

FEDERAL TRADE COMMISSION
WASHINGTON, D. C. 20580

OFFICE OF THE SECRETARY

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Dear Mr. Jacobs:

This letter responds to your request for an advisory opinion concerning the proposed code of ethics of the American Academy of Ophthalmology. The Academy, an organization of physicians specializing in medical and surgical care of the eye, intends to adopt a code of ethics to govern the professional conduct of its members. This code would become part of the Academy's bylaws, to which ophthalmologists agree to subscribe when they join the organization. You have requested that the Commission advise the Academy whether the proposed code of ethics^{1/} complies with Section 5 of the Federal Trade Commission Act and all other applicable statutes administered or enforced by the Commission.

The laws enforced by the Commission do not prohibit professional associations from adopting reasonable ethical codes designed to protect the public. Such self-regulatory activity serves legitimate purposes, and in most cases can be expected to benefit, rather than to injure, competition and consumer welfare. In some instances, however, particular ethical restrictions can unreasonably restrict competition and thereby violate the antitrust laws.

The legality of a professional society's ethical rules under the antitrust laws depends upon their purposes and competitive effects.^{2/} The materials accompanying your request state that the purpose of the proposed code of ethics is "exclusively to protect and benefit patients of ophthalmologists who are members of the Academy." In accordance with its customary practice when

^{1/} Submitted on August 31, 1982 and modified by your submission on January 17, 1983.

^{2/} See National Soc'y of Prof. Eng'rs v. United States, 435 U.S. 679 (1978); American Medical Ass'n, 94 F.T.C. 701 (1979), aff'd, 638 F.2d 443 (2d Cir. 1980), aff'd by an equally divided Court, 452 U.S. 960 (1982).

considering advisory opinion requests, the Commission has relied upon the Academy's statement as to the good faith purpose of the code. Thus, the Commission has focused its attention on the probable effects on competition of the various provisions contained in the Academy's proposed code of ethics.

The Academy's proposed code of ethics contains three sections: (1) "Principles of Ethics," which are aspirational guidelines for professional conduct and are not enforceable; (2) "Rules of Ethics," which establish specific enforceable standards of conduct for members of the Academy; and (3) "Administrative Procedures," which set forth the structure and operations of the Academy's Ethics Committee and the procedures for investigative and disciplinary proceedings concerning ethics complaints. Members found to have violated the rules of ethics may be reprimanded, suspended from the Academy for a definite time period, or permanently expelled.

The ethical principles express the Academy's views regarding the duties of an ethical ophthalmologist. They state, for example, that ophthalmological services must be provided with compassion and integrity, competence must be maintained through continued study, confidentiality of patient communications must be respected, fees should not exploit patients or others, ophthalmologists deficient in character should be reported to the proper authorities, and the patient's welfare must be the ophthalmologist's primary consideration. The Commission does not find any significant threat to competition posed by these proposed guidelines. It is the Commission's opinion that adoption of the proposed "Principles of Ethics" for the purpose described by the Academy would not violate the Federal Trade Commission Act or any other statute enforced by the Commission.

The second section of the code contains the ethical rules, which the Academy intends to enforce. As their titles indicate, these rules address various aspects of professional conduct:

- A. Competence
- B. Informed Consent
- C. Clinical Experiments and Investigative Procedures
- D. Other Opinions
- E. The Impaired Ophthalmologist
- F. Preoperative Assessment
- G. Delegation of Services
- H. Postoperative Care

- I. Medical and Surgical Procedures
- J. Procedures and Materials
- K. Commercial Relationships
- L. Communications to Colleagues
- M. Communications to the Public

Most of these rules do not raise significant antitrust issues. For example, the Academy has proposed rules that would assure to patients such important protections as informed consent, careful preoperative evaluations, and appropriate consultations. Other ethical rules in the proposed code prohibit practices that cause injury to patients, such as misrepresentations of services performed or the ordering of unnecessary procedures for pecuniary gain. Such rules appear unlikely to have anticompetitive effects and may, in some instances, promote competition.

A few of the ethical rules -- because of the nature of the restraints that they impose -- require separate discussion. These are the provisions addressing clinical experiments and investigative procedures, delegation of ophthalmological services, postoperative care, and communications to the public.

Clinical Experiments and Investigative Procedures

Rule C of the Academy's proposed code requires ophthalmologists to obtain approval from "adequate review mechanisms" before undertaking a "clinical experiment" or an "investigative procedure." The ophthalmological procedures subject to this requirement are defined in the rule as "those conducted to develop adequate information on which to base prognostic or therapeutic decisions, or to determine etiology or pathogenesis, in circumstances in which insufficient information exists." The rule does not require a particular type of review mechanism for all cases. In supplemental materials, the Academy has indicated that the concept of an "adequate" review mechanism is intended to be flexible, and that the rule has been drafted to permit use of "informal" review mechanisms, such as a telephone conference with a colleague, when formal review would be impracticable. The rule also provides that informed consent for clinical experiments and investigative procedures "must recognize their special nature and ramifications."

Although unnecessarily strict controls on the use of new ophthalmological procedures could unreasonably restrict competition and innovation, the Academy's proposed rule appears to provide safeguards to patients -- to protect them from uncontrolled experimentation -- with no apparent lessening of competition. Serious

antitrust concerns would be raised, of course, should the rule be applied in a discriminatory manner to discourage vigorous and innovative competitors or be otherwise abused in an attempt to restrain legitimate competition.

Delegation of Services

Rule G addresses delegation of eye care services. This rule declares that certain eye care services may not be delegated to non-physician health care professionals (referred to by the Academy in its rule as "auxiliary health care personnel"). Under the rule, non-delegable services are "those aspects of eye care within the unique competence of the ophthalmologist (which do not include those permitted by law to be performed by auxiliaries)." Materials accompanying your request state that the term "auxiliaries" as used in the code includes optometrists, nurses, technicians, orthoptists and others. Rule G further provides that when an ophthalmologist maintains responsibility to the patient for eye care services not "within the unique competence of the ophthalmologist," these services may be delegated to qualified non-physician health care professionals with adequate supervision.

Rule G addresses practice arrangements between ophthalmologists and non-physician health care professionals, and does not apply to arrangements between ophthalmologists and other physicians, since physicians are not "auxiliaries." The Commission understands that the rule would not prevent ophthalmologists from making arrangements for delegation of eye care services to non-physicians as long as those arrangements are structured and carried out in accordance with applicable state law. State laws regulating health care professionals permit those non-physicians that the Academy has described as "auxiliaries" to provide a variety of eye care services, sometimes as independent practitioners and in other cases under the supervision of a licensed physician. Under the code, such services are not "within the unique competence of the ophthalmologist," and therefore they may be delegated.

It is also the Commission's understanding that the supervision requirement contained in the rule, applicable when an ophthalmologist retains responsibility for eye care that may be delegated, is not intended to mandate a particular type or degree of supervision for all situations. Supervision requirements under state law vary greatly, and may range from direct, on-site supervision to practice under standing orders or telephone consultation. The Academy has indicated in supplementary materials provided to the Commission that the level of supervision required by the rule will be determined by

reference to applicable state law. Finally, the Academy has specifically provided for flexibility in Rule G by the last sentence of the rule, which states: "An ophthalmologist may make different arrangements for the delegation of eye care in special circumstances, such as emergencies, if the patient's welfare and rights are placed above all other considerations."

Serious antitrust concerns would, of course, be raised by an ethical rule that unreasonably interfered with legitimate competition by ophthalmologists working in conjunction with non-physician health care professionals, or prevented optometrists or others from providing services that they are legally and professionally qualified to provide. It is the Commission's opinion, though, based on its understanding set forth above and the Academy's supplemental assurances and explanations, that Rule G should not have these effects.

Postoperative Care

Rule H addresses arrangements for care following eye surgery. Like Rule G, it concerns aspects of eye care -- in this particular rule postoperative eye care -- that are "within the unique competence of the ophthalmologist (which do not include those permitted by law to be performed by auxiliaries)." Rule H declares that those aspects of postoperative eye care must be provided either by the operating ophthalmologist or by another ophthalmologist with whom a referral arrangement has been made. It is the Commission's understanding that the Academy prefers that the operating ophthalmologist provide the aspects of postoperative care covered by Rule H, but that, nonetheless, the code has been drafted to leave Academy members free to refer patients to another ophthalmologist for this postoperative care.

The rule also provides that when a patient is referred for postoperative care, the operating ophthalmologist must make the arrangements before surgery, and the patient and the other ophthalmologist must agree. The rule further declares that fees for postoperative care should reflect the arrangements that have been made, "with advance disclosure to the patient." Finally, Rule H states that "different arrangements" for postoperative eye care may be made in emergencies or other special circumstances, as long as the patient's welfare and rights are the primary consideration. Explanatory materials accompanying your request state that special circumstances include, for example, cases in which no ophthalmologist is available to perform the postoperative care in the geographic area where the patient resides.

Rule H addresses aspects of postoperative eye care falling within the range of services that only physicians are qualified by law to perform. For example, the rule would not prevent ophthalmologists from arranging for optometrists to provide postoperative eye care services consistent with state law. It appears, however, that the rule could affect postoperative care arrangements with physicians who are not ophthalmologists. The question arises whether Rule H's identification of some postoperative eye care services as "within the unique competence of the ophthalmologist" might unreasonably prevent Academy members from referring patients to qualified physicians who are not specialists in ophthalmology, either individual private practitioners or those in health maintenance organizations and other group settings.

Agreements among competitors to exclude another group of competitors from a market are highly suspect under the antitrust laws. Thus, if Rule H were a strict prohibition that had the effect of categorically excluding non-ophthalmologist physicians from some aspects of medical practice, it might raise serious antitrust questions. It is the Commission's understanding, however, that the Academy has endeavored to provide for flexibility in Rule H. One example of this flexibility is the last sentence of the rule, which provides for other referral arrangements in "special circumstances." Another area of flexibility involves the determination of what eye care functions are unique to ophthalmology.

The Commission understands that it is the Academy's position that the precise eye care functions deemed to be "within the unique competence of the ophthalmologist" will vary depending upon the circumstances involved. Although the proposed code defines an "ophthalmologist" as "a physician who is educated and trained to provide medical and surgical care of the eyes and related structures," state statutes and regulations do not define areas of medical specialization, such as ophthalmology, and thus do not delineate an area of medicine that might be considered "within the unique competence of the ophthalmologist." Moreover, the Academy states in its explanatory materials submitted with the proposed code that it is not seeking through its code of ethics to define the appropriate scope of practice of health care personnel. Rather, these supplementary materials set forth a flexible approach, and state that in determining what eye care services fall within the special sphere of the ophthalmologist, the Academy will look to "the circumstances of each situation" and "whatever governing mandatory or voluntary credentialing mechanisms might exist." Thus, as the Commission understands it, Rule H would not preclude an Academy

member from referring patients to a non-ophthalmological specialist for postoperative eye care, as long as the individual physician's training and experience qualified him or her to provide the particular postoperative services.

In light of this flexibility, the Commission concludes that Rule H is a reasonable rule that could provide valuable protection to consumers. As long as it is applied fairly and objectively, and is not interpreted more broadly than necessary to achieve its legitimate goal, it should not unreasonably impair competition. Careful attention will have to be paid to interpretation and enforcement of Rule H, because the lack of any clear definition for "aspects of eye care within the unique competence of the ophthalmologist" may make the rule susceptible to abuses in application. Obviously, if the effect of the rule were to impede new and potentially cost-effective methods for the delivery of quality eye care or to exclude unreasonably family physicians or other doctors from certain aspects of medical practice, serious antitrust concerns would be raised. Nonetheless, based on the available information, it appears that adoption of Rule H would not pose an unlawful threat to competition or consumer welfare.

Communications to the Public

Rule M sets forth several requirements for advertising and other communications to the public. The rule bans false or deceptive communications, both affirmative misrepresentations and misrepresentations arising from the failure to disclose a material fact. It does not ban any particular form of communication, such as testimonials or pictorial representations; rather, it provides that these and other forms of communications must not convey false or deceptive information.

Rule M also prohibits certain specific types of representations. The rule bans communications that: "appeal to an individual's anxiety in an excessive or unfair way"; "create unjustified expectations of results"; "misrepresent an ophthalmologist's credentials, training, experience or ability"; or "contain material claims of superiority that cannot be substantiated."

These provisions elaborate on the rule's general proscription of false or deceptive communications. With respect to appeals to anxiety, the Academy has taken into account the fact that information on health care topics may often create anxiety and has drafted the rule to make clear that it is aimed at those communications that unfairly or oppressively cause anxiety. The Commission

understands that this provision will be enforced reasonably and objectively, to avoid discouraging the dissemination of valuable information to consumers. The ban on communications that "create unjustified expectations of results" prohibits deceptive representations regarding the likely results of ophthalmological treatment. The last two provisions identified above address false or misleading statements about the qualifications of an ophthalmologist. The Commission notes that the rule prohibits "material claims of superiority that cannot be substantiated" and does not contain a ban on "self-laudatory" or "self-aggrandizing" statements.

Finally, Rule M contains two disclosure requirements. Disclosures regarding safety, efficacy, and the availability of alternatives must be made if a communication refers to "benefits or other attributes of ophthalmic procedures or products that involve significant risks," and in some cases descriptions or assessments of alternative treatments must be given. In addition, a communication must include a disclosure that it "results from payment by an ophthalmologist," when this is the case and it is not obvious from the nature, format, or medium of the communication.

The Commission understands that all of the disclosures identified in the rule are required only when necessary to avoid deception. The Academy has specifically represented that the disclosure requirements with respect to communications that "refer to benefits or other attributes of ophthalmic procedures or products that involve significant risks" are intended and will be construed by the Academy to require disclosures only to the extent necessary to prevent deception of the public. The Commission also understands that mere identification of an ophthalmic procedure or product that involves significant risks, without reference to its benefits or other qualitative attributes, will not trigger the disclosure requirement. Furthermore, the Academy has represented that an advertisement for routine eye examinations, such as "safeguard your health; get your eyes checked; careful and thorough eye examinations by appointment," would not need to contain the disclosures identified in Rule M. Similarly, the disclosure requirements of the rule would not be triggered by a communication that advertised the fitting or provision of contact lenses and noted such attributes as improved appearance, user comfort, or inexpensiveness.

Based on its understanding of Rule M and the Academy's supplemental assurances and explanations, the Commission believes that this rule does not pose an unreasonable threat to competition or consumers. Rules that are tailored to prevent false or deceptive advertising serve to enhance the competitive process and provide

valuable consumer protection. Care should be exercised, of course, to ensure that interpretation and enforcement of the rule does not have the effect of suppressing nondeceptive advertising or other communications to the public.

It is the Commission's opinion, based on the foregoing and the Academy's supplemental assurances and explanations, that adoption of the proposed "Rules of Ethics" would not violate the Federal Trade Commission Act or any other laws enforced by the Commission. The Commission notes that the Academy has stated that its aim is to "assure that the code is interpreted and enforced objectively and with fairness." This is essential, for even the most carefully drafted ethical rules can create antitrust problems if they are abused. Rule K, for example, declares that an ophthalmologist must not let his or her clinical judgment and practice be affected by commercial interests. This rule could raise serious concerns if it were broadly interpreted to effect a flat ban on certain types of legitimate commercial relationships.

The final section of the proposed code of ethics describes the administrative procedures that will be used to implement the ethical rules. The procedures established by the code include: notice to the accused of the existence of an investigation; opportunity for a hearing; right to counsel; opportunity to cross-examine witnesses and offer evidence; right to appeal an adverse decision; and preservation of a written record.

Courts have held that when membership in an organization of competing firms or individuals confers a significant competitive advantage, disciplinary measures such as suspension or termination may not be imposed without adequate procedural safeguards. The proposed code provides significant procedural safeguards. It is the Commission's opinion that adoption and use of the "Administrative Procedures" contained in the proposed code would not violate the antitrust laws or any other laws enforced by the Commission.

Accordingly, the Commission concludes that adoption of the American Academy of Ophthalmology's proposed code of ethics would not violate Section 5 of the Federal Trade Commission Act or any other statute enforced by the Commission. This advisory opinion, like all those issued by the Commission, is limited to the proposed conduct described in the petition being considered. It does not, of course, constitute approval for specific instances of implementation of the code that may become the subject of litigation before the Commission or any court, since interpretations and enforcement of

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the code in particular situations may prove to cause significant injury to competition and consumers, and thereby violate the Federal Trade Commission Act. The Commission maintains the right to reconsider the questions involved and, with notice to the requesting party in accordance with Section 1.3(b) of the Commission's Rules of Practice, to rescind or revoke its opinion in the event that implementation of the proposed code of ethics results in significant anticompetitive effects, should the purposes of the code or any of its individual provisions be found not to be legitimate, or should the public interest otherwise so require.

By direction of the Commission.

1s/ -
~~Emily H. Reek~~ *Michael A. Baggage*
Acting Secretary