeon shareholders' collective dissatisfaction with Blue Cross's general surgery rate reductions that went into effect April 1, 1997. Respondent Texas Surgeons' president identified himself as the authorized spokesperson for respondent Texas Surgeons and began negotiating higher rates on behalf of the general surgeon shareholders. During these rate negotiations, which extended to early 1998, respondent Texas Surgeons' president negotiated according to the collective decisions of the: (1) six respondent medical practice groups, made during Texas Surgeons' board of directors meetings or through other mechanisms; and (2) general surgeon shareholders of respondent Texas Surgeons, made during one or more shareholder meetings or through other mechanisms.

21. Respondent Texas Surgeons' collective negotiations with Blue Cross ultimately led to a rate agreement in February 1998 that increased general surgery rates (on average) more than 29% over the pre-existing rates. At various times during the collective rate negotiations, Blue Cross attempted to negotiate on an individual basis with the six respondent medical practice groups or their shareholders. Each consistently rebuffed, refused, or did not respond to Blue Cross's multiple attempts to initiate individual rate negotiations and indicated that they would only negotiate through respondent Texas Surgeons.

22. Respondent Texas Surgeons sent Blue Cross in September 1997 a package containing contract termination notices for each general surgeon who was at that time a shareholder of respondent Texas Surgeons. Respondent Texas Surgeons' cover letter stated that the contract termination notices were due to Blue Cross's "unacceptable" fee schedule. All 26 of these contract termination notices were on Texas Surgeons' letterhead, had the same date of authorship, and contained identical wording.

23. In November 1997, aware of possible antitrust liability due to its ongoing collective rate negotiations, respondent Texas Surgeons requested that Blue Cross sign a letter waiving Blue Cross's right to file a private antitrust action against either respondent Texas Surgeons or any of its shareholders, regarding the Texas Surgeons-Blue Cross rate negotiations. Because Blue Cross refused to waive its antitrust rights, the six respondent medical practice groups decided to involve a third-party agent in an effort to continue their agreements to collectively negotiate rates and to deal with Blue Cross only on collectively determined terms. The six respondent medical practice groups agreed that their third-party agent would convey to Blue Cross only the highest of the various rate authorizations that he obtained from each of the six respondent medical practice groups, and the third-

party agent did so. Blue Cross rejected that collective rate proposal.

24. On December 1, 1997, due to dissatisfaction with Blue Cross's rate offers and the perceived pace of collective rate negotiations, the general surgeon shareholders of respondent Texas Surgeons effected their contract terminations as originally noticed to Blue Cross in September 1997. To apply further pressure on Blue Cross, respondents announced the Blue Cross contract terminations of their general surgeon shareholders in a prominent advertisement in the major Austin daily newspaper on December 14, 1997.

25. Thereafter, respondent BM&A advised two solo practitioner general surgeons that the BM&A general surgeons would no longer provide back-up surgical coverage for any of their patients if they continued to deal with Blue Cross. Both had expanded their hours to cover Blue Cross general surgeries and were key performers within Blue Cross's small remaining panel of Austin area general surgeons. In or around early February 1998, both submitted contract resignation notices to Blue Cross in order to preserve their back-up coverage arrangements with respondent BM&A.

26. After Blue Cross's receipt of resignation notices from the two solo practitioners (as described in Paragraph 25), and after some difficulty in securing the timely services of a general surgeon for a Blue Cross emergency room patient, Blue Cross concluded that it needed to reach a rate agreement with respondent Texas Surgeons as soon as possible to avoid inadequate general surgery coverage for Blue Cross subscribers in the Austin area.

27. In or around early 1998, with full knowledge of antitrust prohibitions on competitors engaging in collective rate negotiations, respondent CSG negotiated and completed, on behalf of all six respondent medical practice groups, a collective rate agreement with Blue Cross. The respondent medical practice

groups completed this collective rate agreement after respondent Texas Surgeons had received notice that its activities were subject to antitrust investigation. After Blue Cross agreed to increase its rates as demanded by the respondents, all of the general surgeon shareholders of respondent Texas Surgeons that had terminated their Blue Cross contracts rejoined the Blue Cross physician panel by early March 1998.

28. The collective rate increases extracted from Blue Cross by respondents caused Blue Cross to extend those increased rates to surgeries usually performed by Austin area physicians other than general surgeons. Blue Cross keeps all surgeons at the same rate levels to enhance provider relations.

RESPONDENTS' COLLECTIVE RATE NEGOTIATIONS WITH UNITED

29. In October 1997, United HealthCare of Texas-Central Texas Region ("United") notified its participating physicians in the Austin area that, effective January 1, 1998, physician fees, including general surgery fees, would be reduced. Fee reductions for surgeries usually performed by physicians other than general surgeons went into effect and remain in effect in the Austin area, but the proposed (and comparable) fee reductions for surgeries usually or frequently performed by general surgeons never went into effect. Instead, as described below, Austin area general surgery fees for United's various plans increased at least 12% to 40% above the rates that United announced in October 1997.

30. In early November 1997, United received a letter from respondent Texas Surgeons stating that, due to United's "unacceptable" fee reductions for 1998, all of the general surgeon shareholders of respondent Texas Surgeons were terminating their individual contracts with United effective January 1, 1998. The

letter listed the names of all 27 general surgeon shareholders of respondent Texas Surgeons at that time.

31. Also in early November 1997, respondent Texas Surgeons' president and acting vice president told United officials that the general surgeon shareholders of respondent Texas Surgeons would rescind their collective termination notices if United were to increase its general surgery fees at least 20% above United's then current 1997 fee schedule.

32. A United official responded that United preferred to negotiate with the general surgeon shareholders of respondent Texas Surgeons (or their six respondent medical practice groups) on an individual basis. The president and acting vice president of respondent Texas Surgeons rejected that option. When the United official retorted that the general surgeon shareholders were under individual contracts, the Texas Surgeons president responded that he would be willing to produce individual termination letters, if so desired by United.

33. Respondent Texas Surgeons' president further advised United that: (1) the general surgeon shareholders were very interested in announcing through a local newspaper advertisement the collective termination of their United contracts, but that they would hold off if United were to agree to engage in a speedy collective fee negotiation; and (2) he had already told some employees of a large Austin area employer under contract with United that the Texas Surgeons shareholders were planning to drop out of United's network effective January 1, 1998. The respondents knew that United would likely consider public awareness of respondents' collective termination notice as imperiling United's ability to renew the many employer contracts that were expiring beginning in January 1998, and that loss of these contracts would cause heavy subscriber enrollment losses for United.

34. United explored the possibility of creating a panel of Austin area general surgeons that did not include any general surgeon shareholders of respondent Texas Surgeons. United concluded that: (1) general surgeon shareholders of respondent Texas Surgeons were needed to maintain adequate general surgery coverage; (2) any attempt to negotiate with them on an individual basis would likely fail; and (3) it had no realistic alternative other than to begin collective fee negotiations.

35. Prior to the start of collective fee negotiations on November 19, 1997, respondent Texas Surgeons required United to sign a letter waiving United's right to file a private antitrust action against respondent Texas Surgeons or any of its general surgeon shareholders, regarding the Texas Surgeons-United fee negotiations. Respondent Texas Surgeons' president, who attended and led the collective fee negotiations that day, was in frequent telephone and fax contact, and deliberated collectively, with representatives of the six respondent medical practice groups who were assembled together to facilitate collective fee negotiations with United.

36. At the November 19, 1997 collective fee negotiations, respondents demanded and received an agreement from United to pay substantially higher fees for 1998 and 1999. Thereafter, in December 1997, respondent Texas Surgeons sent United a letter on Texas Surgeons letterhead, on behalf of all of the general surgeon shareholders, revoking their November 1997 collective termination notice.

37. The 1998 fees that the respondents extracted from United under its various plans are at least 12% to 34% higher, and their 1999 fees are at least 27% to 40% higher, than United's originally proposed fee schedule that went into effect in 1998 for (and that continues to apply to) surgeries usually performed by physicians other than general surgeons.

EFFECTS

38. The acts and practices of the respondents as described herein have had the purpose or effect, or the tendency and capacity, to restrain competition unreasonably in the provision of services by private general surgeon practitioners in the Austin area and to injure consumers in the following ways, among others:

a. to deprive consumers, including individuals, employers (including the State of Texas Employees Retirement System), and third-party payers, of the benefits of competition;

b. to fix or increase the payments or co-payments that individual patients, their employers, and third-party payers make for the services of general surgeons, and, in the case of Blue Cross managed care plans, for surgeries performed by physicians other than general surgeons;

c. to fix the terms and conditions upon which general surgeons would deal with third-party payers, including terms of compensation, and thereby to raise the prices that individuals and employers pay for health plans offered by third-party payers; and

d. to increase by over one million dollars the amount that Blue Cross, United, their individual subscribers, and employers paid from January 1, 1998 through December 31, 1999 to the six respondent medical practice groups, general surgeon shareholders of respondent Texas Surgeons, and other Austin area physicians.

VIOLATIONS

39. The acts and practices of the respondents as described above are to the prejudice and injury of the public and constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. The acts and practices of the respondents, as described above, are continuing and will continue or recur in the absence of the relief requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this eighteenth day of May, 2000, issues its complaint against said respondents.

By the Commission.

DECISION AND ORDER

The Federal Trade Commission ("Commission") having initiated an investigation of certain acts and practices of Texas Surgeons, P.A. ("Texas Surgeons"), Austin Surgeons, P.L.L.C. ("AS"), Austin Surgical Clinic Association, P.A. ("ASCA"), Bruce McDonald & Associates, P.L.L.C. ("BM&A"), Capital Surgeons Group, P.L.L.C. ("CSG"), Central Texas Surgical Associates, P.A. ("CTSA"), and Surgical Associates of Austin, P.A. ("SAA"), hereinafter sometimes referred to as "respondents," and respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition presented to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of 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 Order ("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 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 Texas Surgeons is a professional association organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its office and principal place of business at 4007 Marathon Blvd., Austin, Texas 78756.

2. Respondent AS is a professional limited liability corporation organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its office and principal place of business at 3901 Medical Parkway, #200, Austin, Texas 78756.

3. Respondent ASCA is a professional association organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its office and principal place of business at 2911 Medical Arts Street, Austin, Texas 78705.

4. Respondent BM&A is a professional limited liability corporation organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its office and principal place of business at 4007 Marathon Blvd., Austin, Texas 78756.

5. Respondent CSG is a professional limited liability corporation organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its office and principal place of business at 3705 Medical Parkway, Austin, Texas 78705.

6. Respondent CTSA is a professional association organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its office and principal place of business at 2300 Round Rock Avenue, Round Rock, Texas 78681.

7. Respondent SAA is a professional association organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its office and principal place of business at 1015 East 32nd Street, Austin, Texas 78705.

8. 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

I.

IT IS ORDERED that, for the purposes of this Order, the following definitions shall apply:

A. "Respondent Texas Surgeons" means Texas Surgeons, P.A., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Texas Surgeons, P.A., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

B. "Respondent medical practice groups" means Austin Surgeons, P.L.L.C., Austin Surgical Clinic Association, P.A., Bruce McDonald & Associates, P.L.L.C., Capital Surgeons Group, P.L.L.C., Central Texas Surgical Associates, P.A., and Surgical Associates of Austin, P.A., each of their directors, officers, employees, agents, representatives, predecessors, successors, and assigns; the subsidiaries, divisions, groups, and affiliates controlled by each respondent medical practice group, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "Respondents" means respondent Texas Surgeons and respondent medical practice groups.

D. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

E. "Payer" means any person that purchases, reimburses for, otherwise pays for all or part of, or arranges for the payment of, any health care services for itself or for any

other person. Payer includes, but is not limited to: any health insurance company; preferred provider organization; prepaid hospital, medical, or other health service plan; health maintenance organization; government health benefits program; employer or other person providing or administering self-insured health benefits programs; and patients who purchase health care for themselves.

F. "Physician" means a doctor of allopathic medicine (M.D.) or a doctor of osteopathic medicine (D.O.).

G. "Provider" means any person, including but not limited to any physician, hospital, or clinic, that supplies health care services to any other person.

H. "Qualified risk-sharing joint arrangement" means an arrangement to provide physician services in which: (1) all participating physicians share substantial financial risk from their participation in the arrangement and thereby create incentives for the participating physicians to jointly control costs and improve quality by managing the provision of physician services, such as risk sharing involving (a) the provision of physician services to payers or providers at a capitated rate, (b) the provision of physician services for a predetermined percentage of premium or revenue from payers or providers, (c) the use of significant financial incentives (e.g., substantial withholds) for its participating physicians, as a group, to achieve 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 payment, 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; (2) any agreement concerning reimbursement or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement; and (3) the arrangement does not restrict the ability, or facilitate the refusal, of physicians participating in the arrangement to deal with payers or providers on an individual basis or through any other arrangement.

I. "Qualified clinically-integrated joint arrangement" means an arrangement to provide physician services in which: (1) all participating physicians 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 participating in the arrangement, in order to control costs and ensure the quality of services provided through the arrangement; (2) any agreement concerning reimbursement or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement; and (3) the arrangement does not restrict the ability, or facilitate the refusal, of physicians participating in the arrangement to deal with payers or providers on an individual basis or through any other arrangement.

J. "Reimbursement" means any payment, whether cash or non-cash, or other benefit received for the provision of physician services.

K. "Austin area physician" means any physician who has active staff privileges at one or more hospitals within any of the Texas counties of Travis, Williamson, Hays, Caldwell, and Bastrop.

II.

IT IS FURTHER ORDERED that each respondent, 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:

1. To negotiate on behalf of any physicians with any payer or provider for physician services;

2. To deal, refuse to deal, or threaten to refuse to deal with, or boycott or threaten to boycott, any payer or provider;

3. Regarding any term, condition, or requirement upon which any physicians deal, or are willing to deal, with any payer or provider, including, but not limited to, terms of reimbursement;

4. To restrict the ability, or facilitate the refusal, of any physician to negotiate or deal with any payer or provider on an individual basis or through an arrangement not involving one or more respondents; or

5. To convey to any payer or provider through any Austin area physician any information (including, but not limited to, any actual or contemplated views,

intentions, positions, terms, proposals, or decisions) on behalf of any physician concerning:

a. negotiation of any actual or proposed term, condition, or requirement of dealing with any payer or provider;

b. any actual or contemplated intention or decision with respect to:

(1) entering into, refusing to enter into, threatening to refuse to enter into, withdrawing from, or threatening to withdraw from any actual or proposed agreement with any payer or provider; or

(2) agreeing to, refusing to agree to, or willingness to agree to any actual or proposed term, condition, or requirement of dealing with any payer or provider.

B. Exchanging, transferring, or facilitating in any manner the exchange or transfer among any Austin area physicians of information (including, but not limited to, any views, intentions, positions, terms, proposals, or decisions) concerning:

1. negotiation with any payer or provider of actual or proposed terms, conditions, or requirements regarding reimbursement;

2. any Austin area physician's actual or contemplated intention or decision with respect to:

a. entering into, refusing to enter into, threatening to refuse to enter into, withdrawing from, or threatening to withdraw from any actual or proposed agreement with any payer or provider; or

b. agreeing to, refusing to agree to, or willingness to agree to any actual or proposed term, condition, or requirement of dealing with any payer or provider.

C. Encouraging, urging, suggesting, requesting, advising, pressuring, assisting, inducing, or attempting to induce any non-governmental person to engage in any action that would be prohibited if the person were subject to this Order.

PROVIDED that nothing in this Order shall prohibit any respondent medical practice group from participating in or furthering any arrangement to provide physician services that is limited to physicians who practice medicine within such respondent as a shareholder, owner, or employee.

PROVIDED FURTHER that nothing in this Order shall prohibit conduct that is approved and supervised by the State of Texas insofar as that conduct is protected from liability under the federal antitrust laws pursuant to the state action doctrine.

PROVIDED FURTHER that nothing in this Order shall prohibit any agreement involving, or conduct by, any respondent that is reasonably necessary to form, participate in, or take any other action in furtherance of a qualified risk-sharing joint arrangement or a qualified clinically-integrated joint arrangement, so long as the notification provisions contained in Paragraph V. of this Order have been satisfied.

III.

IT IS FURTHER ORDERED that:

A. Within thirty (30) days after the date on which this Order becomes final, respondent Texas Surgeons shall distribute by first-class mail a copy of this Order, the accompanying complaint, and the Notice in Attachment A to this Order, to:

1. Each payer or provider listed in Attachment B to this Order;

2. Each person who, at any time on or after January 1, 1996, has been an officer, director, manager, participating physician, shareholder, or owner of respondent Texas Surgeons;

3. Each other agent, representative, or employee of respondent Texas Surgeons.

B. Within thirty (30) days after the date on which this Order becomes final, each respondent medical practice group shall distribute by first-class mail a copy of this Order, the accompanying complaint, and the Notice in Attachment A to this Order, to:

1. Each officer, director, manager, participating physician, shareholder, or owner of such respondent who is not a shareholder of respondent Texas Surgeons;

2. Each other agent, representative, or employee of such respondent;

3. Each payer or provider not listed in Attachment B that, at any time from September 1, 1999 to December 31, 1999, has paid such respondent, or any participating

physician of such respondent, for the provision of physician services under an executed contract.

C. For a period of five (5) years after the date this Order becomes final, respondent Texas Surgeons shall:

1. Within thirty (30) days of the date the person assumes such position, distribute by first-class mail a copy of this Order and the accompanying complaint to each new officer, director, manager, participating physician, shareholder, or owner of respondent Texas Surgeons, and to each other new agent, representative, or employee of respondent Texas Surgeons;

2. Annually publish, in an official annual report, newsletter, or memorandum sent to all shareholders, owners, and participating physicians, a copy of this Order and the accompanying complaint with such prominence as is given to official communications or regularly featured articles;

3. Annually brief shareholders, owners, and participating physicians on the meaning and requirements of this Order and the antitrust laws, including penalties for the violation of this Order.

D. For a period of five (5) years after the date this Order becomes final, each respondent medical practice group shall:

1. Within thirty (30) days of the date the person assumes such position, distribute by first-class mail a copy of this Order and the accompanying complaint to each new officer, director, manager, participating physician, shareholder, or owner of such respondent (unless such

person is a shareholder of respondent Texas Surgeons), and to each other new agent, representative, or employee of such respondent;

2. Annually publish, in an official annual report, newsletter, or memorandum sent to all shareholders, owners, and participating physicians of such respondent, a copy of this Order and the accompanying complaint with such prominence as is given to official communications or regularly featured articles;

3. Annually brief shareholders, owners, and participating physicians of such respondent, who are not shareholders of respondent Texas Surgeons, on the meaning and requirements of this Order and the antitrust laws, including penalties for the violation of this Order.

IV.

IT IS FURTHER ORDERED that each respondent shall:

A. File a verified written report with the Commission within sixty (60) days after this Order becomes final, annually thereafter for five (5) years on the anniversary of the date the Order becomes final, and at such other times as the Commission may by written notice require, setting forth in detail the manner and form in which such respondent intends to comply, is complying, and has complied, with this Order. In addition to any other information that may be necessary to demonstrate compliance, respondent Texas Surgeons shall include in such reports information identifying each payer and provider that has communicated with respondent Texas Surgeons concerning a possible contract for physician services, the proposed terms and conditions of any such contract, and respondent Texas Surgeons' response to such payer or provider.

B. Notify the Commission at least thirty (30) days prior to any proposed change in such respondent, such as dissolution, assignment, sale resulting in the emergence of a successor, the creation or dissolution of subsidiaries, or any other change in respondent that may affect compliance obligations arising out of this Order.

V.

IT IS FURTHER ORDERED that, for a period of ten (10) years after the date this Order is entered:

A. Each respondent shall notify the Commission in writing at least thirty (30) days prior to forming, participating in, or taking any action, other than planning, in furtherance of any:

1. Qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement involving two (2) or more Austin area physicians; or

2. Other arrangement that, in dealing or negotiating with any payer or provider, is using, or intends to use, an agent that represents two (2) or more Austin area physicians.

B. If a representative of the Commission makes a written request for information within thirty (30) days after receipt of a notice pursuant to Paragraph V.A.1. of this Order, respondents shall not form, participate in, or take any action, other than planning, in furtherance of the arrangement until thirty (30) days after substantially complying with such request for information or such

shorter waiting period as may be granted by letter from the Bureau of Competition.

PROVIDED that no prior notification is required under this Paragraph for action by a respondent medical practice group in furtherance of any arrangement that is limited to physicians who practice medicine within such respondent as a shareholder, owner, or employee.

VI.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, each respondent 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, correspondences, memoranda, calendars, and other records and documents in the possession or under the control of such respondent relating to any matter contained in this Order; and

B. Upon five (5) business days' notice, and without restraint or interference, to interview officers, directors, employees, agents, and other representatives of any respondent.

VII.

IT IS FURTHER ORDERED that this Order shall terminate on May 18, 2020.

By the Commission.

Attachment A

NOTICE

The Order accompanying this Notice, among other provisions, prohibits Texas Surgeons, P.A. (an association of 26 general surgeons in the Austin, Texas, area) ("Texas Surgeons") and six named medical practice groups (whose physicians comprise almost all of the members of Texas Surgeons) from participating in or facilitating any agreement to:

* negotiate on behalf of physicians with any health plan or any other purchaser of physician services;

* deal, refuse to deal, or threaten to refuse to deal with, or boycott or threaten to boycott, any health plan or any other purchaser of physician services;

* restrict the ability of any physician to negotiate or deal on an independent basis with any health plan or any other purchaser.

Another provision of the Order prohibits Texas Surgeons and the six practice groups from exchanging, or facilitating the exchange of, among any Austin area physicians, certain information relating to negotiations and dealings with health plans and other purchasers of physician services.

The Order permits an arrangement that sets collective price terms or other collective terms and conditions of dealing only if it is a "qualified risk-sharing joint arrangement" or "qualified clinically-integrated joint arrangement" (as defined in the Order). Nothing in the Order prohibits any of the six practice groups from furthering any arrangement to provide physician services that is limited to physicians within the practice group. Further, the Order

does not prohibit any conduct that is approved and supervised by the State of Texas and is protected from liability under the federal antitrust laws by the state action doctrine.

The Texas Surgeons and the six practice groups may participate in an arrangement in which the individual practice groups or individual physicians convey and receive, through a third party, information, offers, and responses from and to health plans or other purchasers, so long as such negotiations remain individual and do not violate the Order. For additional information about how such negotiations can remain individual, see the August 1996 *Statements of Antitrust Enforcement Policy in Health Care* jointly issued by the Federal Trade Commission and the U.S. Department of Justice, including pages 43-52, 89-92, 125-27, and 138-40. A copy of that publication is available through the Commission's web site: www.ftc.gov.

Attachment B

Aetna U.S. Healthcare
10101 Reunion Place, Suite 200
San Antonio, TX 78216

AmeriHealth of Texas
10711 Burnet Road, Suite 312
Austin, TX 78758

Amil International, Inc.
9229 Waterford Centre Blvd., Suite 500
Austin, TX 78758

Blue Cross Blue Shield of Texas, Inc.
9020 Capital of Texas Hwy. North
Building II, Suite 400

Austin, TX 78759

Foundation Health Systems, Inc.
9101 Burnet Road, Suite 104
Austin, TX 78758

Healthsource Texas, Inc.
1701 Directors Blvd., Suite 110
Austin, TX 78744

Humana Health Care Plans
8303 N. MoPac Expressway, Suite 450
Austin, TX 78759

NYLCare Health Plans of the Gulf Coast, Inc.
8701 N. MoPac Expressway, Suite 440
Austin, TX 78759

Prudential Health Care Plan, Inc.
7700 Chevy Chase Drive
Building I, Suite 500
Austin, TX 78752

Scott & White Health Plan
One Chisholm Trail, Suite 200
Round Rock, TX 78681

United HealthCare of Texas, Inc.
1250 S. Capital of Texas Highway
Building One, Suite 400
Austin, TX 78746

Vista Health Plan, Inc.
7801 North I-35
Austin, TX 78753

Analysis of Agreement Containing Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement to a proposed consent order by the Texas Surgeons, P.A. ("Texas Surgeons IPA") and six medical practice groups comprised of Texas Surgeons IPA members – Austin Surgeons, P.L.L.C.; Austin Surgical Clinic Association, P.A.; Bruce McDonald & Associates, P.L.L.C.; Capital Surgeons Group, P.L.L.C.; Central Texas Surgical Associates, P.A.; and Surgical Associates of Austin, P.A. The agreement settles charges by the Federal Trade Commission that the Texas Surgeons IPA and the six medical practice groups (the "respondents") violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by fixing prices and other terms of dealing with third-party payers; collectively refusing to deal with third-party payers or threatening to do so; and agreeing to deal with third-party payers only on collectively determined terms. The proposed consent order has been placed on the public record for thirty (30) days for reception 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 and the comments received, and will decide whether it should withdraw from the agreement or make it and 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 in any way their terms. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by any respondent that the law has been violated as alleged in the complaint.

The Complaint

Under the terms of the agreement, a complaint will be issued by the Commission along with the proposed consent order. The allegations in the Commission's proposed complaint are summarized below.

Respondent Texas Surgeons IPA is an association of general surgeons who practice in the Austin, Texas area. Members of the Texas Surgeons IPA are, and at all times relevant to the complaint have been, the majority of general surgeon private practitioners serving the adult population in the Austin area.

Nearly all of the members of the Texas Surgeons IPA belong to one of six general surgery practice groups, which are also respondents in this matter. At all times relevant to the complaint, the Texas Surgeons IPA has been governed by a board of directors composed of representatives from each of the respondent medical practice groups.

The Texas Surgeons IPA has served as a vehicle for the six respondent medical practice groups (and the few solo practitioner members) to engage in actual or threatened concerted refusals to deal, and to negotiate collectively, in order to obtain higher prices from Blue Cross Blue Shield of Texas ("Blue Cross") and United HealthCare of Texas ("United"). The six respondent medical practice groups actively furthered the unlawful conduct through their collective control of the Texas Surgeons IPA board of directors, and through their direct participation in collective fee negotiations between United and the Texas Surgeons IPA.

In April 1997, Blue Cross changed its reimbursement system from one based on historical charges to one based on a Resource Based Relative Value Scale, similar to the system used by the federal government in its Medicare program. The effect of this

change was to increase rates paid to primary care physicians, and to reduce rates to all physician specialists, including general surgeons. Soon thereafter, respondents, through the Texas Surgeons IPA, began collectively negotiating higher rates.

Despite multiple attempts by Blue Cross to negotiate individually with the six respondent medical practice groups, those groups insisted on negotiating only through the Texas Surgeons IPA. In September 1997, the Texas Surgeons IPA sent Blue Cross a package of identically worded contract termination notices for each general surgeon member of the Texas Surgeons IPA, with a cover letter stating that the termination notices were due to Blue Cross's "unacceptable" rate reductions. In November 1997, the Texas Surgeons IPA asked Blue Cross to waive its right to bring a private antitrust action regarding the Texas Surgeons IPA's rate negotiations with Blue Cross, but Blue Cross refused to sign the waiver. In December 1997, 26 members of the Texas Surgeons IPA, dissatisfied with Blue Cross's payment offers, collectively effected their resignations from Blue Cross, and jointly announced that action in a prominent advertisement in Austin's major daily newspaper.

In early 1998, Blue Cross experienced difficulty in securing the services of a general surgeon for an emergency room patient. At about the same time, two more general surgeons resigned from Blue Cross. These two general surgeons had been advised by one of the respondent medical practice groups that their inclusion in an arrangement with that practice group regarding back-up surgical coverage would end if they continued to deal with Blue Cross.

After these events, Blue Cross concluded that it needed to reach a rate agreement with the respondents as soon as possible to avoid inadequate general surgery coverage for Blue Cross subscribers in the Austin area. The collective rate agreement between the six respondent medical practice groups and Blue Cross that resulted in early 1998 increased Blue Cross general surgery rates nearly 30% above the April 1997 levels.

Respondents began collective price negotiations with United soon after it announced fee reductions for general surgeons and other physicians in October 1997. The new fees went into effect on January 1, 1998 for surgical procedures not usually performed by general surgeons, but comparable proposed fee reductions for general surgeons never went into effect. Instead, respondents caused general surgery fees for United's various plans to increase at least 12% to 40% above the fees that United announced in October 1997.

In early November 1997, United received a written notice from the Texas Surgeons IPA that all of its members would be terminating their contracts with United effective January 1, 1998, due to the proposed fee reductions for 1998. The Texas Surgeons IPA indicated its desire to collectively negotiate higher fees and rejected United's request to negotiate with the six respondent medical practice groups on an individual basis. United explored the possibility of creating a panel of general surgeons that did not include general surgeons from the six respondent medical practice groups, but it concluded that such a panel would not provide adequate general surgery coverage and that it had no realistic alternative to beginning collective fee negotiations with the Texas Surgeons IPA.

Prior to the start of a collective fee negotiation session in November 1997, the Texas Surgeons IPA required United to sign a waiver of its right to bring a private antitrust action against the Texas Surgeons IPA or its members stemming from those fee negotiations. At that collective fee negotiation session, respondents demanded and received an agreement from United to pay higher fees in 1998 and 1999, as described above. Representatives from the six respondent medical practice groups assembled together and collectively participated in this collective

fee negotiation session through frequent telephone and fax contact with the Texas Surgeons IPA's lead negotiator.

The Texas Surgeons IPA did not engage in any activity that might justify collective agreements on the prices they would accept for their services. Respondents' actions have restrained competition among general surgeons in the Austin area and thereby have harmed, or tended to harm, consumers (including third-party payers, subscribers, and their employers) by:

* depriving consumers of the benefits of competition;

* increasing by over one million dollars the amount that Blue Cross, United, their individual subscribers, and employers (including the State of Texas Employees Retirement System and other self-insured employers that utilize the Blue Cross or United physician network) paid for the services of surgeons during the period from January 1, 1998 to December 31, 1999;

* fixing the payments or co-payments that individual patients, their employers, and third-party payers make for the services of surgeons;

* fixing the terms and conditions upon which general surgeons would deal with third-party payers; and

* raising the prices that individuals and employers pay for health plan coverage offered by third-party payers.

The Proposed Consent Order

The proposed order is designed to prevent recurrence of the illegal concerted actions alleged in the complaint, while allowing respondents to engage in legitimate joint conduct. The Commission notes that in 1999, some time after the investigation of this matter began, the State of Texas enacted legislation that permits the State Attorney General to approve, under certain

conditions, joint negotiations between health plans and groups of competing physicians. Texas Senate Bill 1468, 76th Leg., R.S. ch., 1586 (1999). The conduct that gave rise to the investigation and consent agreement predated enactment of the law, and thus was not approved under its terms. Moreover, the conduct described in the complaint would not necessarily have met the conditions for approval set forth in the Act.

Enactment of the statute does not eliminate the need for an order in this matter. The statute permits only collective negotiations that are approved by the Attorney General, imposes conditions under which that approval may be granted, and by its terms expires on September 1, 2003. As is discussed below, the Commission's order does not prohibit future conduct that is approved and supervised by the State of Texas pursuant to its statute and protected from federal antitrust liability under the state action doctrine. It is necessary and appropriate, however, to provide a remedy against future conduct by the respondents that is not approved and supervised by the State of Texas.

The core operative provisions of the proposed order are contained in Section II. Section II.A prohibits respondents from entering into or facilitating any agreement: (1) to negotiate physician services on behalf of any physicians with any payer or provider; (2) to deal, refuse to deal, or threaten to refuse to deal with any payer or provider; (3) regarding any term on which any physicians deal, or are willing to deal, with any payer or provider; (4) to restrict the ability, or facilitate the refusal, of any physician to deal with any payer or provider on an individual basis or through any other arrangement; or (5) to convey to any payer or provider, through any Austin area physician, any information concerning actual or potential dealings by any physician with any payer or provider.

The fifth provision listed above (Section II.A.5 of the proposed order) ensures that communications between any respondent and any payer within a "messenger model" arrangement be conveyed by a neutral third party (someone other than a physician with an active practice in the Austin area). In a messenger model arrangement, physicians individually convey and receive, through a third party, information, offers, and responses from and to payers or providers. *See* Statements of Antitrust Enforcement Policy in Health Care, issued jointly by the Federal Trade Commission and the U.S. Department of Justice (August 28, 1996) at 43-52, 89-92, 125-27, 138-40, 4 *Trade Reg. Rep. (CCH)* ¶ 13,153. In addition, Section V.A.2 of the order ensures that any respondent intending to use a messenger model arrangement provide prior notification to the Commission.

Section II.B prohibits respondents from exchanging, transferring, or facilitating the exchange or transfer of information among Austin area physicians concerning: (1) negotiation with any payer or provider regarding reimbursement terms; or (2) actual or contemplated intentions or decisions with respect to any terms, dealings or refusals to deal with any payer or provider. Section II.C prohibits respondents from encouraging, advising, or pressuring any person, other than the government, to engage in any action that would be prohibited if the person were subject to the order.

Section II contains three provisos. The first permits each respondent medical practice group to participate in arrangements for the provision of physician services that are limited to physicians from the same medical practice group. The second proviso, as noted above, permits respondents to engage in conduct that is approved and supervised by the State of Texas, so long as that conduct is protected from liability under the federal antitrust laws pursuant to the state action doctrine. The state action doctrine protects from federal antitrust liability any private conduct that is both: (1) in accordance with a clearly articulated and affirmatively expressed state policy to supplant competition; and (2) actively supervised by the state itself. *See, e.g., FTC v.*

Ticor Title Insurance Co., 504 U.S. 621 (1992); *California Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc.*, 445 U.S. 97, 105 (1980).

The third proviso allows respondents to engage in conduct (including collectively determining reimbursement and other terms of contracts with payers) that is reasonably necessary to operate any "qualified risk-sharing joint arrangement" or "qualified clinically-integrated joint arrangement," provided respondents comply with the prior notification requirements set forth in Section V of the order. The prior notification mechanism will allow the Commission to evaluate a specific proposed arrangement and assess its likely competitive impact. This requirement will help guard against any recurrence of acts and practices that have restrained competition and injured consumers.

As defined in the order, a "qualified risk-sharing joint arrangement" must satisfy three conditions. First, all physicians participating in the arrangement must share substantial financial risk from their participation in the arrangement. The definition illustrates ways in which physicians might share financial risk, tracking the types of financial risk-sharing set forth in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care. Second, any agreement on prices or terms of reimbursement entered into by the arrangement must be reasonably necessary to obtain significant efficiencies through the joint arrangement. Third, the arrangement must be non-exclusive – *i.e.*, it must not restrict the ability, or facilitate the refusal, of physicians participating in the arrangement to deal with payers individually or through any other arrangement.

A "qualified clinically-integrated joint arrangement" pertains to arrangements in which the physicians undertake cooperative activities to achieve efficiencies in the delivery of clinical services, without necessarily sharing substantial financial risk. As

with risk-sharing arrangements, the definition of clinically integrated joint arrangements reflects the analysis contained in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care. According to the order's definition, the participating physicians must have a high degree of interdependence and cooperation through their use of programs to evaluate and modify their clinical practice patterns, in order to control costs and assure the quality of physician services provided through the arrangement. In addition, as with risk-sharing arrangements, the arrangement must be non-exclusive and any agreement on prices or terms of reimbursement entered into by the arrangement must be reasonably necessary to obtain significant efficiencies through the joint arrangement.

Sections III.A and III.B require respondents to distribute the order and complaint to its members and other specified persons, including payers. Sections III.C and III.D require that each respondent, for the next five years: (1) distribute copies of the order and complaint to new members and other specified persons; (2) publish annually to members and owners a copy of the order and complaint; and (3) brief members and owners annually on the meaning and requirements of the order and the antitrust laws.

Sections IV and VI consist of standard Commission reporting and compliance procedures. Section IV specifies that Texas Surgeons IPA must include in its annual reports information identifying each payer or provider that has communicated with Texas Surgeons IPA concerning a possible contract for physician services, the proposed terms of any such contract, and Texas Surgeons IPA's response to the payer or provider.

Finally, Section VII of the proposed order contains a twenty year "sunset" provision under which the order terminates twenty years after the date the order was issued.

IN THE MATTER OF

ABBOTT LABORATORIES, ET AL.

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

Docket C-3945; File No. 9810395
Complaint, May 22, 2000--Decision, May 22, 2000

This consent order prohibits Respondents Abbot Laboratories and Geneva Pharmaceuticals, Inc. from entering agreements in which the first company to file an ANDA agrees with the NDA holder not to relinquish its right to the 180-day exclusivity period established under the Hatch-Waxman Act, or agreements where the ANDA first filer from agrees not to develop or market a generic drug product that is not the subject of a patent infringement lawsuit. The order also prohibits agreements involving payments to keep a generic drug off the market during patent infringement litigation brought by an NDA holder, and respondents can only enter these arrangements if specific criteria are met. This prohibition includes agreements made in the context of an interim settlement of a patent infringement action, whereby the NDA holder pays the generic not to enter the market, unless the parties obtain court approval through a process that is designed to enhance the court's ability to assess the competitive implications of the agreement. In addition, the order requires that Respondents notify the Commission 30 days before entering into an agreement in which an ANDA first filer agrees with an NDA holder to refrain from going to market.

Participants

For the Commission: *Karen Bokat, Bradley S. Albert, Daniel Kotchen, Robin Moore, David Narrow, Martha Oppenheim, David Pender, Richard A. Feinstein, William K. Tom, Daniel Ducore, Alan A. Fisher, Roy B. Levy,* and *Gregory S. Vistnes.*

For the Respondents: *Jeffrey Weinberger, Munger Tolles & Olson,* and *Wayne Cross, Dewey Ballentine.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that respondents Abbott Laboratories and Geneva Pharmaceuticals, Inc., have engaged in conduct, as described herein, that violates Section 5 of the Federal Trade Commission 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:

The Respondents

1. Respondent Abbott Laboratories ("Abbott") is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Illinois, with its office and principal place of business located at 100 Abbott Park Road, Abbott Park, Illinois 60064. Abbott is engaged principally in the development, manufacture, and sale of a broad line of health care products and services. In 1998, Abbott had net sales of $12.5 billion worldwide and $7.7 billion domestically. Among other products, Abbott manufactures and sells the brand-name product Hytrin, a drug that accounts for over 20% of the net sales of Abbott's U.S. pharmaceutical products division.

2. At all relevant times herein, Abbott has been, and is now, a corporation as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

3. Respondent Geneva Pharmaceuticals, Inc. ("Geneva") is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Colorado, with its office and principal place of business located at 2555 W. Midway Blvd., Broomfield, Colorado 80020. Geneva, an indirect wholly-owned subsidiary of Novartis Corporation, is one of

the leading generic drug manufacturers in the United States. Geneva sought and received approval from the United States Food and Drug Administration ("FDA") to market a generic version of Hytrin.

4. At all relevant times herein, Geneva has been, and is now, a corporation as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

5. Respondents' acts and practices, including the acts and practices alleged herein, are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

Federal Regulation of Pharmaceutical Products

6. Under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., approval by the United States Food & Drug Administration ("FDA") is required before a company may market or sell a pharmaceutical product in the United States. Approval for a new or brand name drug is sought by filing a New Drug Application ("NDA") with the FDA.

7. A generic drug is a product that the FDA has found to be bioequivalent to a brand name drug. Generic drugs are chemically identical to their branded counterparts, but typically are sold at substantial discounts from the branded price. Approval may be sought for a generic version of a brand name drug by filing an Abbreviated New Drug Application ("ANDA") with the FDA.

8. The FDA maintains a book of Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the "FDA Orange Book"), which lists all patents that the brand name manufacturer asserts relate to each brand name drug. If

an applicant intends to market a generic product before the expiration of one or more patents relating to a brand name drug, the applicant must certify to the FDA that the patent or patents listed in the FDA Orange Book are either invalid or not infringed by the generic version of the product (a "Paragraph IV Certification"), and must notify the holder of the approved NDA and the owner of the patent or patents of the filing of the ANDA. If neither the patent holder nor the NDA holder files a patent infringement suit against the ANDA filer within 45 days of receipt of notification of a Paragraph IV Certification, the FDA review and approval process may proceed and, upon FDA approval of the ANDA, the generic product may be marketed. If a patent infringement suit is filed against the ANDA filer within the 45-day period, however, FDA approval of the ANDA is automatically stayed until the earliest of: (i) patent expiration; (ii) a final judicial determination of non-infringement or invalidity in the lawsuit; or (iii) the expiration of a 30-month period from the time the patent holder receives Paragraph IV Certification.

9. The Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 (the "Hatch-Waxman Act"), as currently implemented by the FDA, provides that the first applicant to submit an ANDA with a Paragraph IV Certification for a generic version of a brand name drug ("ANDA first filer") is entitled to a 180-day period of marketing exclusivity ("180-day Exclusivity Period") before the FDA may grant final approval of any other generic manufacturer's ANDA regarding the same brand name drug. This period does not begin to run until either the generic is commercially marketed or a court enters final judgment that the patents subject to the Paragraph IV Certification are invalid or not infringed. No other generic manufacturer may obtain FDA approval to market its product until the ANDA first filer's 180-day Exclusivity Period has expired.

Relevant Product and Geographic Market

10. The relevant product market for assessing respondents' anticompetitive conduct is terazosin hydrochloride ("terazosin HCL"). Terazosin HCL is used principally to treat benign prostatic hyperplasia ("BPH" or enlarged prostate) and hypertension. Both hypertension and BPH are chronic conditions that afflict millions of Americans, many of whom are senior citizens. BPH afflicts at least 50% of the men over 60, and results in 1.7 million men each year making office visits to their physicians. Total U.S. sales of terazosin HCL amount to approximately $540 million per year.

11. Hytrin, which is manufactured and marketed by Abbott, is the pioneer brand name drug in the United States containing terazosin HCL. Hytrin was introduced in 1987. It was the only terazosin HCL product sold in the United States until Geneva introduced such a product on or around August 13, 1999.

12. Other drugs are not effective substitutes for terazosin HCL because they are different in terms of chemical composition, safety, efficacy, and side effects. In addition, there is little price sensitivity between terazosin HCL and non-terazosin HCL products.

13. The relevant geographic market is the United States.

Factual Background

14. Hytrin, which Abbott market in tablet and capsule form, has been one of the company's most important products. Abbott introduced Hytrin tablets in 1987. In 1995, Abbott launched Hytrin capsules, which now account for over 90% of Hytrin sales. In 1998, Abbott's sales of Hytrin amounted to $542

million in the United States alone, accounting for 9.41 million prescriptions. For the first 6 months of 1999, Abbott reported $292 million in U.S. sales of Hytrin, representing over 20% of the net sales of Abbott's pharmaceutical division.

15. Abbott currently holds at least seven patents that relate to terazosin HCL. Abbott's initial patent covering the chemical compound terazosin HCL expired in or around 1994.

16. Geneva filed ANDAs covering a tablet form and a capsule form of generic terazosin HCL. It was the first company to file an ANDA for each form. Geneva submitted its tablet ANDA to the FDA in or around January 1993, and its capsule ANDA was submitted in or around December 1995.

17. In early 1996, Abbott notified the FDA of a new patent ('207 patent) relating to its Hytrin product, and the FDA listed that patent in the FDA Orange Book. In April 1996, Geneva filed a Paragraph IV certification with the FDA, claiming that its generic terazosin HCL tablet and capsule products did not infringe any of Abbott's patents covering terazosin HCL, including Abbott's newly listed '207 patent, and notified Abbott of the Paragraph IV certification.

18. On June 4, 1996, Abbott sued Geneva in the Northern District of Illinois, claiming patent infringement by Geneva's terazosin HCL tablet product. Abbott made no infringement claim against Geneva's terazosin HCL capsule product, even though both of Geneva's products involved the same potential infringement issues.

19. Pursuant to the Hatch-Waxman Act, Abbott's lawsuit triggered a 30-month stay of final FDA approval of Geneva's terazosin HCL tablet ANDA, until December 1998. Because no infringement claim had been filed within the requisite 45-day period, the FDA review and approval process for Geneva's terazosin HCL capsule ANDA could proceed without delay.

20. By early 1998, Geneva, including particularly its CEO, was confident that it ultimately would prevail in its patent infringement dispute with Abbott.

21. Accordingly, Geneva pushed ahead in early 1998 with plans to bring to market as soon as possible its generic terazosin HCL capsule product, which could have received FDA approval at any time. Preparations to launch this product were proceeding on all fronts: the manufacturing team sought to validate with the FDA its terazosin HCL capsule manufacturing process; the purchasing department instructed its product supplier to manufacture commercial quantities of terazosin HCL active ingredient; sales and marketing personnel were contacting customers to inform them of an impending launch and to enter into distribution contracts; and the legal staff was drafting papers to oppose any effort by Abbott to block Geneva's entry.

22. The FDA granted Geneva final approval to market generic terazosin HCL capsules on March 30, 1998.

23. As the first generic company to submit a Paragraph IV Certification for generic terazosin HCL, Geneva was entitled to the 180-day Exclusivity Period pursuant to the Hatch-Waxman Act, as currently interpreted. Unless and until Geneva's 180-day Exclusivity Period had been triggered and had expired, or Geneva relinquished its entitlement to this period of exclusivity, only Geneva would be approved by the FDA to market a generic terazosin HCL product.

Anticompetitive Conduct

24. On March 30, 1998, the very day it was granted FDA approval to market its generic terazosin HCL capsules, Geneva contacted Abbott and announced that it would launch its generic terazosin HCL capsules unless it was paid by Abbott not to enter the market. From Abbott's perspective, a launch of Geneva's generic terazosin HCL product would have had a significant adverse impact on Abbott's financial performance. Abbott forecasted that entry of generic terazosin HCL on April 1, 1998 would have eliminated over $185 million in Hytrin sales in just six months. Because Hytrin was highly profitable, Abbott sought to keep from the market Geneva and all other potential generic competition to Hytrin, until at least February 2000.

25. Over the course of two days, representatives of Abbott and Geneva negotiated the framework for an agreement, whereby Abbott would pay Geneva not to enter the market. Abbott estimated Geneva's revenues from launching generic terazosin HCL at $1 million to $1.5 million per month, but was willing to pay Geneva a "premium" over that not to compete.

26. On April 1, 1998, Abbott and Geneva entered into a written agreement ("Agreement"), pursuant to which Geneva agreed not to enter the market with any generic terazosin HCL capsule or tablet product until the earlier of: (1) the final resolution of the patent infringement litigation involving Geneva's terazosin HCL tablets product, including review through the Supreme Court; or (2) entry of another generic terazosin HCL product. Geneva also agreed – at Abbott's insistence – not to transfer, assign, or relinquish its right to a 180-day Exclusivity Period.

27. In exchange, Abbott agreed to pay Geneva $4.5 million per month in non-refundable payments until a district court judgment in the parties' patent infringement dispute. Respondents agreed that if the district court declared that

Geneva's tablet product did not or would not infringe any valid and enforceable claim of the '207 patent, Abbott would thereafter pay the $4.5 million monthly payments into an escrow fund until the final resolution of the litigation. Under the Agreement, the party prevailing in the litigation would receive the money in the escrow fund.

28. The court hearing the patent litigation was not made aware of the respondents' Agreement.

29. In the words of Geneva's CEO at the time the Agreement was signed, this Agreement represented to Geneva the "best of all worlds," because Geneva obtained a risk-free "monetary settlement on an ongoing basis until the litigation was resolved" and still could market its product exclusively for 180 days after the litigation was over.

30. In accordance with the terms of the Agreement, in April 1998, Geneva refrained from entering the market with its generic terazosin HCL capsules, and instead began receiving monthly payments of $4.5 million from Abbott.

31. On September 1, 1998, the United States District Court for the Northern District of Illinois granted Geneva's motion for summary judgment in its patent tablet litigation with Abbott, invalidating Abbott's patent under the on-sale provision of 35 U.S.C. § 102(b).

32. The district court's decision invalidating Abbott's patent only strengthened Geneva's litigation position. Nonetheless, Geneva, in accordance with the terms of the Agreement, did not enter the generic terazosin HCL market even after the favorable district court decision.

33. On July 1, 1999, the United States Court of Appeals for the Federal Circuit affirmed, without dissent, the summary judgment in favor of Geneva. Under the Agreement, Geneva still could not enter the generic terazosin HCL market until after the Supreme Court either denied Abbott's petition for certiorari or disposed of the patent infringement litigation. Nonetheless, in August 1999, aware of the Commission's investigation, the respondents canceled their Agreement, and on August 13, 1999, Geneva finally introduced its generic terazosin HCL capsule product to the marketplace. The Supreme Court denied certiorari on January 10, 2000.

The Effects of Respondents' Conduct

34. The acts and practices of the respondents as herein alleged have had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition by preventing or discouraging the entry of competition in the form of generic versions of Hytrin into the relevant market.

35. As a result of respondents' conduct as herein alleged, consumers were deprived of the benefits of new competition from Geneva and other generic competitors. Without this lower-priced generic competition, consumers, pharmacies, hospitals, insurers, wholesalers, government agencies, managed care organizations, and others were forced to purchase Abbott's more expensive Hytrin product.

36. Earlier entry of a generic terazosin HCL product would have had a significant procompetitive impact in the relevant market. Pharmacists generally are permitted, and in some instances required, to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed. In addition, there is a ready market for generic products because certain third-party payers of prescription drugs (*e.g.*, managed care plans and Medicaid programs) encourage or insist on the use of generic drugs wherever possible. A generic product can quickly and

efficiently enter the marketplace at substantial discounts, generally leading to a significant erosion of the branded drug's sales within the first year. For example, Abbott's forecasts projected that generic terazosin HCL would capture roughly 70% of Hytrin sales within the first six months alone.

37. The purpose and effect of the $4.5 million monthly payments from Abbott to Geneva during the term of the Agreement were to ensure that Geneva would not enter the relevant market, and would not take any steps, including giving up its right to a 180-day Exclusivity Period, to permit or facilitate the entry of any other generic manufacturer.

38. By prohibiting Geneva from transferring, assigning, or giving up its right to a 180-day Exclusivity Period until the final resolution of the patent infringement litigation involving Geneva's terazosin HCL tablets product, the Agreement had the purpose and effect of preventing Geneva from relinquishing its eligibility for a 180-day Exclusivity Period under the Hatch-Waxman Act. As of February 1999, at least one other generic manufacturer had satisfied the FDA's requirements for approval and was barred from entering the market because Geneva's 180-day Exclusivity Period had not begun to run.

39. The Agreement is not justified by any countervailing efficiency.

Violations Alleged

40. The Abbott-Geneva Agreement as a whole, and particular provisions such as that described in Paragraphs 37 and 38 above, constitute an unreasonable restraint of trade in violation of Section 5 of the Federal Trade Commission Act, as amended.

41. Abbott and Geneva acted with the specific intent that Abbott monopolize the relevant market, and engaged in overt acts described in Paragraphs 24-33 above in furtherance of a conspiracy to monopolize the relevant market, in violation of Section 5 of the Federal Trade Commission Act, as amended.

42. Abbott had monopoly power in the relevant market and monopolized that market in violation of Section 5 of the Federal Trade Commission Act, as amended.

43. The acts and practices described above are anticompetitive in nature and tendency and constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, as amended.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-second day of May, 2000, issues its complaint against said respondents.

By the Commission.

DECISION AND ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of certain acts and practices of Abbott Laboratories (hereinafter referred to as "Respondent Abbott") and Geneva Pharmaceuticals, Inc. ("Geneva"), an indirect wholly-owned subsidiary of Novartis Corporation, and Respondent Abbott having been furnished thereafter with a copy of a draft Complaint which the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent Abbott with violation of the Federal Trade Commission Act; and

Respondent Abbott and counsel for the Commission having thereafter executed an Agreement Containing Consent Order, an admission by Respondent Abbott of all the jurisdictional facts set forth in the aforesaid draft Complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondent Abbott that the law has been violated as alleged in such complaint, 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 Abbott 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 agreement on the public record for a period of thirty (30) days, and having duly considered the comments filed 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 Abbott Laboratories is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Illinois, with its office and principal place of business located at 100 Abbott Park Road, Abbott Park, Illinois 60064.

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

ORDER

I.

IT IS ORDERED that for the purposes of this order, the following definitions shall apply:

A. "Respondent Abbott" means Abbott Laboratories, its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Abbott, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

B. "Commission" means the Federal Trade Commission.

C. "180-day Exclusivity Period" means the period of time established by Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j) *et seq.*).

D. "Agreement" means anything that would constitute an agreement under Section 1 of the Sherman Act or Section 5 of the Federal Trade Commission Act.

E. "ANDA" means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j) *et seq*.

F. "ANDA First Filer" means the party whom the FDA determines is entitled to, or eligible for, a right to a 180-day Exclusivity Period which has not yet expired.

G. "Control" means an entity in which Abbott has an interest greater than 50%.

H. "Drug Product" means a finished dosage form (e.g., tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients, as defined in 21 C.F.R. § 314.3(b).

I. "FDA" means the United States Food and Drug Administration.

J. "NDA" means a New Drug Application, as defined under 21 U.S.C. § 355(b) *et seq*.

K. "NDA Holder" means: (1) the party that received FDA approval to market a Drug Product pursuant to an NDA; (2) a party owning or controlling enforcement of the patent(s) listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the "FDA Orange Book") in connection with the NDA; or (3) the predecessors, subsidiaries, divisions, groups and affiliates controlled by the entities described in subparagraphs (1) and (2) above, as well as the entities' licensees, successors and assigns.

L. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

M. "Relinquishing" means transferring, selling, assigning, waiving, or relinquishing.

II.

IT IS FURTHER ORDERED that Respondent Abbott cease and desist, either directly or indirectly, in connection with the sale of Drug Products in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, from being a party to any Agreement in which Respondent Abbott is an NDA Holder for a Drug Product(s), any other party is the ANDA First Filer for the Drug Product(s), and:

A. the ANDA First Filer is prohibited by such Agreement from relinquishing, or is subject to a penalty, forfeiture, or loss of benefit if it relinquishes, its right to the 180-Day Exclusivity Period; or

B. the ANDA First Filer agrees to refrain from researching, developing, manufacturing, marketing, or selling any Drug Product that could be approved for sale by the FDA pursuant to the ANDA and that is not the subject of a court action alleging patent infringement.

Provided, however, that nothing in this Paragraph II prohibits any agreement which restricts the ANDA First Filer's right to relinquish any rights under its ANDA except as set forth above.

III.

IT IS FURTHER ORDERED that, in any instance where Respondent Abbott is a party to a patent infringement action in which it is the NDA Holder, it shall cease and desist, either directly or indirectly, in connection with the sale of Drug Products in or affecting commerce, as Acommerce@ is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. ' 44, from being a party to any Agreement in which the parties do not agree to dismiss the litigation, and in which the NDA Holder provides anything of value to the alleged infringer and the alleged infringer agrees to refrain during part or all of the course of the litigation from selling the Drug Product at issue, or any Drug Product containing the same chemical entity(ies) at issue. Notwithstanding the above, however, such an Agreement is permissible when entered into in conjunction with a joint stipulation between the parties that the court may enter a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure, if: (1) together with the stipulation for a preliminary injunction, Respondent Abbott provides the court with the proposed Agreement, as well as a copy of the Commission=s complaint, order, and Analysis to Aid Public Comment in this matter; (2) Respondent Abbott has provided Notification, as described in Paragraph V below, to the Commission at least thirty (30) days prior to submitting the stipulation for a preliminary injunction; (3) Respondent Abbott does not oppose any effort by the Commission to participate, in

any capacity permitted by the court, in the court=s consideration of any such action for preliminary relief; and (4) the court issues an order which incorporates the terms of the Agreement. Nothing in this Paragraph shall be interpreted to prohibit or restrict the right of Respondent Abbott to unilaterally seek relief from the court, without notice to the Commission, including but not limited to, applying for preliminary injunctive relief or seeking to extend the 30-month stay pursuant to 21 U.S.C. ' 355(j)(4)(B)(iii).

IV.

IT IS FURTHER ORDERED that Respondent Abbott shall provide Notification as described in Paragraph V below to the Commission at least thirty (30) days before becoming a party to any Agreement made after the date the Agreement Containing Consent Order is signed where it is the NDA Holder and an ANDA First Filer agrees to refrain from selling any Drug Product under its ANDA for any period of time.

V.

The Notification required by Paragraphs III and IV shall be filed with the Secretary of the Commission and shall include the following information, to the extent known and not subject to any legally recognized privilege: (1) identification of the parties involved in the Agreement; (2) identification of all Drug Products involved in the Agreement; (3) identification of all persons who have filed an ANDA with the FDA (including the status of such application) for any Drug Product containing the same chemical entity(ies) as the Drug Product(s) involved in the Agreement; (4) a copy of the proposed Agreement; (5) identification of the court, and a copy of the docket sheet, for any legal action which involves either party to the Agreement and relates to any Drug Product(s) containing the same chemical entity(ies) involved in the Agreement; and (6) all documents which were prepared by or for any officer(s) or director(s) of Respondent Abbott for the purpose of evaluating or analyzing the Agreement.

VI.

IT IS FURTHER ORDERED that Respondent Abbott shall file a verified written report within sixty (60) days after the date this order becomes final, annually thereafter for five (5) years on the anniversary of the date this order becomes final, and at such other times as the Commission may by written notice require, setting forth in detail the manner and form in which Respondent Abbott intends to comply, is complying, and has complied with

this order. Respondent Abbott shall include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with this order.

VII.

IT IS FURTHER ORDERED that Respondent Abbott shall notify the Commission at least thirty (30) days prior to any proposed change in Respondent Abbott such as dissolution, assignment, sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in Respondent Abbott that may affect compliance obligations arising out of this order.

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 Respondent Abbott, Respondent Abbott shall permit any duly authorized representative of the Commission:

A. Access, during office hours and in the presence of counsel, to all facilities, and 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 compliance with this order; and

B. To interview officers, directors, employees, agents, and other representatives of Respondent Abbott, who may have counsel present, regarding such compliance issues.

IX.

IT IS FURTHER ORDERED that with respect to any affiliate of Respondent Abbott in which Respondent Abbott owns 50%, but not more than and not less than 50%: (1) Respondent Abbott shall notify all such affiliates of Abbott's obligations under this Order; (2) Respondent Abbott shall not request, solicit, or direct such affiliates to enter into any agreement which, if entered into by Respondent Abbott, would violate the terms of this Order; (3) Respondent Abbott shall not approve any such agreement if it is presented to Respondent Abbott for its approval; (4) Respondent Abbott shall vote against approval if any such agreement is presented to the affiliate's Board of Directors; and (5) in the event any such agreement is not presented to Respondent Abbott or to the affiliate's Board for approval, Respondent Abbott shall notify the Commission if the affiliate enters into any such agreement and Respondent Abbott acquires knowledge thereof.

X.

IT IS FURTHER ORDERED that this order shall terminate on May 22, 2010.

By the Commission.

STATEMENT OF CHAIRMAN ROBERT PITOFSKY AND COMMISSIONERS SHEILA F. ANTHONY, MOZELLE W. THOMPSON, ORSON SWINDLE, AND THOMAS B. LEARY

The attached Analysis to Aid Public Comment, which accompanied our acceptance of consent agreements with Geneva Pharmaceuticals, Inc. and Abbott Laboratories, describes the conduct of those two companies in agreeing that Abbott would pay Geneva to refrain from selling a generic version of Hytrin, Abbott's branded version of terazosin hydrochloride. It also describes relevant provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), including particularly the provision that gives the first generic company to seek FDA approval a 180-day period during which it has the exclusive right to market the generic version of a brand name drug.

Pursuant to a private agreement not reviewed by any court, Abbott paid Geneva substantial sums not to enter the market with its generic version of Hytrin, and not to transfer, assign or relinquish its 180-day exclusive marketing right to any other producer of generic products that might compete with Abbott. By not selling its generic version, Geneva prevented the start of the 180-day exclusivity period, with the result that neither Geneva nor any other company could introduce a generic version of Hytrin into the market.

The consent orders that we issue today against Abbott and Geneva represent the first resolution of an antitrust challenge by the government to a private agreement whereby a brand name drug company paid the first generic company that sought FDA approval not to enter the market, and to retain its 180-day period of market exclusivity. Because the behavior occurred in the context of the complicated provisions of the Hatch-Waxman Act,

and because this is the first government antitrust enforcement action in this area, we believe the public interest is satisfied with orders that regulate future conduct by the parties. We recognize that there may be market settings in which similar but less restrictive arrangements could be justified, and each case must be examined with respect to its particular facts.

In March we also issued an administrative complaint against two other pharmaceutical companies with respect to conduct that is in some ways similar to the conduct addressed by these consent orders. We anticipate that the development of a full factual record in the administrative proceeding will help to shape further the appropriate parameters of permissible conduct in this area and will guide other companies and their legal advisors.

Pharmaceutical firms should now be on notice, however, that arrangements comparable to those addressed in the present consent orders can raise serious antitrust issues, with a potential for serious consumer harm. Accordingly, in the future, the Commission will consider its entire range of remedies in connection with enforcement actions against such arrangements, including possibly seeking disgorgement of illegally obtained profits.

If firms are uncertain about the limits of permissible behavior under the Hatch-Waxman Act, they may, of course, seek advisory opinions from the staff of this agency.

Analysis to Aid Public Comment

The Federal Trade Commission has accepted for public comment agreements and proposed consent orders with Geneva Pharmaceuticals, Inc. and Abbott Laboratories. The proposed consent orders settle charges that these parties unlawfully agreed

that Geneva would refrain from selling its generic version of one of Abbott's drugs, in exchange for payments from Abbott. The proposed consent orders have been placed on the public record for 30 days to receive comments by interested persons. The proposed consent orders have been entered into for settlement purposes only and do not constitute an admission by Abbott or Geneva that they violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true.

Background

Abbott Laboratories develops, manufactures, and sells a variety of health care products and services. Based in Abbott Park, Illinois, Abbott's 1998 net sales worldwide were approximately $ 12.5 billion. Over 20% of Abbott's net sales of pharmaceutical products in the U.S. are for a drug called Hytrin. Hytrin is used to treat two chronic conditions that affect millions of Americans, particularly senior citizens: hypertension (high blood pressure) and benign prostatic hyperplasia (enlarged prostate).

Geneva is one of the leading generic drug manufacturers in the United States. An indirect wholly-owned subsidiary of Novartis Corp., Geneva is based in Broomfield, Colorado. Geneva developed a generic version of Hytrin, and in March 1998 received approval from the U.S. Food and Drug Administration ("FDA") to market that generic product.

A generic drug is a product that the FDA has found to be bioequivalent to a brand name drug. A company seeking FDA approval to market a new drug must file a New Drug Application ("NDA"). In order to market a generic version of a brand name drug, a company must file an Abbreviated New Drug Application ("ANDA") and receive approval from the FDA.

Generic drugs are chemically identical to their branded counterparts, but typically are sold at substantial discounts from the branded price. A Congressional Budget Office Report estimates that purchasers saved an estimated $8-$10 billion on prescriptions at retail pharmacies in 1994 by purchasing generic drugs instead of the brand name product.[1]

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as "the Hatch-Waxman Act," to facilitate the entry of generic drugs while maintaining incentives to invest in new drug development. In particular, the Hatch-Waxman Act establishes certain rights and procedures in situations where a company seeks FDA approval to market a generic product prior to the expiration of a patent or patents relating to a brand name drug upon which the generic is based. In such cases, the applicant must: (1) certify to the FDA that the patent in question is invalid or is not infringed by the generic product (known as a "paragraph IV certification"); and (2) notify the patent holder of the filing of the certification. If the holder of patent rights files a patent infringement suit within 45 days, FDA approval to market the generic drug is automatically stayed for 30 months, unless before that time the patent expires or is judicially determined to be invalid or not infringed. This automatic 30-month stay allows the patent holder time to seek judicial protection of its patent rights before a generic competitor is permitted to market its product.

In addition, the Hatch-Waxman Act provides an incentive for generic drug companies to bear the cost of patent litigation that may arise when they challenge invalid patents or design around valid ones. The Act grants the first company to file an ANDA in such cases a 180-day period during which it has the exclusive right to market a generic version of the brand name drug. No other generic manufacturer may obtain FDA approval to market

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[1] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* at xiii, 13 (July 1998).

its product until the first filer's 180-day exclusivity period has expired.

Geneva was the first company to file an ANDA for terazosin hydrochloride ("terazosin HCL"), the generic version of Hytrin. It filed applications covering a tablet form and a capsule form of its generic terazosin HCL. Geneva filed a paragraph IV certification with the FDA stating that these products did not infringe any valid patent held by Abbott covering terazosin HCL. In June 1996, Abbott sued Geneva for patent infringement by Geneva's terazosin HCL tablet product, but due to an oversight failed to make an infringement claim against Geneva's capsule product, although both products raised the same potential infringement issues.

Abbott's lawsuit triggered a 30-month stay of final FDA approval of Geneva's terazosin HCL tablet ANDA, until December 1998. No stay applied to the FDA approval process for Geneva's terazosin HCL capsule ANDA, however, because no infringement claim was filed within the statutory time period required by the Hatch-Waxman Act. The FDA granted Geneva final approval to market generic terazosin HCL capsules on March 30, 1998.

The Challenged Agreement

The complaint challenges an agreement whereby Abbott, following the FDA approval of Geneva's generic terazosin HCL capsule product, paid Geneva not to enter the market during their ongoing patent litigation over the tablet product. According to the complaint, on the day it was granted approval to market its generic terazosin HCL capsules, Geneva contacted Abbott and announced that it would launch its generic terazosin HCL capsules unless it was paid by Abbott not to enter. Two days later, on April 1, 1998, Abbott and Geneva entered into an

agreement, pursuant to which Geneva agreed not to enter the market with any generic terazosin HCL capsule or tablet product until the earlier of: (1) the final resolution of the patent infringement litigation involving Geneva's terazosin HCL tablets product, including review through the Supreme Court; or (2) entry of another generic terazosin HCL product.

Geneva also agreed – at Abbott's insistence – not to transfer, assign, or relinquish its 180-day exclusivity right. The effect of this provision was to ensure that no other company's generic terazosin HCL product could obtain FDA approval and enter the market during the term of the agreement, because Geneva's agreement not to launch its product meant that the 180-day exclusivity period would not expire.

In exchange, Abbott agreed to pay Geneva $4.5 million per month until a district court judgment in the parties' patent infringement dispute, and then (assuming Geneva won in the district court) to pay the $4.5 million monthly payments into an escrow fund until the final resolution of the litigation, which Geneva would then receive if its district court victory was upheld.

Abbott's payment to Geneva of $4.5 million a month was well over the $1 to $1.5 million per month that, the complaint states, Abbott believed Geneva would forego by staying off the market. The complaint alleges that Abbott was willing to pay Geneva a "premium" to refrain from competing because of the substantial impact that launch of a generic version of Hytrin would have on Abbott's overall financial situation. Abbott forecasted that entry of generic terazosin HCL on April 1, 1998 would eliminate over $185 million in Hytrin sales in just six months. Accordingly, the complaint charges, Abbott sought to forestall Geneva -- and all other potential generic competition to Hytrin – from entering the market because of the threat they represented to the high profits it was making from Hytrin.

The complaint further charges that, in accordance with the terms of the agreement, Geneva did not enter the market with its generic terazosin HCL capsules, even after the district court and the court of appeals upheld Geneva's position that Abbott's patent was invalid. In August 1999, Abbott and Geneva – aware of the Commission's investigation – terminated their agreement (which by its terms would not have ended until disposition of the litigation by the Supreme Court). Geneva finally brought its generic terazosin HCL capsule product to market on August 13, 1999.

Competitive Analysis

The complaint charges that the challenged agreement prevented competition that Abbott's Hytrin product would otherwise have faced from generic products of Geneva and other potential generic competitors. Generic drugs can have a swift marketplace impact, because pharmacists generally are permitted, and in some instances are required, to substitute lower-priced generic drugs for their branded counterparts, unless the prescribing physician directs otherwise. In addition, there is a ready market for generic products because certain third-party payers of prescription drugs (*e.g.*, state Medicaid programs and many private health plans) encourage or insist on the use of generic drugs wherever possible. Abbott's forecasts, the complaint states, projected that generic terazosin HCL would capture roughly 70% of Hytrin sales within the first six months following its launch. The agreement, however, ensured that Geneva would not offer generic terazosin HCL in competition with Hytrin, and would not take action – such as relinquishing exclusivity rights – that would have permitted the entry of any other generic manufacturer.

These restraints on generic competition had direct and substantial effects on consumers. Without a lower-priced generic alternative, consumers, government agencies, health plans, pharmacies, hospitals, wholesalers, and others were forced to purchase Abbott's more expensive Hytrin product. Other drugs, the complaint states, are not effective substitutes for terazosin HCL because they are different in terms of chemical composition, safety, efficacy, and side effects. There is little price sensitivity between terazosin HCL and other products. Thus, the complaint alleges that the sale of terazosin HCL in the United States is the relevant market within which to assess the effects of the challenged agreement.

The challenged conduct represents an agreement not to compete between potential horizontal competitors. A firm is a potential competitor if there is evidence that entry by that firm is reasonably probable in the absence of the agreement at issue.[2] Geneva certified to the FDA that its entry with generic HCL would not infringe a valid patent, and was confident that it ultimately would prevail in its patent infringement dispute with Abbott, the complaint states. In early 1998, Geneva was making preparations to launch its generic terazosin HCL capsule product as soon as possible. After receiving FDA approval for the capsule product, Geneva threatened to launch that product unless Abbott paid it not to do so. The challenged agreement directly restrained competition between these potential competitors.

In addition, the agreement created a bottleneck that prevented any other potential competitors from entering the market, because no other ANDA filer could obtain FDA approval until Geneva's 180 day exclusivity period expired. Other companies were developing generic terazosin HCL products, and at least one other generic manufacturer had satisfied the FDA's requirements for approval by February 1999, but was barred from entering the

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[2] Federal Trade Commission and United States Department of Justice, *Antitrust Guidelines for the Licensing of Intellectual Property* at § 1.1 n.6 (1995).

market because Geneva's failure to launch its product meant its 180-day exclusivity right had not even begun to run.

The complaint states that the challenged agreement is not justified by any countervailing efficiency. Although **the** agreement between Abbott and Geneva provided substantial private benefits to both parties, the facts in this matter demonstrate that the broad restraints were not justified by any benefits to competition and consumer welfare. The Commission considered whether the agreement could be considered a procompetitive effort to effectuate a temporary settlement of a patent dispute, akin to a court-ordered preliminary injunction. However, it finds that any legitimate interest in resolving patent disputes cannot justify the harm to consumers imposed by the agreement in this case. The restraint imposed exceeds what likely would be available to the parties under a court-ordered preliminary injunction. For example, it: (1) barred Geneva's entry beyond the pendency of the district court litigation; (2) provided large up-front payments that could be expected to create disincentives for Geneva to enter (in contrast to a court-ordered bond to cover damages actually incurred as a result of the court's injunction); (3) barred Geneva from relinquishing its exclusivity rights; (4) prohibited Geneva from developing or marketing non-infringing generic products. Moreover, the restraints contained in the agreement were entered into without any judicial finding that Abbott was likely to succeed on the merits of its infringement suit, without any consideration of whether Abbott would suffer irreparable injury, and without any weighing of the equities, including any consideration of the public interest.

The complaint also charges that Abbott had a monopoly in the market for terazosin HCL, and, by entering into the agreement with Geneva, Abbott sought to preserve its dominance by delaying the entry of Geneva and other generic companies into the market. As detailed above, there were no countervailing

justifications for Abbott's conduct. In addition, the complaint alleges that Abbott and Geneva conspired to monopolize the market for terazosin HCL. As stated in the complaint, Abbott and Geneva acted with specific intent that Abbott monopolize the market for terazosin HCL, and entered into a conspiracy to achieve that goal. Finally, the parties' agreement otherwise amounts to an unfair method of competition in violation of Section 5 of the FTC Act.

The Proposed Orders

The proposed orders are designed to remedy the unlawful conduct charged in the complaint. Although the particular agreement challenged in the complaint has been terminated, prospective relief is necessary to prevent a recurrence of similar agreements with respect to other drugs. Private agreements in which the brand name drug company (the NDA holder) pays the first generic to seek FDA approval (the first filer) not to enter the market can substantially delay generic competition and raise serious antitrust issues. Moreover, the FDA, which has expressed concern about such private agreements, has observed that the incentives for companies to enter into such arrangements are becoming greater, as the returns to the brand name company from extending its monopoly increasingly exceed the potential economic gains to the generic applicant from its 180 days of market exclusivity.[3]

In essence, the proposed orders:

- bar two particular types of agreements between brand name drug companies and potential generic competitors -- restrictions on giving up Hatch-Waxman 180-day exclusivity rights and on entering the market with a non-infringing product;

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[3] FDA Proposed Rule Regarding 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed.Reg. 42873, 42882-83 (August 6, 1999).

- require that agreements involving payments to the generic company to stay off the market be approved by the court when undertaken in the context of an interim settlement of patent litigation, with notice to the Commission to allow it time to present its views to the court;

- require respondents to give the Commission written notice 30 days before entering into such agreements in other contexts; and

- require that Geneva waive its right to 180-day marketing exclusivity for its generic terazosin HCL tablet product, so that other generic tablet producers can immediately enter the market.

Paragraph II prohibits two kinds of agreements between "an NDA Holder" and "the ANDA First Filer" (that is, the party possessing an unexpired right to Hatch-Waxman 180-day exclusivity). Paragraph II.A. bars agreements in which the first company to file an ANDA agrees with the NDA holder not to relinquish its right to the 180-day exclusivity period established under the Hatch-Waxman Act. Paragraph II.B. prohibits the ANDA first filer from agreeing not to develop or market a generic drug product that is not the subject of a patent infringement lawsuit. The order prohibits restrictions on giving up exclusivity rights and on competing with a non-infringing product because under the circumstances of this case these restraints are not justified.

Paragraph II's focus on agreements between an NDA holder and the ANDA first filer does not mean that the Commission believes that there is no risk of competitive harm in other contexts. In particular, Abbott or Geneva's participation in an

agreement in which a generic company that is not the ANDA first filer is paid by the NDA holder not to market a non-infringing product could raise substantial competitive concerns. Given the variety of circumstances in which the restraints may arise, however, and the possibility that some legitimate justifications might exist in some other contexts, the Commission believes that it is appropriate at this time to limit the flat bans in Paragraph II to agreements between NDA holders and ANDA first filers.

Paragraph III bans private agreements involving payments to keep a generic drug off the market during patent infringement litigation brought by an NDA holder. Abbott and Geneva can enter into such arrangements only if (a) they are presented to the court and embodied in a court-ordered preliminary injunction, and (b) the following other conditions are met: (i) along with any stipulation for preliminary injunction, they provide the court with a copy of the Commission's complaint, order, and this Analysis to Aid Public Comment in this matter, as well as the proposed agreement between the parties; (ii) at least 30 days before submitting the stipulation to the court, they provide written notice to the Commission; and (iii) they do not oppose Commission participation in the court's consideration of the request for preliminary relief.

Thus, the proposed orders bar agreements made in the context of an interim settlement of a patent infringement action, whereby the NDA holder pays the generic not to enter the market, unless the parties obtain court approval through a process that is designed to enhance the court's ability to assess the competitive implications of the agreement. This remedy, in addition to facilitating the court's access to information about the Commission's views, also makes the process public and thereby may prompt other generic drug manufacturers (or other interested parties) to alert the court to potential anticompetitive provisions that could delay their entry into the market. Furthermore, the Commission believes that the requirement that the agreement be filed on the public record with the court will deter Abbott and Geneva from entering into anticompetitive agreements.

Paragraph IV addresses certain agreements to stay off the market that are not covered by Paragraph III because they do not involve interim relief in a litigated matter. Such situations would include agreements that are part of a final settlement of the litigation, and situations in which no litigation has been brought. In these circumstances, there is no judicial role in ordering relief agreed to by the parties. The Commission is concerned about such private agreements in which the first filer is paid by the NDA holder not to enter the market, because of the substantial risk of competitive harm that they may create. Thus, the order requires that Abbott and Geneva notify the Commission 30 days before entering into an agreement in which an ANDA first filer agrees with an NDA holder to refrain from going to market. Such notice will assist the Commission in detecting anticompetitive agreements before they have caused substantial injury to consumers. Absent the order, there is no mechanism for the antitrust enforcement agencies to find out about such agreements.

The form of notice that Abbott and Geneva must provide to the Commission under Paragraphs III and IV of the orders is set forth in Paragraph V. In addition to supplying a copy of the proposed agreement, they are required to provide certain other information to assist the Commission in assessing the potential competitive impact of the agreement. Accordingly, the orders require them to identify, among other things, all others who have filed an ANDA for a product containing the same chemical entities as the product at issue, and the court that is hearing any relevant legal proceedings involving either party. In addition, they must provide the Commission with all documents that evaluate the proposed agreement.

In addition, the proposed order against Geneva requires that it waive its 180-day marketing exclusivity period for its generic terazosin HCL tablet product. Although Geneva's exclusivity

right with respect to the terazosin capsules product has expired, its exclusivity period for the tablet product still remains as a barrier to entry. This provision of the order will therefore open the market to greater generic competition in terazosin HCL products.

The proposed orders also contain certain reporting and other provisions that are designed to assist the Commission in monitoring compliance with the order and are standard provisions in Commission orders.

The orders will expire in 10 years.

Opportunity for Public Comment

The proposed orders have been placed on the public record for 30 days in order to receive 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 agreements and the comments received and will decide whether it should withdraw from the agreements or make the proposed orders final.

The purpose of this analysis is to facilitate public comment on the agreements. The analysis is not intended to constitute an official interpretation of the agreements, the proposed complaint, or the proposed consent orders, or to modify their terms in any way.

IN THE MATTER OF

GENEVA PHARMACEUTICALS, ET AL.

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

Docket C-3946; File No. 9810395
Complaint, May 22, 2000--Decision, May 22, 2000

This consent order prohibits Respondents Abbot Laboratories and Geneva Pharmaceuticals, Inc. from entering agreements in which the first company to file an ANDA agrees with the NDA holder not to relinquish its right to the 180-day exclusivity period established under the Hatch-Waxman Act, or agreements where the ANDA first filer from agrees not to develop or market a generic drug product that is not the subject of a patent infringement lawsuit. The order also prohibits agreements involving payments to keep a generic drug off the market during patent infringement litigation brought by an NDA holder, and respondents can only enter these arrangements if specific criteria are met. This prohibition includes agreements made in the context of an interim settlement of a patent infringement action, whereby the NDA holder pays the generic not to enter the market, unless the parties obtain court approval through a process that is designed to enhance the court's ability to assess the competitive implications of the agreement. In addition, the order requires that Respondents notify the Commission 30 days before entering into an agreement in which an ANDA first filer agrees with an NDA holder to refrain from going to market.

Participants

For the Commission: *Karen Bokat, Bradley S. Albert, Daniel Kotchen, Robin Moore, David Narrow, Martha Oppenheim, David Pender, Richard A. Feinstein, William K. Tom, Daniel Ducore, Alan A. Fisher, Roy B. Levy,* and *Gregory S. Vistnes.*

For the Respondents: *Jeffrey Weinberger, Munger Tolles & Olson,* and *Wayne Cross, Dewey Ballentine.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that respondents Abbott Laboratories and Geneva Pharmaceuticals, Inc., have engaged in conduct, as described herein, that violates Section 5 of the Federal Trade Commission 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:

The Respondents

1. Respondent Abbott Laboratories ("Abbott") is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Illinois, with its office and principal place of business located at 100 Abbott Park Road, Abbott Park, Illinois 60064. Abbott is engaged principally in the development, manufacture, and sale of a broad line of health care products and services. In 1998, Abbott had net sales of $12.5 billion worldwide and $7.7 billion domestically. Among other products, Abbott manufactures and sells the brand-name product Hytrin, a drug that accounts for over 20% of the net sales of Abbott's U.S. pharmaceutical products division.

2. At all relevant times herein, Abbott has been, and is now, a corporation as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

3. Respondent Geneva Pharmaceuticals, Inc. ("Geneva") is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Colorado, with its office and principal place of business located at 2555 W. Midway Blvd., Broomfield, Colorado 80020. Geneva, an indirect wholly-owned subsidiary of Novartis Corporation, is one of

the leading generic drug manufacturers in the United States. Geneva sought and received approval from the United States Food and Drug Administration ("FDA") to market a generic version of Hytrin.

4. At all relevant times herein, Geneva has been, and is now, a corporation as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

5. Respondents' acts and practices, including the acts and practices alleged herein, are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

Federal Regulation of Pharmaceutical Products

6. Under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., approval by the United States Food & Drug Administration ("FDA") is required before a company may market or sell a pharmaceutical product in the United States. Approval for a new or brand name drug is sought by filing a New Drug Application ("NDA") with the FDA.

7. A generic drug is a product that the FDA has found to be bioequivalent to a brand name drug. Generic drugs are chemically identical to their branded counterparts, but typically are sold at substantial discounts from the branded price. Approval may be sought for a generic version of a brand name drug by filing an Abbreviated New Drug Application ("ANDA") with the FDA.

8. The FDA maintains a book of Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the "FDA Orange Book"), which lists all patents that the brand name manufacturer asserts relate to each brand name drug. If

an applicant intends to market a generic product before the expiration of one or more patents relating to a brand name drug, the applicant must certify to the FDA that the patent or patents listed in the FDA Orange Book are either invalid or not infringed by the generic version of the product (a "Paragraph IV Certification"), and must notify the holder of the approved NDA and the owner of the patent or patents of the filing of the ANDA. If neither the patent holder nor the NDA holder files a patent infringement suit against the ANDA filer within 45 days of receipt of notification of a Paragraph IV Certification, the FDA review and approval process may proceed and, upon FDA approval of the ANDA, the generic product may be marketed. If a patent infringement suit is filed against the ANDA filer within the 45-day period, however, FDA approval of the ANDA is automatically stayed until the earliest of: (i) patent expiration; (ii) a final judicial determination of non-infringement or invalidity in the lawsuit; or (iii) the expiration of a 30-month period from the time the patent holder receives Paragraph IV Certification.

9. The Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 (the "Hatch-Waxman Act"), as currently implemented by the FDA, provides that the first applicant to submit an ANDA with a Paragraph IV Certification for a generic version of a brand name drug ("ANDA first filer") is entitled to a 180-day period of marketing exclusivity ("180-day Exclusivity Period") before the FDA may grant final approval of any other generic manufacturer's ANDA regarding the same brand name drug. This period does not begin to run until either the generic is commercially marketed or a court enters final judgment that the patents subject to the Paragraph IV Certification are invalid or not infringed. No other generic manufacturer may obtain FDA approval to market its product until the ANDA first filer's 180-day Exclusivity Period has expired.

Relevant Product and Geographic Market

10. The relevant product market for assessing respondents' anticompetitive conduct is terazosin hydrochloride ("terazosin HCL"). Terazosin HCL is used principally to treat benign prostatic hyperplasia ("BPH" or enlarged prostate) and hypertension. Both hypertension and BPH are chronic conditions that afflict millions of Americans, many of whom are senior citizens. BPH afflicts at least 50% of the men over 60, and results in 1.7 million men each year making office visits to their physicians. Total U.S. sales of terazosin HCL amount to approximately $540 million per year.

11. Hytrin, which is manufactured and marketed by Abbott, is the pioneer brand name drug in the United States containing terazosin HCL. Hytrin was introduced in 1987. It was the only terazosin HCL product sold in the United States until Geneva introduced such a product on or around August 13, 1999.

12. Other drugs are not effective substitutes for terazosin HCL because they are different in terms of chemical composition, safety, efficacy, and side effects. In addition, there is little price sensitivity between terazosin HCL and non-terazosin HCL products.

13. The relevant geographic market is the United States.

Factual Background

14. Hytrin, which Abbott markets in tablet and capsule form, has been one of the company's most important products. Abbott introduced Hytrin tablets in 1987. In 1995, Abbott launched Hytrin capsules, which now account for over 90% of Hytrin sales. In 1998, Abbott's sales of Hytrin amounted to $542

million in the United States alone, accounting for 9.41 million prescriptions. For the first 6 months of 1999, Abbott reported $292 million in U.S. sales of Hytrin, representing over 20% of the net sales of Abbott's pharmaceutical division.

15. Abbott currently holds at least seven patents that relate to terazosin HCL. Abbott's initial patent covering the chemical compound terazosin HCL expired in or around 1994.

16. Geneva filed ANDAs covering a tablet form and a capsule form of generic terazosin HCL. It was the first company to file an ANDA for each form. Geneva submitted its tablet ANDA to the FDA in or around January 1993, and its capsule ANDA was submitted in or around December 1995.

17. In early 1996, Abbott notified the FDA of a new patent ('207 patent) relating to its Hytrin product, and the FDA listed that patent in the FDA Orange Book. In April 1996, Geneva filed a Paragraph IV certification with the FDA, claiming that its generic terazosin HCL tablet and capsule products did not infringe any of Abbott's patents covering terazosin HCL, including Abbott's newly listed '207 patent, and notified Abbott of the Paragraph IV certification.

18. On June 4, 1996, Abbott sued Geneva in the Northern District of Illinois, claiming patent infringement by Geneva's terazosin HCL tablet product. Abbott made no infringement claim against Geneva's terazosin HCL capsule product, even though both of Geneva's products involved the same potential infringement issues.

19. Pursuant to the Hatch-Waxman Act, Abbott's lawsuit triggered a 30-month stay of final FDA approval of Geneva's terazosin HCL tablet ANDA, until December 1998. Because no infringement claim had been filed within the requisite 45-day period, the FDA review and approval process for Geneva's terazosin HCL capsule ANDA could proceed without delay.

20. By early 1998, Geneva, including particularly its CEO, was confident that it ultimately would prevail in its patent infringement dispute with Abbott.

21. Accordingly, Geneva pushed ahead in early 1998 with plans to bring to market as soon as possible its generic terazosin HCL capsule product, which could have received FDA approval at any time. Preparations to launch this product were proceeding on all fronts: the manufacturing team sought to validate with the FDA its terazosin HCL capsule manufacturing process; the purchasing department instructed its product supplier to manufacture commercial quantities of terazosin HCL active ingredient; sales and marketing personnel were contacting customers to inform them of an impending launch and to enter into distribution contracts; and the legal staff was drafting papers to oppose any effort by Abbott to block Geneva's entry.

22. The FDA granted Geneva final approval to market generic terazosin HCL capsules on March 30, 1998.

23. As the first generic company to submit a Paragraph IV Certification for generic terazosin HCL, Geneva was entitled to the 180-day Exclusivity Period pursuant to the Hatch-Waxman Act, as currently interpreted. Unless and until Geneva's 180-day Exclusivity Period had been triggered and had expired, or Geneva relinquished its entitlement to this period of exclusivity, only Geneva would be approved by the FDA to market a generic terazosin HCL product.

Anticompetitive Conduct

24. On March 30, 1998, the very day it was granted FDA approval to market its generic terazosin HCL capsules, Geneva contacted Abbott and announced that it would launch its generic terazosin HCL capsules unless it was paid by Abbott not to enter the market. From Abbott's perspective, a launch of Geneva's generic terazosin HCL product would have had a significant adverse impact on Abbott's financial performance. Abbott forecasted that entry of generic terazosin HCL on April 1, 1998 would have eliminated over $185 million in Hytrin sales in just six months. Because Hytrin was highly profitable, Abbott sought to keep from the market Geneva and all other potential generic competition to Hytrin, until at least February 2000.

25. Over the course of two days, representatives of Abbott and Geneva negotiated the framework for an agreement, whereby Abbott would pay Geneva not to enter the market. Abbott estimated Geneva's revenues from launching generic terazosin HCL at $1 million to $1.5 million per month, but was willing to pay Geneva a "premium" over that not to compete.

26. On April 1, 1998, Abbott and Geneva entered into a written agreement ("Agreement"), pursuant to which Geneva agreed not to enter the market with any generic terazosin HCL capsule or tablet product until the earlier of: (1) the final resolution of the patent infringement litigation involving Geneva's terazosin HCL tablets product, including review through the Supreme Court; or (2) entry of another generic terazosin HCL product. Geneva also agreed – at Abbott's insistence – not to transfer, assign, or relinquish its right to a 180-day Exclusivity Period.

27. In exchange, Abbott agreed to pay Geneva $4.5 million per month in non-refundable payments until a district court judgment in the parties' patent infringement dispute. Respondents agreed that if the district court declared that

Geneva's tablet product did not or would not infringe any valid and enforceable claim of the '207 patent, Abbott would thereafter pay the $4.5 million monthly payments into an escrow fund until the final resolution of the litigation. Under the Agreement, the party prevailing in the litigation would receive the money in the escrow fund.

28. The court hearing the patent litigation was not made aware of the respondents' Agreement.

29. In the words of Geneva's CEO at the time the Agreement was signed, this Agreement represented to Geneva the "best of all worlds," because Geneva obtained a risk-free "monetary settlement on an ongoing basis until the litigation was resolved" and still could market its product exclusively for 180 days after the litigation was over.

30. In accordance with the terms of the Agreement, in April 1998, Geneva refrained from entering the market with its generic terazosin HCL capsules, and instead began receiving monthly payments of $4.5 million from Abbott.

31. On September 1, 1998, the United States District Court for the Northern District of Illinois granted Geneva's motion for summary judgment in its patent tablet litigation with Abbott, invalidating Abbott's patent under the on-sale provision of 35 U.S.C. § 102(b).

32. The district court's decision invalidating Abbott's patent only strengthened Geneva's litigation position. Nonetheless, Geneva, in accordance with the terms of the Agreement, did not enter the generic terazosin HCL market even after the favorable district court decision.

33. On July 1, 1999, the United States Court of Appeals for the Federal Circuit affirmed, without dissent, the summary judgment in favor of Geneva. Under the Agreement, Geneva still could not enter the generic terazosin HCL market until after the Supreme Court either denied Abbott's petition for certiorari or disposed of the patent infringement litigation. Nonetheless, in August 1999, aware of the Commission's investigation, the respondents canceled their Agreement, and on August 13, 1999, Geneva finally introduced its generic terazosin HCL capsule product to the marketplace. The Supreme Court denied certiorari on January 10, 2000.

The Effects of Respondents' Conduct

34. The acts and practices of the respondents as herein alleged have had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition by preventing or discouraging the entry of competition in the form of generic versions of Hytrin into the relevant market.

35. As a result of respondents' conduct as herein alleged, consumers were deprived of the benefits of new competition from Geneva and other generic competitors. Without this lower-priced generic competition, consumers, pharmacies, hospitals, insurers, wholesalers, government agencies, managed care organizations, and others were forced to purchase Abbott's more expensive Hytrin product.

36. Earlier entry of a generic terazosin HCL product would have had a significant procompetitive impact in the relevant market. Pharmacists generally are permitted, and in some instances required, to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed. In addition, there is a ready market for generic products because certain third-party payers of prescription drugs (*e.g.*, managed care plans and Medicaid programs) encourage or insist on the use of generic drugs wherever possible. A generic product can quickly and

efficiently enter the marketplace at substantial discounts, generally leading to a significant erosion of the branded drug's sales within the first year. For example, Abbott's forecasts projected that generic terazosin HCL would capture roughly 70% of Hytrin sales within the first six months alone.

37. The purpose and effect of the $4.5 million monthly payments from Abbott to Geneva during the term of the Agreement were to ensure that Geneva would not enter the relevant market, and would not take any steps, including giving up its right to a 180-day Exclusivity Period, to permit or facilitate the entry of any other generic manufacturer.

38. By prohibiting Geneva from transferring, assigning, or giving up its right to a 180-day Exclusivity Period until the final resolution of the patent infringement litigation involving Geneva's terazosin HCL tablets product, the Agreement had the purpose and effect of preventing Geneva from relinquishing its eligibility for a 180-day Exclusivity Period under the Hatch-Waxman Act. As of February 1999, at least one other generic manufacturer had satisfied the FDA's requirements for approval and was barred from entering the market because Geneva's 180-day Exclusivity Period had not begun to run.

39. The Agreement is not justified by any countervailing efficiency.

Violations Alleged

40. The Abbott-Geneva Agreement as a whole, and particular provisions such as that described in Paragraphs 37 and 38 above, constitute an unreasonable restraint of trade in violation of Section 5 of the Federal Trade Commission Act, as amended.

41. Abbott and Geneva acted with the specific intent that Abbott monopolize the relevant market, and engaged in overt acts described in Paragraphs 24-33 above in furtherance of a conspiracy to monopolize the relevant market, in violation of Section 5 of the Federal Trade Commission Act, as amended.

42. Abbott had monopoly power in the relevant market and monopolized that market in violation of Section 5 of the Federal Trade Commission Act, as amended.

43. The acts and practices described above are anticompetitive in nature and tendency and constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, as amended.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-second day of May, 2000, issues its complaint against said respondents.

By the Commission.

DECISION AND ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of certain acts and practices of Abbott Laboratories ("Abbott") and Geneva Pharmaceuticals, Inc. (hereinafter referred to as "Respondent Geneva"), an indirect wholly-owned subsidiary of Novartis Corporation, and Respondent Geneva having been furnished thereafter with a copy of a draft complaint which the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent Geneva with violation of the Federal Trade Commission Act; and

Respondent Geneva and counsel for the Commission having thereafter executed an Agreement Containing Consent Order, an admission by Respondent Geneva of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondent Geneva that the law has been violated as alleged in such complaint, 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 Geneva 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 agreement on the public record for a period of thirty (30) days, and having duly considered the comments filed 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. Geneva Pharmaceuticals, Inc., an indirect wholly-owned subsidiary of Novartis Corporation, is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Colorado, with its office and principal place of business located at 2555 W. Midway Blvd., Broomfield, Colorado 80020.

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

ORDER

I.

IT IS ORDERED that for the purposes of this order, the following definitions shall apply:

A. "Respondent Geneva" means: (1) Geneva Pharmaceuticals, Inc., and its successors and assigns; (2) any entity that the parent of Geneva Pharmaceuticals, Inc. controls and that engages in the manufacture or sale of Drug Products in the United States for which it is, or becomes, an ANDA First Filer; (3) any predecessor, subsidiary, division, group and affiliate controlled by the entities described in subparagraphs (1) and (2) above that engages in the manufacture or sale of Drug Products in the United States for which it is, or becomes, an ANDA First Filer; (4) successors and assigns of the entities described in subparagraphs (2) and (3) above that are or become ANDA first filers; and (5) the respective directors, officers, employees, agents and representatives of each acting in their capacities as such.

B. "Commission" means the Federal Trade Commission.

C. "180-day Exclusivity Period" means the period of time established by Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j) *et seq.*).

D. "Agreement" means anything that would constitute an agreement under Section 1 of the Sherman Act or Section 5 of the Federal Trade Commission Act.

E. "ANDA" means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j) *et seq*.

F. "ANDA First Filer" means the party whom the FDA determines is entitled to, or eligible for, a right to a 180-day Exclusivity Period which has not yet expired.

G. "Control" has the same meaning as the definition of the term in 16 C.F.R. § 801.1(b).

H. "Drug Product" means a finished dosage form (e.g., tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients, as defined in 21 C.F.R. § 314.3(b).

I. "FDA" means the United States Food and Drug Administration.

J. "NDA" means a New Drug Application, as defined under 21 U.S.C. § 355(b) *et seq*.

K. "NDA Holder" means: (1) the party that received FDA approval to market a Drug Product pursuant to an NDA; (2) a party owning or controlling enforcement of the patent(s) listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the "FDA Orange Book") in connection with the NDA; or (3) the predecessors, subsidiaries, divisions, groups and affiliates controlled by the entities described in subparagraphs (1) and (2) above, as well as the entities' licensees, successors and assigns.

L. "Parent" has the same meaning as "ultimate parent entity" in 16 C.F.R. § 801.1(a).

M. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

N. "Relinquishing" means transferring, selling, assigning, waiving, or relinquishing.

II.

IT IS FURTHER ORDERED that Respondent Geneva cease and desist, either directly or indirectly, in connection with the sale of Drug Products in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, from being a party to any Agreement in which one party is an NDA Holder for a Drug Product(s), any other party is the ANDA First Filer for the Drug Product(s), and:

A. the ANDA First Filer is prohibited by such Agreement from relinquishing, or is subject to a penalty, forfeiture, or loss of benefit if it relinquishes, its right to the 180-Day Exclusivity Period; or

B. the ANDA First Filer agrees to refrain from researching, developing, manufacturing, marketing, or selling any Drug Product that could be approved for sale by the FDA pursuant to the ANDA and that is not the subject of a court action alleging patent infringement.

Provided, however, that nothing in this Paragraph II shall prohibit Agreements involving the complete transfer of rights in a Drug Product.

III.

IT IS FURTHER ORDERED that, in any instance where Respondent Geneva is a party to a patent infringement action in which it is either the NDA Holder or the alleged infringer, it shall cease and desist, either directly or indirectly, in connection with the sale of Drug Products in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, from being a party to any

Agreement in which the parties do not agree to dismiss the litigation, and in which the NDA Holder provides anything of value to the alleged infringer and the alleged infringer agrees to refrain during part or all of the course of the litigation from selling the Drug Product at issue, or any Drug Product containing the same chemical entity(ies) at issue. *Notwithstanding the above, however*, such an Agreement is permissible when entered into in conjunction with a joint stipulation between the parties that the court may enter a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure, if: (1) together with the stipulation for a preliminary injunction, Respondent Geneva provides the court with the proposed Agreement, as well as a copy of the Commission's complaint, order, and Analysis to Aid Public Comment in this matter; (2) Respondent Geneva has provided Notification, as described in Paragraph V below, to the Commission at least thirty (30) days prior to submitting the stipulation for a preliminary injunction; (3) Respondent Geneva does not oppose any effort by the Commission to participate, in any capacity permitted by the court, in the court's consideration of any such action for preliminary relief; and (4) the court issues an order which incorporates the terms of the Agreement. Nothing in this Paragraph shall be interpreted to prohibit or restrict the right of Respondent Geneva to unilaterally seek relief from the court, without notice to the Commission, including, but not limited to, applying for preliminary injunctive relief or seeking to extend the 30-month stay pursuant to 21 U.S.C. § 355(j)(4)(B)(iii).

IV.

IT IS FURTHER ORDERED that Respondent Geneva shall provide Notification as described in Paragraph V below to the Commission at least thirty (30) days before entering into, enforcing, or otherwise participating in any Agreement made after the date the Agreement Containing Consent Order is signed whereby an ANDA First Filer agrees with an NDA Holder to

refrain from selling any Drug Product under its ANDA for any period of time.IV.

V.

The Notification required by Paragraphs III and IV shall be filed with the Secretary of the Commission and shall include the following information, to the extent known, and not subject to any legally recognized privilege: (1) identification of the parties involved in the Agreement; (2) identification of all Drug Products involved in the Agreement; (3) identification of all persons who have filed an ANDA with the FDA (including the status of such application) for any Drug Product containing the same chemical entity(ies) as the Drug Product(s) involved in the Agreement; (4) a copy of the proposed Agreement; (5) identification of the court, and copy of the docket sheet, for any legal action which involves either party to the Agreement and relates to any Drug Product(s) containing the same chemical entity(ies) involved in the Agreement; and (6) all documents which were prepared by or for any officer(s) or director(s) of Respondent Geneva for the purpose of evaluating or analyzing the Agreement.

VI.

IT IS FURTHER ORDERED that, within ten (10) days of signing the Agreement Containing Consent Order in this matter, Respondent Geneva shall notify the FDA in writing that Respondent Geneva is relinquishing any and all eligibility for, and entitlement or right to, a 180-day Exclusivity Period for ANDA No. 74-315 (terazosin HCL tablets).

VII.

IT IS FURTHER ORDERED that Respondent Geneva shall file a verified written report within sixty (60) days after the date this order becomes final, annually thereafter for five (5) years on the anniversary of the date this order becomes final, and at such other times as the Commission may by written notice require,

setting forth in detail the manner and form in which Respondent Geneva intends to comply, is complying, and has complied with this order. Respondent Geneva shall include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with this order.

VIII.

IT IS FURTHER ORDERED that Respondent Geneva shall notify the Commission at least thirty (30) days prior to any proposed change in Respondent Geneva such as dissolution, assignment, sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in Respondent Geneva that may affect compliance obligations arising out of this order.

IX.

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 Respondent Geneva, Respondent Geneva shall permit any duly authorized representative of the Commission:

A. Access, during office hours and in the presence of counsel, to all facilities, and 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 compliance with this order; and

B. To interview officers, directors, employees, agents, and other representatives of Respondent Geneva, who may have counsel present, regarding such compliance issues.

X.

IT IS FURTHER ORDERED that this order shall terminate on May 22, 2010.

By the Commission.

STATEMENT OF CHAIRMAN ROBERT PITOFSKY AND COMMISSIONERS SHEILA F. ANTHONY, MOZELLE W. THOMPSON, ORSON SWINDLE, AND THOMAS B. LEARY

The attached Analysis to Aid Public Comment, which accompanied our acceptance of consent agreements with Geneva Pharmaceuticals, Inc. and Abbott Laboratories, describes the conduct of those two companies in agreeing that Abbott would pay Geneva to refrain from selling a generic version of Hytrin, Abbott's branded version of terazosin hydrochloride. It also describes relevant provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), including particularly the provision that gives the first generic company to seek FDA approval a 180-day period during which it has the exclusive right to market the generic version of a brand name drug.

Pursuant to a private agreement not reviewed by any court, Abbott paid Geneva substantial sums not to enter the market with its generic version of Hytrin, and not to transfer, assign or relinquish its 180-day exclusive marketing right to any other producer of generic products that might compete with Abbott. By

not selling its generic version, Geneva prevented the start of the 180-day exclusivity period, with the result that neither Geneva nor any other company could introduce a generic version of Hytrin into the market.

The consent orders that we issue today against Abbott and Geneva represent the first resolution of an antitrust challenge by the government to a private agreement whereby a brand name drug company paid the first generic company that sought FDA approval not to enter the market, and to retain its 180-day period of market exclusivity. Because the behavior occurred in the context of the complicated provisions of the Hatch-Waxman Act, and because this is the first government antitrust enforcement action in this area, we believe the public interest is satisfied with orders that regulate future conduct by the parties. We recognize that there may be market settings in which similar but less restrictive arrangements could be justified, and each case must be examined with respect to its particular facts.

In March we also issued an administrative complaint against two other pharmaceutical companies with respect to conduct that is in some ways similar to the conduct addressed by these consent orders. We anticipate that the development of a full factual record in the administrative proceeding will help to shape further the appropriate parameters of permissible conduct in this area and will guide other companies and their legal advisors.

Pharmaceutical firms should now be on notice, however, that arrangements comparable to those addressed in the present consent orders can raise serious antitrust issues, with a potential for serious consumer harm. Accordingly, in the future, the Commission will consider its entire range of remedies in connection with enforcement actions against such arrangements, including possibly seeking disgorgement of illegally obtained profits.

If firms are uncertain about the limits of permissible behavior under the Hatch-Waxman Act, they may, of course, seek advisory opinions from the staff of this agency.

Analysis to Aid Public Comment

The Federal Trade Commission has accepted for public comment agreements and proposed consent orders with Geneva Pharmaceuticals, Inc. and Abbott Laboratories. The proposed consent orders settle charges that these parties unlawfully agreed that Geneva would refrain from selling its generic version of one of Abbott's drugs, in exchange for payments from Abbott. The proposed consent orders have been placed on the public record for 30 days to receive comments by interested persons. The proposed consent orders have been entered into for settlement purposes only and do not constitute an admission by Abbott or Geneva that they violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true.

Background

Abbott Laboratories develops, manufactures, and sells a variety of health care products and services. Based in Abbott Park, Illinois, Abbott's 1998 net sales worldwide were approximately $ 12.5 billion. Over 20% of Abbott's net sales of pharmaceutical products in the U.S. are for a drug called Hytrin. Hytrin is used to treat two chronic conditions that affect millions of Americans, particularly senior citizens: hypertension (high blood pressure) and benign prostatic hyperplasia (enlarged prostate).

Geneva is one of the leading generic drug manufacturers in the United States. An indirect wholly-owned subsidiary of

Novartis Corp., Geneva is based in Broomfield, Colorado. Geneva developed a generic version of Hytrin, and in March 1998 received approval from the U.S. Food and Drug Administration ("FDA") to market that generic product.

A generic drug is a product that the FDA has found to be bioequivalent to a brand name drug. A company seeking FDA approval to market a new drug must file a New Drug Application ("NDA"). In order to market a generic version of a brand name drug, a company must file an Abbreviated New Drug Application ("ANDA") and receive approval from the FDA.

Generic drugs are chemically identical to their branded counterparts, but typically are sold at substantial discounts from the branded price. A Congressional Budget Office Report estimates that purchasers saved an estimated $8-$10 billion on prescriptions at retail pharmacies in 1994 by purchasing generic drugs instead of the brand name product.[1]

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as "the Hatch-Waxman Act," to facilitate the entry of generic drugs while maintaining incentives to invest in new drug development. In particular, the Hatch-Waxman Act establishes certain rights and procedures in situations where a company seeks FDA approval to market a generic product prior to the expiration of a patent or patents relating to a brand name drug upon which the generic is based. In such cases, the applicant must: (1) certify to the FDA that the patent in question is invalid or is not infringed by the generic product (known as a "paragraph IV certification"); and (2) notify the patent holder of the filing of the certification. If the

[1] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* at xiii, 13 (July 1998).

holder of patent rights files a patent infringement suit within 45 days, FDA approval to market the generic drug is automatically stayed for 30 months, unless before that time the patent expires or is judicially determined to be invalid or not infringed. This automatic 30-month stay allows the patent holder time to seek judicial protection of its patent rights before a generic competitor is permitted to market its product.

In addition, the Hatch-Waxman Act provides an incentive for generic drug companies to bear the cost of patent litigation that may arise when they challenge invalid patents or design around valid ones. The Act grants the first company to file an ANDA in such cases a 180-day period during which it has the exclusive right to market a generic version of the brand name drug. No other generic manufacturer may obtain FDA approval to market its product until the first filer's 180-day exclusivity period has expired.

Geneva was the first company to file an ANDA for terazosin hydrochloride ("terazosin HCL"), the generic version of Hytrin. It filed applications covering a tablet form and a capsule form of its generic terazosin HCL. Geneva filed a paragraph IV certification with the FDA stating that these products did not infringe any valid patent held by Abbott covering terazosin HCL. In June 1996, Abbott sued Geneva for patent infringement by Geneva's terazosin HCL tablet product, but due to an oversight failed to make an infringement claim against Geneva's capsule product, although both products raised the same potential infringement issues.

Abbott's lawsuit triggered a 30-month stay of final FDA approval of Geneva's terazosin HCL tablet ANDA, until December 1998. No stay applied to the FDA approval process for Geneva's terazosin HCL capsule ANDA, however, because no infringement claim was filed within the statutory time period required by the Hatch-Waxman Act. The FDA granted Geneva final approval to market generic terazosin HCL capsules on March 30, 1998.

The Challenged Agreement

The complaint challenges an agreement whereby Abbott, following the FDA approval of Geneva's generic terazosin HCL capsule product, paid Geneva not to enter the market during their ongoing patent litigation over the tablet product. According to the complaint, on the day it was granted approval to market its generic terazosin HCL capsules, Geneva contacted Abbott and announced that it would launch its generic terazosin HCL capsules unless it was paid by Abbott not to enter. Two days later, on April 1, 1998, Abbott and Geneva entered into an agreement, pursuant to which Geneva agreed not to enter the market with any generic terazosin HCL capsule or tablet product until the earlier of: (1) the final resolution of the patent infringement litigation involving Geneva's terazosin HCL tablets product, including review through the Supreme Court; or (2) entry of another generic terazosin HCL product.

Geneva also agreed – at Abbott's insistence – not to transfer, assign, or relinquish its 180-day exclusivity right. The effect of this provision was to ensure that no other company's generic terazosin HCL product could obtain FDA approval and enter the market during the term of the agreement, because Geneva's agreement not to launch its product meant that the 180-day exclusivity period would not expire.

In exchange, Abbott agreed to pay Geneva $4.5 million per month until a district court judgment in the parties' patent infringement dispute, and then (assuming Geneva won in the district court) to pay the $4.5 million monthly payments into an escrow fund until the final resolution of the litigation, which Geneva would then receive if its district court victory was upheld.

Abbott's payment to Geneva of $4.5 million a month was well over the $1 to $1.5 million per month that, the complaint states, Abbott believed Geneva would forego by staying off the market. The complaint alleges that Abbott was willing to pay Geneva a "premium" to refrain from competing because of the substantial impact that launch of a generic version of Hytrin would have on Abbott's overall financial situation. Abbott forecasted that entry of generic terazosin HCL on April 1, 1998 would eliminate over $185 million in Hytrin sales in just six months. Accordingly, the complaint charges, Abbott sought to forestall Geneva -- and all other potential generic competition to Hytrin – from entering the market because of the threat they represented to the high profits it was making from Hytrin.

The complaint further charges that, in accordance with the terms of the agreement, Geneva did not enter the market with its generic terazosin HCL capsules, even after the district court and the court of appeals upheld Geneva's position that Abbott's patent was invalid. In August 1999, Abbott and Geneva – aware of the Commission's investigation – terminated their agreement (which by its terms would not have ended until disposition of the litigation by the Supreme Court). Geneva finally brought its generic terazosin HCL capsule product to market on August 13, 1999.

Competitive Analysis

The complaint charges that the challenged agreement prevented competition that Abbott's Hytrin product would otherwise have faced from generic products of Geneva and other potential generic competitors. Generic drugs can have a swift marketplace impact, because pharmacists generally are permitted, and in some instances are required, to substitute lower-priced generic drugs for their branded counterparts, unless the prescribing physician directs otherwise. In addition, there is a ready market for generic products because certain third-party payers of prescription drugs (*e.g.*, state Medicaid programs and many private health plans) encourage or insist on the use of

generic drugs wherever possible. Abbott's forecasts, the complaint states, projected that generic terazosin HCL would capture roughly 70% of Hytrin sales within the first six months following its launch. The agreement, however, ensured that Geneva would not offer generic terazosin HCL in competition with Hytrin, and would not take action – such as relinquishing exclusivity rights – that would have permitted the entry of any other generic manufacturer.

These restraints on generic competition had direct and substantial effects on consumers. Without a lower-priced generic alternative, consumers, government agencies, health plans, pharmacies, hospitals, wholesalers, and others were forced to purchase Abbott's more expensive Hytrin product. Other drugs, the complaint states, are not effective substitutes for terazosin HCL because they are different in terms of chemical composition, safety, efficacy, and side effects. There is little price sensitivity between terazosin HCL and other products. Thus, the complaint alleges that the sale of terazosin HCL in the United States is the relevant market within which to assess the effects of the challenged agreement.

The challenged conduct represents an agreement not to compete between potential horizontal competitors. A firm is a potential competitor if there is evidence that entry by that firm is reasonably probable in the absence of the agreement at issue.[2] Geneva certified to the FDA that its entry with generic HCL would not infringe a valid patent, and was confident that it ultimately would prevail in its patent infringement dispute with Abbott, the complaint states. In early 1998, Geneva was making preparations to launch its generic terazosin HCL capsule product

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[2] Federal Trade Commission and United States Department of Justice, *Antitrust Guidelines for the Licensing of Intellectual Property* at § 1.1 n.6 (1995).

as soon as possible. After receiving FDA approval for the capsule product, Geneva threatened to launch that product unless Abbott paid it not to do so. The challenged agreement directly restrained competition between these potential competitors.

In addition, the agreement created a bottleneck that prevented any other potential competitors from entering the market, because no other ANDA filer could obtain FDA approval until Geneva's 180 day exclusivity period expired. Other companies were developing generic terazosin HCL products, and at least one other generic manufacturer had satisfied the FDA's requirements for approval by February 1999, but was barred from entering the market because Geneva's failure to launch its product meant its 180-day exclusivity right had not even begun to run.

The complaint states that the challenged agreement is not justified by any countervailing efficiency. Although the agreement between Abbott and Geneva provided substantial private benefits to both parties, the facts in this matter demonstrate that the broad restraints were not justified by any benefits to competition and consumer welfare. The Commission considered whether the agreement could be considered a procompetitive effort to effectuate a temporary settlement of a patent dispute, akin to a court-ordered preliminary injunction. However, it finds that any legitimate interest in resolving patent disputes cannot justify the harm to consumers imposed by the agreement in this case. The restraint imposed exceeds what likely would be available to the parties under a court-ordered preliminary injunction. For example, it: (1) barred Geneva's entry beyond the pendency of the district court litigation; (2) provided large up-front payments that could be expected to create disincentives for Geneva to enter (in contrast to a court-ordered bond to cover damages actually incurred as a result of the court's injunction); (3) barred Geneva from relinquishing its exclusivity rights; (4) prohibited Geneva from developing or marketing non-infringing generic products. Moreover, the restraints contained in the agreement were entered into without any judicial finding that Abbott was likely to succeed on the merits of its infringement

suit, without any consideration of whether Abbott would suffer irreparable injury, and without any weighing of the equities, including any consideration of the public interest.

The complaint also charges that Abbott had a monopoly in the market for terazosin HCL, and, by entering into the agreement with Geneva, Abbott sought to preserve its dominance by delaying the entry of Geneva and other generic companies into the market. As detailed above, there were no countervailing justifications for Abbott's conduct. In addition, the complaint alleges that Abbott and Geneva conspired to monopolize the market for terazosin HCL. As stated in the complaint, Abbott and Geneva acted with specific intent that Abbott monopolize the market for terazosin HCL, and entered into a conspiracy to achieve that goal. Finally, the parties' agreement otherwise amounts to an unfair method of competition in violation of Section 5 of the FTC Act.

The Proposed Orders

The proposed orders are designed to remedy the unlawful conduct charged in the complaint. Although the particular agreement challenged in the complaint has been terminated, prospective relief is necessary to prevent a recurrence of similar agreements with respect to other drugs. Private agreements in which the brand name drug company (the NDA holder) pays the first generic to seek FDA approval (the first filer) not to enter the market can substantially delay generic competition and raise serious antitrust issues. Moreover, the FDA, which has expressed concern about such private agreements, has observed that the incentives for companies to enter into such arrangements are becoming greater, as the returns to the brand name company from extending its monopoly increasingly exceed the potential

economic gains to the generic applicant from its 180 days of market exclusivity.[3]

In essence, the proposed orders:

- bar two particular types of agreements between brand name drug companies and potential generic competitors -- restrictions on giving up Hatch-Waxman 180-day exclusivity rights and on entering the market with a non-infringing product;

- require that agreements involving payments to the generic company to stay off the market be approved by the court when undertaken in the context of an interim settlement of patent litigation, with notice to the Commission to allow it time to present its views to the court;

- require respondents to give the Commission written notice 30 days before entering into such agreements in other contexts; and

- require that Geneva waive its right to 180-day marketing exclusivity for its generic terazosin HCL tablet product, so that other generic tablet producers can immediately enter the market.

Paragraph II prohibits two kinds of agreements between "an NDA Holder" and "the ANDA First Filer" (that is, the party possessing an unexpired right to Hatch-Waxman 180-day exclusivity). Paragraph II.A. bars agreements in which the first company to file an ANDA agrees with the NDA holder not to relinquish its right to the 180-day exclusivity period established under the Hatch-Waxman Act. Paragraph II.B. prohibits the ANDA first filer from agreeing not to develop or market a generic

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[3] FDA Proposed Rule Regarding 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed.Reg. 42873, 42882-83 (August 6, 1999).

drug product that is not the subject of a patent infringement lawsuit. The order prohibits restrictions on giving up exclusivity rights and on competing with a non-infringing product because under the circumstances of this case these restraints are not justified.

Paragraph II's focus on agreements between an NDA holder and the ANDA first filer does not mean that the Commission believes that there is no risk of competitive harm in other contexts. In particular, Abbott or Geneva's participation in an agreement in which a generic company that is not the ANDA first filer is paid by the NDA holder not to market a non-infringing product could raise substantial competitive concerns. Given the variety of circumstances in which the restraints may arise, however, and the possibility that some legitimate justifications might exist in some other contexts, the Commission believes that it is appropriate at this time to limit the flat bans in Paragraph II to agreements between NDA holders and ANDA first filers.

Paragraph III bans private agreements involving payments to keep a generic drug off the market during patent infringement litigation brought by an NDA holder. Abbott and Geneva can enter into such arrangements only if (a) they are presented to the court and embodied in a court-ordered preliminary injunction, and (b) the following other conditions are met: (i) along with any stipulation for preliminary injunction, they provide the court with a copy of the Commission's complaint, order, and this Analysis to Aid Public Comment in this matter, as well as the proposed agreement between the parties; (ii) at least 30 days before submitting the stipulation to the court, they provide written notice to the Commission; and (iii) they do not oppose Commission participation in the court's consideration of the request for preliminary relief.

Thus, the proposed orders bar agreements made in the context of an interim settlement of a patent infringement action, whereby the NDA holder pays the generic not to enter the market, unless the parties obtain court approval through a process that is designed to enhance the court's ability to assess the competitive implications of the agreement. This remedy, in addition to facilitating the court's access to information about the Commission's views, also makes the process public and thereby may prompt other generic drug manufacturers (or other interested parties) to alert the court to potential anticompetitive provisions that could delay their entry into the market. Furthermore, the Commission believes that the requirement that the agreement be filed on the public record with the court will deter Abbott and Geneva from entering into anticompetitive agreements.

Paragraph IV addresses certain agreements to stay off the market that are not covered by Paragraph III because they do not involve interim relief in a litigated matter. Such situations would include agreements that are part of a final settlement of the litigation, and situations in which no litigation has been brought. In these circumstances, there is no judicial role in ordering relief agreed to by the parties. The Commission is concerned about such private agreements in which the first filer is paid by the NDA holder not to enter the market, because of the substantial risk of competitive harm that they may create. Thus, the order requires that Abbott and Geneva notify the Commission 30 days before entering into an agreement in which an ANDA first filer agrees with an NDA holder to refrain from going to market. Such notice will assist the Commission in detecting anticompetitive agreements before they have caused substantial injury to consumers. Absent the order, there is no mechanism for the antitrust enforcement agencies to find out about such agreements.

The form of notice that Abbott and Geneva must provide to the Commission under Paragraphs III and IV of the orders is set forth in Paragraph V. In addition to supplying a copy of the proposed agreement, they are required to provide certain other information to assist the Commission in assessing the potential

competitive impact of the agreement. Accordingly, the orders require them to identify, among other things, all others who have filed an ANDA for a product containing the same chemical entities as the product at issue, and the court that is hearing any relevant legal proceedings involving either party. In addition, they must provide the Commission with all documents that evaluate the proposed agreement.

In addition, the proposed order against Geneva requires that it waive its 180-day marketing exclusivity period for its generic terazosin HCL tablet product. Although Geneva's exclusivity right with respect to the terazosin capsules product has expired, its exclusivity period for the tablet product still remains as a barrier to entry. This provision of the order will therefore open the market to greater generic competition in terazosin HCL products.

The proposed orders also contain certain reporting and other provisions that are designed to assist the Commission in monitoring compliance with the order and are standard provisions in Commission orders.

The orders will expire in 10 years.

Opportunity for Public Comment

The proposed orders have been placed on the public record for 30 days in order to receive 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 agreements and the comments received and will decide whether it should withdraw from the agreements or make the proposed orders final.

The purpose of this analysis is to facilitate public comment on the agreements. The analysis is not intended to constitute an official interpretation of the agreements, the proposed complaint, or the proposed consent orders, or to modify their terms in any way.