

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 a 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.

By direction of the Commission.

Donald S. Clark,
Secretary.

Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle, and Thomas B. Leary

The Analysis to Aid Public Comment, published today along with proposed consent orders against Geneva Pharmaceuticals, Inc. and Abbott Laboratories, describes the conduct of those two companies in agreeing that Abbot 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 Abbot. 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.

These consent orders 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.

We have today 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, as

well as the public comments on these consent orders, will help to shape further the appropriate parameters of permissible conduct in this area, and 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.

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FEDERAL TRADE COMMISSION

[File No. 971 0038]

Colegio de Cirujanos Dentistas de Puerto Rico; Analysis to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before June 2, 2000.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Ave., NW, Washington, D.C. 20580.

FOR FURTHER INFORMATION CONTACT: Richard Feinstein or Steven Osnowitz, FTC/S-3115, 600 Pennsylvania Ave., NW, Washington, D.C. 20580. (202) 326-2574 or 326-2746.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and Section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the above-captioned consent agreement containing a consent

order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for March 21, 2000), on the World Wide Web, at "<http://www.ftc.gov/ftc/formal.htm>." A paper copy can be obtained from the FTC Public Reference Room, Room H-130, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580, either in person or by calling (202) 326-3627.

Public comment is invited. Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Ave., NW., Washington, D.C. 20580. Two paper copies of each comment should be filed, and should be accompanied, if possible, by a 3½ inch diskette containing an electronic copy of the comment. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission ("Commission") has accepted, subject to final approval, a proposed consent order settling charges that the Colegio de Cirujanos Dentistas de Puerto Rico ("Colegio"), an association of dentists in Puerto Rico: (1) organized boycotts and refusals to deal, and engaged in other anticompetitive conduct, designed to raise prices for dental services; and (2) prohibited its members from engaging in certain types of truthful, nondeceptive advertising. The proposed consent order has been placed on the public record for sixty (60) days to receive comments by interested persons. The proposed consent order has been entered into for settlement purposes only and does not constitute an admission by the Colegio that it violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true.

The Complaint

The Colegio is an association of approximately 1800 dentists licensed to practice dentistry in Puerto Rico. Puerto Rico law requires, with certain limited exceptions, that dentists maintain membership in the Colegio to practice in Puerto Rico. Accordingly, the Colegio's members constitute the vast

majority of dentists practicing in Puerto Rico.

The complaint charges that the Colegio restrained competition among dentists in Puerto Rico by, among other things, fixing the terms under which individual dentists would deal with health insurers and other payers of health care services, and orchestrating or threatening boycotts of payers by its members to obtain higher reimbursement. According to the proposed complaint, the Colegio promulgated a Code of Ethics that bars dentists from contracting with any health insurance plan ("plan") that is not endorsed by the Colegio. The Colegio refused to approve plans unless they: reimbursed dentists on a fee-for-service basis rather than capitation; were open to participation by all dentists; and were "responsive" to raising fees at the Colegio's request. Plans sought the Colegio's endorsement or approval in order to secure a sufficient number of participating dentists.

The complaint also alleges that the Colegio acted as the collective bargaining agent for its members. Through its Committee on Prepaid Dental Services, and in other ways, the Colegio engaged in discussions with numerous payers about fees and other terms its members would accept from these payers. For example, from 1992 through 1994, the Colegio successfully negotiated on behalf of its members to obtain fee increases from the two largest payers for dental coverage in Puerto Rico, Triple S and La Cruz Azul. In another instance, the complaint charges, the Colegio organized dentists to refuse to deal with a new plan proposed by Triple S that would have paid dentists a set amount per enrollee rather than the traditional fee for service, and Triple S was compelled to cancel the plan.

The complaint further alleges that the Colegio set the prices and other terms under which its member dentists would deal with plans operating under Puerto Rico's Health Insurance Act of 1993 (the "Reform"), a program to provide health care services to the indigent. During 1995, for example, the Colegio successfully blocked Triple S attempts to implement a new plan in the North Region of the Reform, and defeated Triple S plans to implement a 10% discount for dental fees. In the Central Region of the Reform, the Colegio succeeded in forcing PCA to agree that payments to dentists would be based on fee for service, and that its dental panels would be open to all Colegio members. When PCA attempted in 1996 to revise its dental contracts for the Central Region, in order to provide for

utilization and quality audits, the Colegio withheld its endorsement, and PCA was unable to secure contracts with a sufficient number of dentists to offer the plan.

The complaint charges that the Colegio has acted to prevent certain forms of truthful, nondeceptive advertising. Its Code of Ethics bans advertising that is not "professionally acceptable," use of most illustrations, advertisements deemed not in good taste, and all personal solicitations. The complaint further alleges that the Colegio applied its ban on unprofessional advertising against dentists from Ponce, Puerto Rico, who truthfully advertised their willingness to accept Reform patients from neighboring areas where dentists were conducting a boycott of the Reform.

According to the complaint, the Colegio has not integrated the practices of its members in any economically significant way, nor has it created any efficiencies that might justify the acts and practices alleged in the complaint. Rather, the complaint charges that the Colegio's conduct has had the purpose and effect of restraining competition among dentists and injuring consumers by, among other things, fixing or increasing prices for dental services; fixing the terms and conditions upon which dentists would deal with payers, thereby raising the price to consumers of insurance coverage; raising prices paid by the Reform and delaying the offerings of dental services under the Reform; and depriving consumers of truthful information about dental services.

The Proposed Consent Order

The proposed consent order prohibits the Colegio from continuing the illegal conduct described in the complaint. Specifically, Part II of the order prohibits the Colegio from endorsing or approving, refusing to endorse or approve, or prohibiting or declaring unethical a dentist's participation in a health plan based on the amount, manner of calculating, or other terms relating to reimbursement for dental services, or on whether the plan is open to participation by all Colegio members. The Colegio also is prohibited from (1) negotiating on behalf of any dentists with any payer or provider; (2) refusing to deal, boycotting, or threatening to boycott any payer or provider; or (3) determining any terms, conditions, or requirements upon which dentists will deal with any provider, including terms of reimbursement, and whether the plan is open to participation by all Colegio members.

Further, the Colegio is prohibited from communicating to any payer or provider any term, condition, or requirement on which Colegio members are willing or unwilling to deal with a payer or provider, and from communicating with any member concerning the desirability or appropriateness of any term or condition of a payer relating to dental services, or whether the plan is open to participation by all Colegio members. The Colegio cannot facilitate in any manner, or transfer the exchange of, information concerning dentists' intentions to contract with any payer, or under what terms.

The proposed order does not restrict legitimate communications between the Colegio and payers. Health care practitioners' provision of certain kinds of information to payers is not likely to raise antitrust concerns, but instead may serve to promote competition and benefit consumers. For example, the DOJ/FTC Statements of Enforcement Policy in Health Care (1996) define two "antitrust safety zones" dealing with the provision of information to payers, and state that conduct falling within these safety zones will not be challenged by the enforcement agencies absent extraordinary circumstances.¹ The proposed order does not prohibit the Colegio from engaging in activities encompassed in these safety zones, or from communicating with payers about other matters, unless the communication is part of an agreement or course of conduct specifically prohibited by the order.

The proposed order likewise does not restrict the right of the Colegio to provide government bodies with information and opinions in an effort to influence legislation or regulatory action. A proviso states explicitly that the order does not prohibit the Colegio from petitioning any federal, state, or Commonwealth government executive agency or legislative body concerning legislation, rules, or procedures, or from

¹ Statement 5 provides a safety zone for providers' collective provision of "factual information concerning the providers' current or historical fees or other aspects of reimbursement, such as discounts or alternative reimbursement methods accepted * * *" so long as collection of the information meets certain requirements designed to ensure that the exchange of price or cost data is not used by competing providers to discuss or coordinate costs or prices. Statements at 44-45. The safety zone in Statement 4 covers the provision of "underlying medical data that may improve purchasers' resolution of issues relating to the mode, quality, or efficiency of treatment," as well as providers' "development of suggested practice parameters—standards for patient management developed to assist providers in clinical decisionmaking—that also may provide useful information to patients, providers, and purchasers." Statements at 41.

participating in any federal, state, or Commonwealth administrative or judicial proceeding, insofar as the activity is protected from antitrust scrutiny by the *Noerr-Pennington* doctrine.² That doctrine does not, however, protect price-fixing agreements, refusals to deal, or similar conduct designed to obtain higher prices from government purchasers.³

Part III of the proposed order prohibits the Colegio from restricting truthful advertising of dental services or solicitation of patients. The Colegio, however, can formulate, adopt, disseminate, and enforce reasonable ethical guidelines governing the conduct of its members with respect to representations that respondent reasonably believes would be false or deceptive within the meaning of Section 5 of the Federal Trade Commission Act, or with respect to uninvited in-person solicitation of actual or potential patients who, because of their particular circumstances, are vulnerable to undue influence.

Part IV of the proposed order requires the Colegio to distribute copies of the order and accompanying complaint to its employees and members, and to payers or providers who since January 1, 1995, communicated a desire or interest in contracting for dentists' services. Part IV also requires the Colegio to maintain certain records pertaining to advertising for a period of ten years, while other order provisions will remain in effect for twenty years. Parts V and VI of the proposed order impose certain reporting requirements, while Part VII of the proposed order provides for access to the Colegio's documents and personnel. Parts V, VI, and VII are to assist the Commission in monitoring compliance with the proposed order.

Opportunity for Public Comment

The proposed order has been placed on the public record for sixty (60) days in order to receive public comments from interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

² See, e.g., *FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411 (1990); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965); *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961).

³ *FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. at 424-425.

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

By direction of the Commission.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Information Collection Activities: Submission for OMB Review; Comment Request

The Department of Health and Human Services, Office of the Secretary publishes a list of information collections it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) and 5 CFR 1320.5. The following are those information collections recently submitted to OMB.

Project 1. First Follow-Up Survey of Youth and Site Visit and Focus Group Protocols for the Federal Evaluation of Initiatives Funded Under Section 510 of the Maternal and Child Health Block Grant Program—The Personal Responsibility and Work Opportunity Reconciliation Act (Public Law 104-193) established Section 510 of the Maternal and Child Health Block Grant Program, the purpose of which is to support state efforts promoting abstinence only education. The Balanced Budget Act of 1997 (Pub. L. 105-33) established a requirement to "evaluate programs under Section 510." This proposed information collection will gather follow-up information for the evaluation—NEW—Respondents: Individuals, state or local governments—Burden Information for First Follow-Up Survey—Number of Respondents: 6,510; Average Burden per Response: .75 hours; Burden: 4,883 hours—Burden Information for Focus Groups—Number of Respondents: 380; Average Burden per Response: 2 hours; Burden: 760 hours—Burden Information for Executive Interviews—Number of Respondents: 330; Average Burden per Response: 1.5 hours; Burden: 495 hours—Total Burden: 6,138 hours.

OMB Desk Officer: Allison Eydt.

Copies of the information collection packages listed above can be obtained