Federal Trade Commission

Report of the Presiding Officer on
Proposed Trade Regulation Rule:

OPHTHALMIC PRACTICE RULES

16 CFR Part 456
Public Record 215-63

THIS REPORT CONTAINS THE PRESIDING OFFICER'S RECOMMENDED DECISION BASED UPON HIS FINDINGS AND CONCLUSIONS AS TO THE RELEVANT AND MATERIAL EVIDENCE IN THE RULEMAKING RECORD. IT HAS NOT BEEN REVIEWED OR APPROVED BY THE COMMISSION OR ITS OPERATING BUREAUS.

JAMES P. GREENAN
PRESIDING OFFICER

MAY 1, 1986

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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of	)	
OPHTHALMIC PRACTICE RULES; PROPOSED TRADE REGULATION RULE	)	PUBLIC RECORD NO. 215-63
[16 C.F.R. 456]	)	

REPORT OF THE PRESIDING OFFICER

By James P. Greenan, Presiding Officer

I. INTRODUCTION

A. Preliminary matters. On January 4, 1985, the notice of proposed rulemaking (NPR) for this proceeding was published in the Federal Register.[1] The notice included a general description of the proposed rule and a discussion of the proposed rule provisions. The notice sets forth the reference to the legal authority under which the rulemaking was proposed.[2] Section A of the notice sets forth a statement of the Commission's reasons for the proposed rule. Section B is a section-by-section analysis of the proposal. Section C of the notice sets forth an invitation to comment either orally or in writing on the proposed rule. Section D sets forth a series of sixteen questions concerning issues in the proceeding and contains a statement that the Commission has decided to employ a modified version of the

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[1] 50 Fed. Reg. 598 (1985).

[2] 15 U.S.C. 41 et seq. was cited as the legal authority without reference to any specific section of that act.

rulemaking procedures specified in §1.13 of the Commission's Rules of Practice, proceeding with a single Notice of Proposed Rulemaking and the "no designated issues" format.[3] Section E of the notice announces the dates and locations at which public hearings on the rulemaking proposal would be held.[4] Sections F, G and H of the notice sets forth instructions to witnesses at public hearings, the requirements for notification of interest and announces post-hearing procedures. Section I contains a statement concerning the Rulemaking Record. Section J of the notice sets forth a preliminary regulatory analysis of the proposal and Section K an initial regulatory flexibility analysis. The text of the proposed trade regulation rule was set forth in Section L of the notice.

Following publication of the notice, a rulemaking record was established. The organization and location of the contents of this record are described in Appendix II of this report. The staff report to the Commission on the proposed rule entitled "State Restrictions on Vision Care Providers: The Effects on Consumers" ('Eyeglasses II') was placed in Category B of the rulemaking record together with materials the staff gathered in

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[3] 50 Fed. Reg. 598 at 602. [See Rule 1.20, Part 1, Subpart B, Commission's Rules of Practice, 16 C.F.R. 1.20, which authorizes the use of such alternative procedures as may be prescribed in the notice commencing the rulemaking.]

[4] The Notice of Proposed Rulemaking announced that public hearings in San Francisco, California, would commence on June 17, 1985. Pursuant to an Order of the Presiding Officer (Presiding Officer's Order No. 6, issued May 17, 1985, R-A-21), these hearings were re-scheduled to commence on July 1, 1985, and appropriate notice to such effect was published. [50 Fed. Reg. 23996, June 7, 1985].

its investigation prior to the initiation of the proceeding. A memorandum from the Director, Bureau of Consumer Protection, to the Commission, dated April 13, 1984, is also included in this Category. This memorandum transmitted to the Commission the final memorandum of Recommendations for Action (April 13, 1984) by the staff which was prepared following its analysis of the comments received in response to an advance notice of proposed rulemaking. Additional evidence obtained by the staff was placed in Category C of the rulemaking record during the period for receipt of written comment.

The advance notice of proposed rulemaking ("ANPR") [5] and comments received in response to this notice were placed in Category C of the rulemaking record.

Other materials gathered by the staff during the course of its pre-notice investigations considered to be non-probative of the issues were either placed in the public record (as distinguished from the rulemaking record) established for this proceeding or otherwise made available for inspection by the public.

In this report, references to material contained in the rulemaking record are made in the text or in the footnotes using the following abbreviations and format:

Tr. References to material in the transcript of the hearings.

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[5] 45 Fed. Reg. 79823 (December 2, 1980).

HX. References to material contained in exhibits presented and accepted into evidence at the hearings (Hearing Exhibits).

R. Written material consisting of written comments and other material submitted by the Commission staff and interested persons as well as other material placed in the rulemaking record at the direction of the Presiding Officer.

References to documents contained in the written portion of the rulemaking record show the category in which the document was placed, the number of the document, and the internal page number of the document on which the reference appears. By way of example, citation to a comment appearing at page 15 in a document filed in Category F would be cited in the following manner: R-F-13 at 15. The numbers of the binders in which documents may be found appear in Appendix II. A list of hearing exhibits showing the binder number in which each appears is also included in Appendix II.

B. Grouping of persons with the same or similar interests. In accord with the instructions contained in the notice of proposed rulemaking, persons filing notification of interest to question witnesses were initially placed in two groups. [6] The groups were:

Group A: Optometric Associations

[6] Presiding Officer's Order No. 2 issued April 30, 1985, R-A-8. The members of the two groups are listed in an attachment to the order.

Group B: Commercial Vision Care Providers.

At the conclusion of public hearings conducted in Washington, D.C., upon motion by the Group Representative for Group B, an order was entered granting a request to restructure Group B prior to beginning the scheduled hearings in San Francisco, California.[7] The order directed creation of a new group for the San Francisco hearings, designated as:

Group C: Individual and Corporate Vision Care Providers.

C. Public hearings. All of the public hearings were held before James P. Greenan who had been designated as Presiding Officer by Henry B. Cabell, Chief Presiding Officer, under the provisions of §1.13(c) of the Rules of Practice.[8]

All persons who sought to express their views on the proposed rule and who complied with the instructions in the notice of proposed rulemaking were permitted to do so. [50 Fed. Reg. 598 at 603]. Only one witness appearing at the hearings was sworn.[9] A verbatim transcript of the hearings was made by the Commission's official reporter and has been included in the

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[7] Presiding Officer's Order No. 8, issued June 19, 1985, R-A-26.

[8] Memorandum from Chief Presiding Officer, dated January 7, 1985, R-A-2.

[9] William Erxleben, representing the Washington State Optometric Association, a former Federal Trade Commission employee, requested and was granted the right to give his testimony and to answer questions posed by staff and the group representatives after having been sworn. This action was taken to satisfy the requirements of §4.1(b)(7)(i)(C) of the Rules of Practice. See Tr. 1411.

rulemaking record.[10]

Hearings on the proposed rule were conducted in Washington, D.C., from May 20 through May 28, 1985, and in San Francisco, California, during the period of July 1 through July 12, 1985. During these periods a total of 15 days of hearings were held and approximately 70 witness presentations were made. Witnesses were heard individually and grouped into panels as each presentation warranted. In total, approximately 94 individuals participated as witnesses in the hearings.

Examination and cross-examination of witnesses were conducted by members of the Commission staff and the Group Representatives. On occasion, individuals designated by a Group Representative were permitted to examine a witness on behalf of the group. No delays in the proceeding occurred as the result of examination or cross-examination. In accordance with the instructions contained in the notice of proposed rulemaking, questions were permitted on any issue relevant to the proceeding and within the scope of the testimony. Questioning which was not considered by me to be appropriate for full and true disclosure as to relevant issues was disallowed. In addition, questioning was restricted to fixed time limits established for the Commission staff and each group. The time limits were established by agreement between the staff, the Group Representatives and the Presiding Officer. During the course of

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[10] The transcripts of testimony were placed in Category J. Exhibits introduced at the hearings, were also placed in Category J and individually identified by an appropriate number in the category.

the proceeding, where appropriate, time limits which had previously been agreed upon were extended as necessary to afford interested parties and staff an opportunity for completion of reasonable cross-examination. These control measures proved to be entirely adequate and were sufficient to prevent any undue delay to the proceedings.

At no time during the hearings did the Presiding Officer find it necessary to conduct cross-examination on behalf of the staff or any of the Group Representatives. Further, because the record is not overburdened with objections or other colloquy, the transcripts of testimony offer a fairly clean and uncluttered exposition of the viewpoints and opinions aired in the proceeding.

While most of the motions and requests filed in this proceeding were in written form and appropriately filed in Category A of the rulemaking record together with the rulings thereon, certain motions and requests were made orally during the course of public hearings. All oral motions and requests are fully recorded in the transcripts of the proceeding. Rulings on these oral motions and requests were made in both oral and written form and either are recorded fully in the transcripts of the proceeding or filed in Category A of the rulemaking record.

Any motions or requests not heretofore or herein specifically ruled upon, either directly or by necessary effect of the findings, conclusions and recommendations set forth in this report, are hereby denied.

D. Post hearing matters - Rebuttal submissions. On the final day of public hearings, a time for filing rebuttal submissions was established in accordance with the directions of the Commission set forth in the NPR. Subsequently, it was found advisable to extend the rebuttal period for an additional twenty-one days beyond the date initially established.[11] This action, however, was not cause for any delay in the proceedings.

All interested persons were afforded the right to file rebuttal submissions based upon identified, properly cited matters already on the record. Twenty-four such submissions were received from interested persons and the Commission's staff. These submissions were placed in the rulemaking record in Category K.

E. Commission's reasons for proposing rule. A statement of the Commission's reasons for the proposed rule is set forth in Section A of the NPR. These reasons are based upon its consideration of the results of an initial staff investigation set forth in a publicly available report prepared by the staff[12], and upon the 247 comments from consumers, industry members and government officials received in response to the ANPR.

Based upon evidence received during the course of an earlier trade regulation rule proceeding affecting the ophthalmic

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[11] Presiding Officer's Order No. 11, issued September 16, 1985, R-A-38.

[12] State Restrictions on Vision Care Providers: The Effect on Consumers ("Eyeglasses II"), Bureau of Consumer Protection, July, 1980, R-B-2-1.

industry [13], the Commission had previously directed the staff to initiate an investigation to determine, among other things, whether restrictions on forms of commercial ophthalmic practice were unfair acts or practices within the meaning of Section 5(a)(1) of the Federal Trade Commission Act. During the course of its investigation the staff examined four types of restrictions imposed by state law and assessed the impact on the price, quality and availability of these restrictions.

The Commission advised that, with respect to the proposed rule provisions concerning commercial practice restrictions, the staff report presents evidence that state laws which restrict the ability of optometrists to practice in commercial settings raise consumer prices but do not maintain or enhance the quality of vision care. In so stating, the Commission outlined the results obtained from the 1980 Bureau of Economic Study ("BE Study")[14] and the 1983 study of contact lens wearers by the Bureaus of Consumer Protection and of Economics ("CLS" or "CL Study")[15].

The Commission advised staff's recommendation that the Commission engage in rulemaking proceedings regarding commercial practice restrictions is based primarily on the results of these studies, which contradict the claim that the entry of commercial

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[13] Trade Regulation Rule Regarding Advertising of Ophthalmic Goods and Services, 16 C.F.R. 456, Public Record 215-52 ("Eyeglasses I").

[14] Effects of Restrictions on Advertising and Commercial Practice on the Professions: The Case of Optometry, Bureau of Economics, 1980, R-B-2-31.

[15] A Comparative Analysis of Cosmetic Contact Lens Fitting by Ophthalmologists, Optometrists and Opticians, Bureau of Consumer Protection, Bureau of Economics, 1983, R-B-5-1.

firms into the market lowers the overall level of quality of vision care. The results of the studies also show that average prices are significantly higher where commercial practice is restricted. Finally, the Commission advised that it has reason to believe that these restrictions may be unfair acts or practices within the meaning of Section 5 of the Federal Trade Commission Act.

In connection with the existing Eyeglasses Rule (Trade Regulation Rule Regarding Advertising of Ophthalmic Goods and Services), the Commission announced that confusion has arisen as to whether eye doctors are required by that rule to state that patients whom they had examined were suitable candidates for contact lenses by writing "OK for contacts" or similar language on the prescription. In its report the staff had recommended that the Commission not employ rulemaking to address the questions of who should be permitted to fit contact lenses. Therefore, the proposed trade regulation rule would modify the definition of the term "prescription" contained in the existing Eyeglasses Rule to eliminate all references to contact lenses. The Commission stated that this modification is consistent with the staff's recommendation not to use rulemaking.

The Commission also has proposed several nonsubstantive changes to clarify the existing Eyeglasses Rule.

In the notice of proposed rulemaking, the Commission has plainly stated that it has not adopted any findings or conclusions of the staff and that all findings in this proceeding shall be based solely on the rulemaking record. [50 Fed. Reg.

598 at 600].

F. Description of proposed rule. The proposed rule is in the form of a revision to the existing Eyeglasses Rule, 16 C.F.R. Part 456.

§456.1 defines relevant terms and contains new definitions, as well as technical modifications to terms in the existing Eyeglasses Rule.

The notice of proposed rulemaking announces that §456.2 through §456.6 of the Eyeglasses Rule have been deleted in accordance with the court's decision in American Optometric Association v. FTC, 626 F.2d 897 (D.C. Cir. 1980), which remanded those portions of the rule to the Commission for further consideration.

New §456.2 contains minor modifications to the release of prescription requirement of the Eyeglasses Rule (originally §456.7) which was upheld by the Court in American Optometric Association v. FTC.

§456.3 excludes ophthalmologists, optometrists or sellers in the employ of any federal, state or local governmental entity from the requirements of §456.2 of the proposal.

§456.4(a) would prohibit state or local governments from enforcing certain existing bans on commercial ophthalmic practice. Subsection (a)(1) would prevent state and local governments from enforcing prohibitions of employer-employee or other business relationships between optometrists or opticians and persons other than ophthalmologists and optometrists. Subsection (a)(2) would prohibit enforcement of state or local

restrictions on the number of offices that an optometrist, optician or any other person may operate. Subsection (a)(3) would prohibit enforcement of state or local restrictions that prohibit optometrists from locating an office in a pharmacy, department store, shopping center, retail optical dispensary, or other mercantile location. Subsection (a)(4) would prohibit enforcement of all state or local bans that prevent optometrists from practicing or holding themselves out to the public under a trade name.

§456.5 sets forth a Declaration of Commission Intent, and, subsections (b) through (e) thereunder serve primarily to explain the limited scope of §456.4(a) by providing examples of how the states might regulate commercial practice, if necessary, short of prohibiting it altogether.

G. Nature of the rulemaking record. The rulemaking record in this proceeding, as of the date of this report, contains some 15,726 pages. Less than 3,100 pages are devoted to testimony received at the public hearings. The remainder consists of written submissions in the form of comments received prior to the hearings, hearing exhibits, rebuttal submissions following the hearings, and staff submissions of certain materials gathered during the course of its investigation and in response to the ANPR.

Written and oral submissions in support of the rule include specific allegations of competitive and consumer injury resulting from public restrictions on permissable forms of ophthalmic practice. Those who oppose the rule included state and local

officials, optometric associations and others who challenge the Commission's authority to preempt existing public restrictions on forms of practice and/or contend that the elimination of such restraints will reduce the quality of eye care available to the consuming public and neither increase the general access of the entire population to vision care nor reduce prices attendant to providing vision care. Included in both the written and oral submissions of those opposing the rule and in the rebuttal statements which were filed are allegations that the studies by the Bureau of Economics and Bureau of Consumer Protection relied upon by the staff in its recommendation to the Commission for initiation of rulemaking are seriously flawed and fail to support the recommendations of the staff. These submissions and rebuttal also contend that the present restraints extant in the various states insure quality of care for the citizens of these states and should only be amended or rescinded through action taken at the local level by elected officials of the various and several states.

I have reviewed the entire rulemaking record and have considered all relevant and material evidence as set forth in the testimony of witnesses at the hearings and the written submissions admitted into the record.

I make the following findings and conclusions:

II. FINDINGS AND CONCLUSIONS

A. Modifications to Existing Rule.

1. Definitions

§456.1 defines relevant terms and contains new definitions as well as technical modifications to terms in the existing Eyeglasses Rule, relating to Advertising of Ophthalmic Goods and Services, 16. C.F.R. 456.

1. §456.1(a) substitutes the term "patient" for the term "buyer" to conform more closely to industry usage. The record shows there is no opposition to the proposed change.

2. §456.1(d) defines ophthalmic services as the measuring, fitting, and adjusting of ophthalmic goods to the face subsequent to an eye examination. While the Commission proposes no change in this section, the Opticians Association of America (OAA) has recommended the substitution of language for the purpose of clarification. Calling attention to the preceding section, §456.1(c) which defines ophthalmic goods to include contact lenses, OAA argues that §456.1(d) should define services to include measuring, fitting, and adjusting contact lenses which are fitted to the "eyes", as opposed to spectacles which are fitted to the "face", as indicated in the proposed definition. OAA recommends that §456.1(d) be amended to define services as the measuring, fitting, and adjusting of ophthalmic goods subsequent to an eye examination, thereby including services provided both in connection with eyeglasses or spectacles, as well as contact lenses. R-H-80 at 14.

3. §456.1(e) defines an ophthalmologist as any Doctor of Medicine or Osteopathy who performs eye examinations, and §456.1(f) defines an optometrist as any Doctor of Optometry. These two changes substitute the terms "ophthalmologist" and "optometrist" for the general word "refractionist" to define those categories of providers - Doctors of Medicine, Osteopathy and Optometry - who are qualified under state law to perform eye examinations. This change was proposed for two reasons. First, the use of the term refractionist in the original rule has caused confusion because it is not generally used by consumers or the industry. Second, certain provisions of the proposed rule permitting commercial practice do not apply to ophthalmologists. The term refractionist has been deleted so that this distinction is clear. While comment was received objecting to the use of the word "ophthalmologist" and suggesting substitution of the word "physician" to conform with more accurate language used in various state licensing statutes,[1] the record contains no substantial objection to this proposed change. Likewise, the record indicates that, in one state at least, optometrists are allowed to use therapeutic pharmaceutical drugs in diagnosing and treating certain conditions. This allowance for use of drugs by optometrists imposes on them duties not imposed on refractionists.[2] However, such fact does not warrant a further

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[1] Joseph Lavigna, President, Board of Examiners of Ophthalmic Dispensers and Ophthalmic Technicians, State of New Jersey, R-E-33 at 2.

[2] John Robinson, O.D., Secretary, North Carolina Board of footnote (cont)

modification of §456.1(f).

4. §456.1(h) defines a prescription as the written specifications for spectacle lenses which are derived from an eye examination, including all of the information specified by state law, if any, necessary to obtain spectacle lenses. The record shows no objection to this proposed definition.

5. §456.1(i) defines a seller as any person or his or her employee or agent, who sells or provides ophthalmic goods and services directly to the public. One comment was received objecting to use of the word seller and recommended substitution of the word optician or ophthalmic dispenser to connote more accurately those persons other than duly licensed optometrists and physicians who are qualified to dispense ophthalmic goods and services.[3] There were no other objections to the proposed definition.

6. §456.1(j) defines trade name bans as any state law, rule or regulation which prohibits optometrists from practicing or holding themselves out to the public under the name of the person by whom they are employed or a name other than the name shown on their licenses or certificates of registration. The record indicates no objection to this proposed definition.

CONCLUSIONS, §456.1, DEFINITIONS.

A. With the exception of subsection 456.1(d), the record discloses no substantial opposition to the changes in definitions

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Examiners in Optometry. Tr. 2975-76.

[3] Lavigna, note 1 at 2.

proposed by the Commission.

B. The definition of ophthalmic services proposed in subsection 456.1(d) is technically incorrect in describing ophthalmic services as the measuring and fitting and adjusting of ophthalmic goods "to the face" so long as the definition of "ophthalmic goods" contained in subsection 456.1(c) describes such goods as consisting of contact lenses as well as eyeglasses and their components. A more appropriate wording of the definition, to bring both subsections 456.1(c) and (d) into accord with each other, should take into consideration the recommendation made by OAA to define ophthalmic services as services given subsequent to an eye examination, eliminating any reference to goods fitted "to the face". See Finding 2.

2. Separation of Examination and Dispensing.

7. The proposed changes to §456.2 involve substitution of terminology to conform to the amended definitions set forth in §456.1. However, a wide range of comment on the application and effect of the existing prescription release rule was forthcoming, prompted by a series of questions set forth in the NPR. In particular, the Commission has sought to determine how the existing requirement is functioning, the extent of consumer knowledge about the requirement, and whether modifications to the requirement may be necessary, among other things.

8. The American Optometric Association (AOA) is urging the repeal of the requirement embodied in proposed §456.2 as being unnecessary. In the alternative, AOA seeks modification of the

requirement to provide for the release of the spectacle prescription only on the request of a patient made at the time of the examination. AOA, R-H-81 at 55. It is argued the Commission's staff has indicated that most consumers are now aware they have the right to obtain their prescriptions and shop around for eyeglasses. The staff has concluded it seems likely that most consumers who do not ask for prescriptions do not want to shop around. R-H-81 at 55-56. In light of evidence sponsored by the staff, repeal of the prescription release requirement is clearly appropriate, according to AOA. Requiring doctors to give prescriptions to patients who do not need or want them is unnecessary, involves a paperwork burden for doctors, may be confusing to some patients, is hard to enforce and generally serves no useful purpose. R-H-81 at 56. Citing to a memorandum from the Director, Bureau of Consumer Protection in April, 1984, R-B-1 at 6, AOA agrees that "[i]f a consumer does not want his or her prescription, it makes little sense to require a doctor to issue one anyway. Such a requirement wastes the doctor's time." R-H-81 at 56. In the alternative, AOA argues for amendment to the rule for release of the prescription to the patient upon request and only at the time of the eye examination. AOA believes there is no evidence a significant number of doctors wrongfully refuse to provide prescriptions to patients who request them at a later date and that any modification of the existing rule should not call for release at a date later than the time of examination. AOA also contends that it would be neither necessary nor appropriate to expand the prescription

release rule to require a doctor or dispenser to provide upon request a copy of the patient's spectacle prescription after the dispensing process is completed, and that there is no evidence to demonstrate that a significant number of consumers who request such prescriptions have been unable to get them. R-H-81 at 57-58. The California Optometric Association (COA) supports the AOA recommendation for modification of the present rule to an "on request" requirement and suggests the modified requirement extend only as long as the patient's prescription is accurate. R-H-98 at 18.

9. The National Association of Optometrists and Opticians (NAOO) seeks continuation of the current prescription release requirement, pointing out that while the Commission's own evidence in this rulemaking demonstrates many of the abuses which the prescription release requirement was designed to address have been eliminated, at least to an extensive degree, compliance with the remedial aspects of the existing rule is not high. NAOO alleges that a substantial number of dispensing ophthalmologists and optometrists continue to fail to provide their patients with prescriptions unless specifically requested. R-H-78a at 92. NAOO initially supported a form of "on request" modification to the prescription release rule. R-H-78a at 92-95. However, the association changed its position and advised in testimony during public hearings that NAOO members acknowledge that information developed during the proceedings and the entire rulemaking process may point to the need to continue the mandatory prescription release requirement. HX-J-8(a) at 2.

NAOO also believes consumers should have a copy of their prescription returned to them after the original prescription is filled, although it was observed that there does not appear to be any indication consumers who request a copy after dispensing are being denied access to these prescriptions. R-H-78a at 95-96.

10. Continued support for the current prescription release provision was forthcoming from the OAA because of the optician's total dependence upon the prescription which is generated by the doctors and placed in the hands of the consumer. Donald L. Klauer, Tr. 629. Arguing in opposition to the AOA recommendation for recision or modification of the requirement, OAA believes that the population of eyeglass wearers is not static and that thousands of consumers become first time wearers each year. It is important that these consumers have the protection of mandatory prescription release, Klauer, Tr. 631-32. OAA noted the three essential reasons found by the Commission which require that a copy of the prescription be tendered to the consumer and stated these reasons are as valid at the present time as when the existing rule was promulgated in 1978. Klauer, Tr. 630. Similar support for continuing the current requirement was received from the California Association of Dispensing Opticians (CADO) R-H-112 at 2-4. According to the witness for CADO, the only ones who may benefit by any modification of the rule would be doctors who wish to limit or eliminate competition and capitalize on merchandising eyewear to a captive audience. Michael J. Tiernan, Tr. 1260-61.

11. A staff-sponsored survey was conducted in February, 1981, in order to determine how providers of vision care were complying with the prescription release requirements of the Eyeglasses I rule. The survey concluded that 37.3 percent of all refractionists[4] technically complied with the rule's prescription release requirements, an additional 18.9 percent substantially complied with this provision and 44.1 percent did not comply. Less than 1 percent of refractionists were reported to have violated the rule's prohibition. Urban refractionists were significantly more likely to comply with the provisions of the rule than rural refractionists. The study also revealed that all consumers who requested their prescription either received it or were told they could have it if they wanted it. The survey concluded that in the 44.1 percent of cases where refractionists were reported to not comply with the rule, patients did not ask for prescriptions.[5] The survey also reported 85.9 percent of consumers were aware of the fact that one does not have to purchase eyeglasses from the examining refractionist and that consumers may ask for copies of prescriptions after an eye examination. Market Facts, R-B-6-1, Appendix C at 2. In addition, the survey shows that mandatory release allows consumers who wish to comparison shop to do so. According to the

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[4] The term refractionist is used throughout the "Final Report FTC Eyeglasses Study: An Evaluation of the Prescription Release Requirement," Public Sector Research Group, Market Facts, December 17, 1981. R-B-6-1 (Hereinafter Market Facts survey). As previously noted, the Commission proposes amending the rule by substituting ophthalmologist or optometrist for refractionist.

[5] Id., at 3.

report, 69.9 percent purchased from their refractionist without comparison shopping; 7.3 percent purchased from their refractionist after shopping around; and 22.8 percent purchased from someone other than the refractionist who conducted the latest eye examination. R-B-6-1 at 35. Summarizing the data upon which the survey is based, the Commission's Chief of the Office of Impact Evaluation indicated he does not find a significant difference between patients going for an eye examination for the first time and asking for or receiving a prescription and those who previously had examinations. The evidence seemed to be that first timers are more likely to ask for a prescription or more likely to get a prescription than one who has been there before. Dr. Thomas J. Maronick, Tr. 890-91.

12. In sharp contrast to the staff-sponsored survey results were those which were presented by the American Association of Retired Persons (AARP) based upon a survey conducted for the association by an outside firm. AARP, HX-J-37(b) and (c). According to AARP, their survey concluded that 83 percent of consumers questioned replied they were not aware of the prescription release requirement. Edmond Eggen, Tr. 1452.[6] The survey figures reported by AARP indicate that 45 percent of those

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[6] The results of the survey furnished by AARP can be accorded no more weight than that given to other opinion testimony. While a full report of the survey, description of methodology and other materials were furnished for the record as required by Sec. F.4 of the NPR, the witness who appeared at public hearings, Mr. Eggen, was not qualified to respond to questions concerning design of the survey questionnaire, analysis of the data or facts surrounding the methodology as actually implemented to conduct the survey. See Tr. 1464-73. Interested parties were therefore unable to fully excercise their rights to cross-examine on the methodology and results of the survey.

examined for glasses did not get a copy of a prescription at the last examination. Eggen, Tr. 1448-49. The survey also inquired into why respondents did not receive a prescription, and sought information on shopping for eyeglasses and to test consumer awareness. Eggen, Tr. 1449-53.[7]

13. OAA believes the language of §456.2 should be reformed to express the intent of the Commission concerning release of spectacle prescriptions for those who wear or intend to purchase contact lenses. OAA, R-H-80 at 12. Specifically, OAA fears that the proposed language of the section does not reflect the expression of intent set forth by the Commission in the NPR. OAA points to the statement by the Commission relating to the proposed change in the term "prescription" which advises:

> "This proposed change would not affect the current requirement that optometrists and ophthalmologists give spectacle prescriptions to all patients whose eyes they examine, including those patients who wear or intend to purchase contact lenses." 50 Fed. Reg. 598, 600.

In OAA's view, an inconsistency arises when this statement is read against the proposed change of the definition of prescription, which deletes any reference to contact lenses and refers only to spectacle lenses. If the proposed definition of "prescription" is adopted, OAA believes it essential to insert a phrase in §456.2 on separation of examination and dispensing to clarify that the provision is intended to include release of a spectacle prescription to those patients who wear or intend to

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[7] See Rebuttal Statement of Anne Cahill, Robert R. Nathan Associates, Inc., for comments raising criticism of the design of the survey questionnaire and interpretation of data. R-K-8.

purchase contact lenses. R-H-80 at 12-13.[8]

CONCLUSIONS, §456.2, SEPARATION OF EXAMINATION AND DISPENSING.

A. The record contains no substantial opposition to the substitution of terminology to conform to the amended definitions proposed in §456.1.

B. Although the Commission's rulemaking proposal does not undertake to make a substantive change in the prescription release requirement as contained in the existing rule, the notice of proposed rulemaking called for comment on a series of questions (10-14) dealing with possible modifications of the existing rule. The testimony and written submissions received in response to the Commission's request are insufficient upon which to base a recommendation for any fundamental change in the existing requirement. The testimony and written submissions essentially comprise a series of arguments that the Commission

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[8] Although the NPR expressly states the Commission's intent to eliminate all references to contact lenses from the prescription release provision, indicating it had no reason to believe that a significant number of dispensers and fitters are currently refusing to provide consumers with their prescriptions or contact len specifications, 50 Fed. Reg. 598, 600, one of the interested parties to the proceeding placed on the rulemaking record evidence concerning availability of contact lens specifications. The purpose of this presentation is to persuade the Commission to reconsider the staff recommendation on this subject set forth in the 1980 Staff Report. Upon review of the survey presentation, the testimony given thereto and the rebuttal submissions filed in response, I have concluded that the presentation is unpersuasive and fails to substantively demonstrate a widespread failure on the part of original fitters of contact lenses to make available contact lens specifications to consumers. See testimony of Dr. Joseph Seriani and Stephen Wu, Tr. 3044-89; USA Lens Survey Report, HX-J-70(b); Rebuttal Statement of Anne Cahill, Robert R. Nathan Associates, Inc., R-K-10.

should or should not make changes in the existing requirement, depending upon the point of view of the person or organization making the recommendation. Support for any change generally comes from optometrists while opticians and consumers generally oppose a more restrictive requirement. The survey evidence introduced into the record by the FTC staff demonstrates the fact that the release requirement has served to elevate consumer awareness of their right to receive a prescription. However, the survey indicates that noncompliance on the part of a substantial minority of refractionists remains a problem. Inasmuch as any of the changes in the prescription release requirement contemplated in the questions set forth for comment in the NPR involve a substantive, rather than technical, modification of the current requirement, I can find no substantial evidence in this record which would form the basis for such a modification. See Findings 8-12.

C. OAA's view that the language of subsection 456.2(a) is inconsistent with the definition of "prescription" which is restricted to spectacle lenses, when read against the Commission's statement of intent that changes are not intended to affect current requirements that spectacle prescriptions be given to patients who wear or intend to purchase contact lenses, is well taken. A modification of subsection 456.2(a) to indicate that the requirement extends to spectacle lens prescriptions for patients intending to purchase spectacles or contact lenses would serve to clarify the intention of the Commission. See Finding 13.

3. Federal or State Employees.

14. The language of §456.3 has been redrafted to delete references to the remanded portions of the Eyeglasses I rule and to clarify its meaning. This provision exempts practitioners who work for any federal, state or local government from the rule's release of prescription requirements irrespective of whether those governmental entities have regulations which would otherwise conflict with the rule. If practitioners work only part-time for the government, the exemption only applies when they are engaged in their governmental duties. The record shows no opposition to the proposed change.

CONCLUSIONS, §456.3, FEDERAL OR STATE EMPLOYEES

A. The substance of this section of the proposal is explanitory in nature, intended to clarify application of a final rule to federal, state or local employees. The provision is unopposed on the record.

B. State Bans on Commercial Practice.

15. The terms "professional" and "commerical" generally were used throughout the proceeding to distinguish in two groups the practitioners in the optometric profession. This distinction was crafted in the 1980 Staff Report and based, apparently, on categorizations formulated in staff research work. However, at several points in the proceeding various parties indicated that the terms do not accurately describe the practitioners in the profession. NAOO, in written comment, urged the Commission "...to resist a dichotomous categorization of optometrists as

'professional' or 'commercial'. All optometrists are professionals, yet, all derive income from their services and the sale of the products they prescribe and are thus, commercial." NOAA, R-H-78a at iii. One of the California Optometric Association witnesses advised that the profession should be broken into three groups, commercial, corporate and professional optometry. Dr. Edward Elliott, Tr. 2866-67. The 1980 Staff Report discusses various forms of commercial practice including corporate employment of optometrists, lease arrange-ments between optical retailers and optometrists, side-by-side arrangements where the optometric practice and the optical dis-pensary are located next to each other. Staff, R-B-2-1 at 3-4. Despite this divergence of views on the appropriateness of the terminology employed, the terms "professional" and "commercial" are most generally used in this report to indicate private practitioners on the one hand and corporate and/or commercial practitioners on the other.

16. Limitations or prohibitions on the forms of commercial ophthalmic practice considered in this rulemaking are imposed within a substantial number of states.[1] These limitations or prohibitions arise in a number of ways, including direct restriction by statute or through regulations promulgated by state boards of optometry. In some instances, various limitations or prohibitions may be described as having been

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[1] State Restrictions on Vision Care Providers: The Effects on Consumers, Report of the Staff, R-B-2-1, at 28; Comment of the National Association of Optometrists and Opticians (NAOO), R-H-78b, Appendix B, at 1-140.

indirectly imposed by court decisions and/or attorney general opinions. Staff, R-B-2-1, at 10-27.[2]

17. State optometric boards, practitioners and others supporting present restrictions on forms of commercial practice and opposing any changes which would affect enforcement of present laws or regulations concerning restrictions addressed by §456.4 of the proposed rule advance an array of arguments for retention of the status quo. Certain of these are legal and legislative arguments which will be considered elsewhere in this report. The principal arguments, however, go to the question of the quality of vision care that may be anticipated in the practice of optometry in a commercial setting. In essence, these arguments reflect the view that, by their nature, employer-employee or other business relationships encompassed by this proposal, lead to a diminution of quality of care.[3]

18. The staff, in its 1980 report, states the primary argument made against commercial firms in the ophthalmic market is that they provide low quality vision care. The quality-based arguments against commercial practice fall into two general

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[2] The notice of proposed rulemaking has been criticized as failing to give the interested public and States a reasonable specification of which statutes the Commission considers to be "total bans." American Optometric Association (AOA), R-H-81, at 17, note 17.

[3] See, for example, written statement of the Oregon Board of Optometry, Department of Human Resources, for a summary of nine different consequences which the Board believes follow from the practices of corporate optometry. While the Board's statement is directed to mercantile corporations, the list of consequences were mentioned repeatedly by others in relation to all employer-employee and other business relationships. R-E-69 at 2. See also testimony of Dr. Keith Eldred, Secretary, Wyoming Board of Examiners in Optometry. Tr. 2003-04.

categories. The first includes those which focus on the evils alleged to be associated with high-volume practice: practicing in a commercial environment may cause the practitioner to employ a variety of cost-cutting and revenue generating techniques in order to increase his or her profits. The second stresses the dangers of lay-owned optometric practices: lay interference in the traditional doctor-patient relationship and with professional judgments concerning patient welfare. R-B-2-1 at 29-30.

19. Proponents of this rulemaking do not concede that the only issue giving rise to these restrictions is quality of care, arguing instead that competitive and economic reasons are the basis for some of the restrictions. The staff report advises that in some instances, restrictive regulations may maintain or elevate the quality of care. In other cases, the quality defense is little more than a public relations technique employed by a profession to fend off governmental or public scrutiny or anti-competitive or anti-consumer conduct which results in consumer injury. R-B-2-1 at xii. NAOO, in the person of one of its witnesses, states it a bit differently. "...allegations that commercial optometry is not as good as private optometry are false and misleading and based more on matters of economic competition than actual differences in eye care provided." Dr. Richard Moroff, Tr. 2028.

1. Restrictions on Forms of Commercial Practice - §456.4. (a). §456.4(a)(1) addresses employer-employee or other business relationships between optometrists or sellers and persons other than ophthalmologists and optometrists.

20. Restrictions in this area may include: (a) prohibiting employment of optometrists by lay persons or firms, (b) the formation of partnerships by optometists and unlicensed individuals, (c) ownership of stock in an optical practice by unlicensed persons or firms, (d) the leasing of space to an optometrist by unlicensed persons or firms, (e) splitting or dividing fees with unlicensed persons, (f) aiding or abetting an unlicensed person in the practice of optometry, and (g) franchising. Staff, R-B-2-1, at 12-15; NAOO, R-H-78a at 32.

21. The argument for continued enforcement of current restrictions seen necessary to protect the quality of vision care is that the commercial practice of optometry in its many forms places economic considerations ahead of patient care to the detriment of quality of care. In a commercial setting, it is alleged, optometrists are high volume practitioners having a much higher overhead due to higher rent, heavy traffic, high visability locations and frequently are required to make a payment of fees. The only way to make such a practice work, it is contended, is to increase volume. Dr. D. W. Conner, Jr., Indiana Optometric Association, Tr. 661; See also Dr. James Scholles, AOA, Tr. 1296-97. The consequence of increased volume, according to opponents of the proposal, is a lack of thoroughness in the eye examination because of time restrictions alloted for the examination in commercial settings. A sharp distinction is drawn between minimum examinations required either by statute or regulation and what some regard as examinations sufficient to insure so-called quality eye care. Dr. Leonard Strulowitz, New

Jersey Board of Optometrists, Tr. 29. According to the President-elect of the American Optometric Association minimum examinations required by the state to be administered to each patient are not necessarily "thorough" eye examinations. The specific tests performed for each patient may vary according to the age of the individual, type and severity of conditions present, or other factors.

Dr. Gerald Easton, Tr. 119-29. Others asserting that examinations are less thorough in a commercial setting advised that an optometrist working in such setting must be first responsive to his employer in the conduct of his practice.

Dr. Harold Glazier, Maryland Board of Optometric Examiners, Tr. 906. An attorney representing the Texas State Optometric Association advised that statutes and regulations such as those falling within the ambit of §456.4(a) were drafted to address a concern that those persons who manufacture and sell eyeglasses would seek to dominate and control the optometric profession. The substance of the concern is that corporations (and by inference, unlicensed individuals as well) with an eye to the bottom line of a profit and loss statement seek to increase sales of ophthalmic products by directly or indirectly controlling optometrists who prescribe their products. The statutes and regulations were developed on the assumption that the length of time a doctor spends on examination should be dictated by the professionalism of the doctor and the needs of the patient, not by an employer who sells more lenses if the doctor sees a higher volume of patients in a day. Fred Niemann, Jr., Tr. 999-1000.

In instances of direct employer-employee relationships, it was suggested that corporations whose profits depend upon the sale of glasses could reasonably be expected to urge employee-doctors to perform shorter exams and see more patients so that a greater number of lenses could be prescribed. Niemann, Tr. 1005; See also Dr. Thurman James Ray, Tr. 2449.

22. In commercial settings other than where a direct employer-employee relationship exists, such as the practice of optometry under a leasing arrangement with a chain opticianry, or under a franchise arrangement, it was argued that the economic pressures imposed by such arrangements are of a nature as to pressure an optometrist to practice high volume optometry. It was suggested that the consequences, insofar as the thoroughness of eye examinations is concerned, would be essentially the same as if the pressures of an employment situation existed. Dr. Charles Beier, Kansas State Board of Examiners in Optometry, Tr. 2136-37; Dr. William C. Van Patten, Nevada State Board of Examiners in Optometry, Tr. 2251-53.

23. Many leasing and franchising arrangements may be subject to "fee splitting" statutes and regulations under the interpretations of various jurisdictions. Leasing arrangements, for instance, between optometrists and nonoptometrists, based on a percentage of gross revenues are regarded as being "fee splitting" in some jurisdictions. Dr. Van Patten, of the Nevada State Board characterized such arrangements as resulting in a loss of autonomy on the part of the optometrist and labeled such leasing arrangements as only a subterfuge for fee splitting. The

witness advised that whoever holds the lease is benefitting from the fruits of an individual optometrist's worth and that the loss of autonomy results in harm to the consumer. Van Patten, Tr. 2251-53. Franchising agreements would be in violation of Nevada state laws prohibiting fee splitting, according to the witness, who indicated that such agreements are harmful to the consumer because the optometrist is limited by where he buys his materials, thereby losing his autonomy. Even in franchising agreements which did not place the optometrist under a requirement to buy materials or use a franchisor's laboratory, the witness would still have reservations about the form of practice. Van Patten, Tr. 2256-57. It was also suggested, in connection with lease arrangements, that the cancellation clause in a lease is purposely established for a short period of time, perhaps 30 days, as another method of controlling a lessee-doctor, to enable the lessor to set hours and days of operation and controlling the percentage of prescription business which is steered to a lessor-optician. Dr. Robert C. Corns, Tr. 271-73.

24. Individual noncommerical optometrists offered personal views on the alleged lack of patient concern and quality of eye care on the part of commerical establishments, illustrated by means of anecdotal statements concerning patients previously under the care of commercial optometrists who had later come to

the witnesses for attention[4], or the recounting of previous experiences derived while in the employ of commercial optometry.[5] While these anecdotes serve to illustrate the concerns about commercial optometry by those opposing the Commission's proposal, the record does not afford any basis for concluding that the experiences recounted by these individuals represent more than isolated occurrences.

25. Optometrists practicing under various forms of so-called commercial relationships vigorously oppose the allegations of those supporting continued enforcement of statutes and regulations restricting employer-employee and other relationships. The principal organization representing commercial providers argues that, notwithstanding their form of business organization, all optometrists are trained in the same schools of optometry, pass the same licensing examinations, use the same equipment, attend the same continuing educational courses, face the same requirements for the acceptable standard of care under state law and in civil suits for malpractice and provide the same ophthalmic goods to their patients. The same incentives to provide quality optometric service to patients and to be financially successful exist in both private practice and practices affiliated with vision care firms. Further, it is

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[4] See, for example, testimony of Dr. James Honaker, President, Kentucky Board of Optometric Examiners, Tr. 733; Dr. Leonard Strulowitz, New Jersey Board of Optometrists. Tr. 21.

[5] See, for example, testimony of Dr. P. Harold Woodring, Tr. 2346; Dr. Gary Schwab, Tr. 2479. See also Cathy Dabb for testimony by a non-optometric employee in a commercial firm, Tr. 2421.

urged that all optometrists are professional, deriving income from their services and the sale of the products they prescribe. This argument concludes that all optometrists are therefore "commercial." NAOO, R-H-78a at i-ii. Indeed, in this regard, many witnesses appearing on behalf of various state boards agreed that the proposed rule would not affect the authority of the various states to establish educational or licensure requirements for optometrists, or minimum equipment requirements or minimum examination requirements.[6] Rulemaking opponents do not agree, however, that the same incentives for quality service exist in private and commercial practices.

26. Witnesses associated with the practice of commercial optometry in various capacities disputed the characterization of commercial practice advanced by rule opponents. In particular, it was repeatedly argued that the professionalism and ethics of the individual practitioner will be the determinant as to whether quality care is rendered in a commercial setting and not the particular form which an individual practice may take. Dr. Richard Zaback, Tr. 1913; Moroff, Tr. 2028. It was agreed that interference with the professional judgment of an optometrist by a nonoptometrist could and should be prohibited by state legislation. Jonathan Solish, R. H. Teagle Corporation, Tr. 1363.

27. Individual practitioners in the commercial area,

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[6] See, for example, testimony of Arkansas Attorney General Steve Clark, Tr. 3040-42; Dr. Harold Glazier, President, Maryland Board of Optometric Examiners. Tr. 932; Dr. Dennis Kuwabara, Chairman, Hawaii Board of Examiners in Optometry, Tr. 1393; Dr. Burt C. Corwin, President, South Dakota State Board of Examiners in Optometry, Tr. 1793.

representatives of commercial opticianry employing optometrists and others contend that the quality of eye examinations rendered in commercial environments is at least the equal of that provided by private practitioners. It was pointed out that the quality of care is important to commercial establishments because the reputation of the establishment is based on the care it renders. R. M. Feldman, Spectron, Inc., Tr. 90-91. Efforts to control the quality of care being delivered by employed optometrists include annual audits and record reviews by the employing corporation, Franklin D. Rozak, Cole National Corporation, Tr. 331; shopper surveys to insure compliance with minimum examination requirements, Dr. Arnold Goodman, Sterling Optical Co., Tr. 336; continuing education seminars on various topics aimed at making sure practitioners are aware of contemporary standards, David Loomis, Pearle Vision Centers, Inc., Tr. 338.

28. Employees of commercial organizations uniformly testified that they were not placed under pressure to examine a minimum number of patients each day or write a certain number of prescriptions. See Dr. Mark Allmaras, Tr. 2031. Certain commercial employers stated, however, that compensation may be paid, in part, based upon the number of examinations given on a particular day and the number of contact lenses prescribed, while indicating that optometrists in such cases were paid a basic salary and that a bonus was paid on examinations and a commission on sale of contact lenses. Dr. James Ellis, Tr. 1964-66. Other employers indicated, however, that salary was the sole compensation received by an employed optometrist while advising

that the salary was not tied to an amount or volume of business done by an employed optometrist. Rozak, Tr. 352. Still others compensated employees with a minimum guarantee in fees. Jerry Ingalls, Western States Optical, Inc., Tr. 2182.

29. In employment situations, commercial employers are in a position to impose specific requirements to insure quality and uniformity of optical examinations. Rozak, Tr. 331; Goodman, Tr. 335. However, in commercial situations in which a corporation is a lessor or franchisor, the corporations admit to problems controlling quality of care during the examination process. In such instances, if a corporation is attempting to control the quality of care of a franchisee or lessee, state boards of optometry have demonstrated that they will come down and take disciplinary action, including revocation of the lessee's or franchisee's license. Rozak, Tr. 331.

30. Commercial firms admit that action by state boards of optometry threatening discipline of a leasing or franchised optometrist, where quality control measures are instituted by the commercial firm, is obviously harmful to the optmetrist himself and regarded as harmful to the lessor (or franchising) commercial firm as well. Rozak, Tr. 331-32; E. Dean Butler, Precision Lens Crafters, Tr. 334.

31. Commercial corporations believe that employing an optometrist is more likely to ensure that better and more comprehensive examinations will be given to patients than may be the case by lessees, (and presumably, franchisees) because corporate quality of care policies can be asserted against the employed

optometrist. Rozak, Tr. 340.

32. Commercial optical corporations believe there is no better way to deal with the quality of care issue in connection with lessees than through the lease instrument itself and provisions therein which permit a leasing corporation to terminate a lease if problems of quality are beginning to develop. According to the corporations, short term leases with optometrists permit corporations and leasing opticians to deal in an indirect way with a quality issue or any other issue that may relate to the corporation's overall reputation. Rozak, Tr. 341-42. In addition to non-payment of rent, examples of matters giving rise to lease termination include failure to appear at the practice or acting in a grossly unprofessional manner. Dr. Steve Tuckerman, Tuckerman Optical Co., Tr. 2070. The commercial position on the use of leases quite naturally reflects a sharply differing view from the view of those who contend that short term leases are merely another economic restraint placed on the optometrist in a commercial environment to insure that the generation of income is the paramount consideration in the optometrist's practice. Corns, Tr. 266-67.

33. Leasing is one of the major contractual arrangements between commercial firms and opticans in areas in which the employer-employee relationship is banned. Leases are generally negotiated between a corporate optician and a leasing optometrist. In many instances, the corporate firm subleases space from a general merchandiser such as Sears or Montgomery Ward, establishes an optical department within the store and then

subleases a portion of the leased space to an optometrist. The leasing fee may be paid based on a percentage of gross income, Solish, Tr. 1367, or as a flat fee, Allmaras, Tr. 2030. The fee will ordinarily include both office space and equipment and permit the lessor to provide both optical and optometric services at one location. Feldman, Tr. 80. The fee appears to be low in the instances reported in the record and the explanation is offered that rents are set on the low side to attact new practitioners, usually people recently out of optometric school and not in a position to make a major investment in a private practice themselves. Feldman, Tr. 98-99; Rozak, Tr. 354.

34. In franchising arrangements between a franchising corporation and a franchisee optometrist the franchisee pays a fee for the purpose of operating under the franchised tradename or trademark. Under such arrangements, franchisees gain benefits from group buying arrangements and economies of scale, together with whatever expertise and support system may be provided by the franchisor. Loomis, Tr. 355; Solish, Tr. 1364-65; Dr. Barry Davis, Texas State Optical, Tr. 1963. Franchised optometrists usually conduct their practices in close proximity to the optical dispensary of the franchisor. Generally the fee paid by these franchised practitioners is a percentage of gross revenues. However, individual franchisees testified that their franchise agreements do not contain requirements for minimum volume or revenue to be paid the franchisor. The overall franchise fee may, however, reflect costs to the franchisor for setting up the individual optometric franchise, including the actual

construction of a building and the equipping of the practice. See Zaback, Tr. 1956.

35. The advantages of franchising, as contrasted to company-owned chain operations, include the possibility of expanding across state boundaries much more rapidly if one is not limited to the use of one's own capital and human resources. The ability to provide incentives to one who operates his own business in a way such incentives cannot be provided an employee was described as a non-economic advantage. If one operates his own company, additional labor can be translated into additional dollars, providing a level of incentive which cannot be supplied by a company that manages by hiring and firing employees. Philip F. Zeidman, International Franchise Association, Tr. 610. The franchising industry itself has argued, in connection with this proposal, that franchisors establish a system, the great bulk of which has to do with the operation of a business, advertising, layout appearance, site selection, employee selection, promotion, marketing, trade press, etc., which does not place a franchisor in the position of controlling the professional conduct of the optometrist. Zeidman, Tr. 615.

36. Franchisors argue that "fee splitting" laws are being improperly applied to the franchising situation. The franchisee is not fee splitting but paying for the use of a trademark. The franchise royalty is the predominant technique a franchisor uses as the reimbursement for the value of its name, its system, expertise, etc. The only single measure of value is gross volume of revenue produced, paid in the form of the franchise royalty.

Zeidman, Tr. 611; Loomis, Tr. 355.

37. Practitioners and others involved with optometry in a commercial setting state that present day offices are furnished with the latest in equipment to permit the administration of complete optometric examinations. Davis, Tr. 1915; Zaback, Tr. 1956. In this regard, the record does not indicate that allegations concerning lack of quality care on the part of commercial optometry are generally attributed to lack of the necessary equipment to carry out the examination and detection or diagnostic processes.

38. The employment of an optometrist by unlicensed persons or firms is the most often cited relationship giving rise to support for restrictions or prohibitions on the practice of commercial optometry. Throughout the proceeding, professional or private practice optometrists characterized the employer-employee relationship as one which placed restrictions on the scope of eye care rendered, either by coercing employed optometrists to perform assembly line examinations or by failure to conduct adequate examinations due to erosion of optometic skills caused by the methods of commercial practice. The employer-employee relationship is also alleged to dilute the doctor-patient relationship due to lack of continuity of care or the failure to provide or control follow-up care. Dr. John Kennedy, Tr. 1150; Dr. Jay Enoch, Tr. 1885-86; Honacker, Tr. 704; Glazier, Tr. 899-900. Likewise, the finger of accusation was pointed at the commercial optometrist as having implicitly surrendered professional integrity in order to satisfy an employer and gain

compensation for his work. See Conner, Tr. 659; Easton, Tr. 151. Patient care suffers when so-called big business controls the doctors and that priorities get reversed with volume and profits coming ahead of patient care. See Dr. Jeffery Gonnason, Tr. 1218. Private practitioners, when questioned on whether the profit motive applied to their practices agreed that while this was true, the independent optometrist's first loyalty is to his patient and the patient's health. See Conner, Tr. 659. At least one private practitioner did agree that with a light case load or limited patients, the private practitioner might be subject to economic considerations as well. Dr. V. Eugene McCrary, Tr. 180. There was acknowledgement that optometists who employ other optometrists could also dictate that these employees follow the types of examination practices which are alleged to result from employment by lay persons or corporations. Easton, Tr. 141. Nothing in this record indicates that optometrists employing other optometrists may not, if they wish, establish limitations on time for examinations, offer financial incentives for the number of patients seen, or require they resort to other practices which form the basis for some commercial practice restrictions.

39. Private practitioners and others were in general agreement that the lack of quality which is alleged to be found in commercial practices is due to the system or type of practice itself and not to any deficiency in the training or qualifications of those graduating from optometric schools who may enter the commercial field upon graduation and after

licensing. See McCrary, Tr. 177; Beier, Tr. 2112.

40. Corporations and others in the commercial field believe that enforcement of restrictions on commercial practice results, in many instances, from bias on the part of state boards of optometry inasmuch as such boards are usually composed of private, noncommercial practitioners and/or appointed citizen members. The clear implication of this testimony is that commercial optometry does not receive a fair hearing in most jurisdictions because of lack of representation on these boards. Feldman, Tr. 83; Ellis, Tr. 1929-31; Ingalls, Tr. 2171. It appears, from the record, that noncommercial optometrists hold membership on only two state boards, Texas and Ohio. Ingalls, Tr. 2178. Texas has balanced representation with a nine member board composed of 3 private and 3 commercial members as well as 3 lay persons. Dr. E. Richard Friedman, Tr. 2404. The President of the Ohio State Board of Optometry is also a former practitioner in the commercial field and the owner of a regional optical company. Tuckerman, Tr. 2027.

41. Addressing the major type of restriction covered by §456.4(a)(1) the trade association for opticianry took the position that laws and regulations which prevent an optical dispensing firm from associating with prescribers gives prescribers who themselves dispense or who own interests in optical stores an unfair competitive advantage. State laws that prevent financial or other associations that would otherwise be lawful between doctors and lay persons or opticians are unfair, and such laws and regulations prevent competition among

providers, it is argued. Optometrists can hire opticians or others to sell and dispense glasses and lenses. Opticians are totally dependent on the prescription of the doctors in order to sell and should have the right to employ refractionists and to lease space to or from them. Donald L. Klauer, Opticians Association of America, Tr. 628.

(b). §456.4(a)(2) of the proposal is directed toward prohibitions or restrictions which limit the number of offices an optometrist or seller may own or operate.

42. While general quality of care arguments were made in connection with this issue, specific arguments concerning lack of continuity of care or control of patient follow-up were also raised. The staff report advises that the overriding objection to branch offices is based on the view that the owner of an optometric practice should be physically present to insure the adequate performance of his or her employees. R-B-2-1 at 32.

43. Although several jurisdictions impose no limitation on the number of branch offices a practitioner may have, (See R-B-2-1 at 28), private practitioners appearing from those areas in which branch office restrictions do exist were strongly supportive of the continuation of the restrictions. While generally affirming the overall justification as reported by the staff, specific concern was also expressed that a branch office practice, particularly where optometrists present other than the person in whose name the branch office is operated are present, will offer lower quality care due to lack of adequate supervision. Dr. Martin G. Raymon, R-H-39 at 1; Dr. Lewis A.

Smith, R-H-54 at 1. Others argued that as branch office operations expand, the ability of the practitioners in whose name the office is licensed to personally see individual patients is diminished and, with lowered personal interest in individual patients, the practitioner's interest in the branch practice may become purely monetary. Dr. John Kavanagh, R-H-58 at 1. Still others described branch office restrictions as necessary to keep individual practitioners from spreading themselves too thinly. Beier, Tr. 2143. Lack of continuity of care was repeatedly stressed as another reason for branching restrictions. The argument is made that a patient who seeks out a practitioner for continuing care is entitled to see the same practitioner on each visit, but by visiting branch offices these patients may not be assured of seeing the same optometrist. Dr. Ronald L. Fiegel, R-H-65 at 2. Concern was expressed that patient confusion may result in branching situations as to whom is providing the care. It was suggested, in these situations, problems will be created for patients with acute needs and may place pressure on the optometrist to have care provided by unqualified personnel when the optometrist is not available. Dr. Merle K. Pickel, Jr., R-H-96 at 1. Others alleged that optometrists may require unqualified lay personnel to examine patients due to doctor unavailability in order to maintain branch offices in operation. Dr. Rick D. Bauer, R-H-126 at 1; Dr. J. William Clement, R-H-139 at 1.

44. Some witnesses supported restrictions on the number of branch offices a practitioner may have, but do not support an

absolute ban on branch offices. Generally, these witnesses would limit offices to a total of two, that is, the home office and one branch office, in the belief that two is the number that one person can handle competently and professionally. McCrary, Tr. 168. It was conceded, however, that as the number of optometrists in a practice increased, it is at least mathematically possible that the number of branch offices which could be operated competently may be increased. McCrary, Tr. 194.

45. Where permitted, both private practitioners as well as commercial practitioners are found to operate one or more branch offices. Glazier, Tr. 929. Where states do not restrict the number of branch offices, a satisfactory level of care apparently can be maintained, particularly in practices in which more than one optometrist is associated. Glazier, Tr. 930.

46. Optometrists with commercial affiliation and others, including opticians, opposed continued enforcement of branch office restrictions. NAOO observes that the impact of branch office restrictions falls primarily on individual optometrists. There is also a significant effect on vision care firms. Branch office restrictions prevent vision care firms from employing or leasing to an optometrist for optometric coverage at multiple locations, for example. Optometrists who own franchises and achieve enhanced efficiency in marketing, advertising and purchasing through affiliation with other franchises, may be prevented from owning multiple offices, or from achieving staffing efficiencies in offices they are permitted to own, by branch office restrictions. R-H-78a at 60. It is contended that

no public interest can be discerned which is served by limiting optometrists to personally practicing at only one location or from owning practices at which employees, lessees, or independent contractors may practice. R-H-78a at 63. Eyexam 2000, a commercial optical firm employing optometrists is permitted by the rules of the State Board of Optometry to operate only two offices in the State of Kentucky, for instance. The founder of Eyexam 2000 advised that he would lose his license to practice in Kentucky if he opened a third office. Inasmuch as his company is a multi-state commercial optical concern employing more than 50 optometrists, he stated that he failed to see how the opening of a third office in Kentucky would do anything other than imporve the availability and quality of eyecare services in the state. Ellis, HX-J-48(c) at 3 and 6. Another witness, commenting on the effect of the statutes in California, pointed out that while the state does not prevent an optometrist from owning, maintaining, or operating more than one branch office as long as he is in personal attendance at each of those offices 50 percent of the time, the state statute also makes it a misdemeanor to maintain more than one branch office. According to the witness, the prohibition against branch offices has been viewed as effectively limiting any California optometry franchise to two locations. Solish, Tr. 1359.

47. Representatives of state governments offered various reasons for restrictions on the number of branch offices. For instance, the representative of the Kentucky Board of Optometric Examiners indicated that if the current restriction is lifted,

corporations would establish multiple offices thereby misleading consumers into believing they could receive the services of a particular doctor at a certain branch office. Kentucky has also apparently experienced enforcement problems in the past in branch office locations because indication was given that despite a requirement the full name of an optometrist available to give service be disclosed in a branch office, the disclosure is not always made. These enforcement problems are cited as the basis for objecting to the lifting of branch office restrictions. Honaker, Tr. 704-05 and 710. Others emphasized that restrictions are necessary to keep optometrists from being "spread too thin", Beier, Tr. 2143, and advised that the inability of a state to restrict the number of branch offices creates a problem of accountability for professional services. Donald C. Jackson, Georgia State Board of Examiners in Optometry, R-E-24 at 2; Dr. R. Lewis Scott, Secretary-Treasurer, International Association of Boards of Examiners in Optometry, Inc., R-E-28 at 1-2. In some instances, states report that there are no restrictions on the number of branch offices which an optometrist may open, but advise that certain clearance procedures must be observed which, in essence, do not appear to limit the right of an optometrist to open a branch office. However, the manner in which these clearance procedures are implemented is not disclosed on the record. A representative from the State of Maine testified that while Maine does not limit the number of offices which may be opened, it is necessary that an application be filed with the State Board of Optometry and that the board determine whether the

opening of a branch office is in the public interest. The witness indicated that "need" is one criteria to determine whether the branch office would be in the public interest, as well as the question of whether the doctor can properly service the branch office. Dr. Norman Varnum, Maine Board of Optometry, Tr. 758-59. Otherwise, optometrists may open only one branch office without the board's permission. Varnum, Tr. 758. The State of South Dakota permits any number of office locations, but new rules will require that application be filed with the state board before a new office is opened and that the office be inspected. Corwin, Tr. 1782,1790. North Carolina does not restrict the number of branch offices, but does require that each practice location be registered with the state board and duplicate licenses obtained for each branch. Dr. John Robinson, North Carolina Board of Examiners in Optometry, Tr. 2966. Likewise, Nevada has no limit on the number of branch offices which may be operated, but the board of optometry has rules in effect which require that if an office is open, the individual optometrist whose name is on the door must spend 50 percent of his time at the establishment. Van Patten, Tr. 2262. The net effect of this regulation, like that in effect in California, would seem to limit individual optometrists to two offices, a main office and a branch office, accounting for 100 percent of the doctor's time.

48. Individual private practitioners and others offered a variety of justifications for current restrictions on branch offices. One witness placed the restrictions in Oklahoma in a

historical context, testifying that the old rationale for restricting branch offices was sanitation. However, he gave as the most recent reason for the restriction the need to accomodate new doctors coming into the state, primarily from optometric school. Noting that Oklahoma permits one branch office, the witness testified that anytime someone establishes a branch office, it kills the potential for a full-time office. Defending the view that branch office restrictions are not anti-competitive, the witness believes that competition occurs through actions of the state board to bring more optometrists into the state, rather than increasing the opportunity for an optometrist already in the state to practice through a branch office. J. Leroy Oxford, Oklahoma Optometric Association, Tr. 2559-60, 2562. Other individual practitioners testified that various states do not limit the number of branch offices but require additional licensing through state boards, Gonnason, Tr. 1245-47, or some form of notification to state boards, Dr. Raul Alderette, Colorado Optometric Association, Tr. 1738. The most often noted objection to relieving bans on branch offices relates to the alleged inability of an optometrist operating several branch offices to assume personal responsibility for patients visiting the various offices. Easton, Tr. 141; McCrary, Tr. 173-74. It was urged that even in those situations where an optometrist hires other optometrists to work in one or more branch offices, the restriction is still practical, since those working with him can operate outside his direct control in multiple-branching situations. "The owner of the practice is the

one licensed to practice at this location, yet patients may not be under his direct control and care." Raymon, R-H-39 at 1. One practitioner advised that a doctor can only maintain a limited number of offices himself, and that it is outright public deception for a doctor's office to be labeled under one name and yet be serviced by another doctor, not to mention the possibility of lay personnel examining patients. Bauer, R-H-126 at 1.

49. A staff-sponsored witness addressed economic considerations relating to branch office restrictions concluding that such restrictions control the production and delivery of services. They limit volume and therefore volume-related economies. According to the testimony, these restrictions limit return to trade names and retard the development of quality control techniques that might be used across multiple outlets, and such restrictions restrain the production and delivery of services and would show up in the price of services that consumers finally pay. John E. Kwoka, Jr., Tr. 498, 512. A practitioner in a written statement submitted for the record offered essentially the same observation in more personal terms. "...based on our own experience over several years, we can see that larger practices tend to be better organized and more efficient. With the installation of computerized bookkeeping systems and word processors our administrative costs have decreased. And with a larger practice we are able to purchase goods at lower costs...we are able to provide professional services and goods to the public at less cost than if we practiced separately and apart from each other." Dr. Miles

J. Newman, R-H-90 at 2.

(c). §456.4(a)(3) of the proposed rule seeks to eliminate enforcement of restrictions prohibiting an optometrist from practicing in a pharmacy, department store, shopping center, retail optical dispensary or other mercantile locations.

50. The staff report asserts that location restrictions are imposed in a number of ways. Thirteen states restrict by statute the ability of optometrists to locate in mercantile establishments. In fifteen other states, location of optometric practice is restricted through board of optometry regulations. Generally, these provisions state that an optometrist's license to practice may be revoked or suspended for practicing in an office not devoted exclusively to the practice of optometry or other health care profession, or where material or merchandise is displayed pertaining to a commercial undertaking not bearing any relation to the practice of optometry or other health care profession. The practical consequence of the restrictions, according to the staff report, is to eliminate the possibility of locating an optometric practice in a department or drug store. The staff further reports that another category of location restrictions seeks to prevent optometrists from locating near retail opticians. These restraints on "side-by-side" operations are for the purpose of preventing any patronage system from developing. The staff concludes, however, that this type of restriction may also prevent the growth of high-volume practice. Several courts have held that statutory provisions or board of optometry or opticianry regulations prohibiting

mercantile location are constitutional and within the state's police power. In general, courts have applied a rational relation test and have been unwilling to delve into the merits of the quality justification offered in support of location restrictions. R-B-2-1 at 18-20.

51. Based upon its assessment of these restrictions, staff concludes that side-by-side practices appear to have developed to provide the functional equivalent to mercantile location and corporate employment in areas where those practices are banned. R-B-2-1 at 19-20. The report also observes it is asserted that large retail optical firms rely on convenient locations to attract customers and obtain a substantial portion of their business from walk-in customers. If true, the ability of an optical firm to operate in a high traffic area such as a shopping center or department store may ultimately determine whether it is possible to develop a high-volume practice. In addition, if side-by-side operations were permitted, nondispensing optometrists might be able to compete for patients who prefer one-stop shopping and, therefore, ordinarily select the services of a dispensing optometrist or ophthalmologist. R-B-2-1 at 18, note 51 at 19.

52. NAOO contends that the laws and regulations which prohibit optometrists from locating in mercantile locations were adopted specifically to prevent optometrists from obtaining the exposure to prospective customers which accompanies such a practice location. It is asserted, in this regard, that practicing in convenient locations not only benefits patients, it

enhances the business opportunities for the optometrist. Customers attracted to a department store, pharmacy, mall, strip center or shopping center to buy other goods and services, or to patronize other businesses, are exposed to the services offered by a vision care firm practicing at such a location. It is argued, for example, that consumers satisfied with the service and quality at a particular pharmacy when purchasing prescription drugs, over-the-counter medicines, and other health care products may choose to avail themselves of optometric services offered at those locations. R-H-78a at 46. NAOO believes that no meritorious quality of care argument to support these restrictions can be discerned. With the exception of those few optometists who own the real estate on which their practices are located, all optometrists practice on premises leased from commercial landlords. There is no basis for argument, it is stated, that landlords who operate retail businesses will subvert the professional judgment of tenant-optometrists in an effort to increase profits, while other commercial landlords will not. In fact, logic suggests that the opposite would be true, according to NAOO. A retail business which serves as the landlord for an optometric practice does not harm the goodwill associated with the host's primary business by providing substandard care. The leases that many host department stores sign with optometrists obligate those practitioners not to harm the reputation of the host and to resolve all disputes with patients to the patients' satisfaction. R-H-78a at 47-48. Concerning restrictions on side-by-side practice, NAOO states that while few states totally

prohibit lease agreements between optometrists and opticians, many states have adopted laws and regulations which impose unwarranted costs on those practices by forcing optometrists who lease space from vision care firms to physically separate their practices from the firms. These restrictions have given birth to a form of business organization commonly referred to as the "two-door" or "side-by-side" practice. In their strictest form, these laws require total separation of the practices. NAOO argues that separation of the optometrist and the optician hinders consumers who wish to use the services of an optician and optometrist at the same location. The dispensing optometrist examines and dispenses from the same location, which enables him to integrate the two functions. NAOO offers the view that while there is nothing inappropriate in the integration of these two functions, it is inherently inefficient when it is done by an optometrist personally performing both examination and dispensing functions. It requires a trained optometrist to spend a significant amount of his time providing dispensing services which could more easily be provided by a less highly trained individual who would perforce require a lesser level of compensation. NAOO concludes its argument stating that regulations which require total separation of the practices are an obvious attempt to prevent the optometrist/optician combination from doing precisely what a dispensing optometrist does on a regular basis, examining and dispensing from one office. R-H-78a at 51-52. NAOO argues that the restrictions impose substantial economic losses on optometrists and opticians in side-by-side practices in the form

of increased building and equipment costs as well as staffing costs. R-H-78a at 52-58.

53. The president of one commercial opticianry doing business in the State of Massachusetts testified as to what he described as the harassement by the State Board of Optometry involving optometrists subleasing space from his business in side-by-side situations. Although no Massachusetts statute specifically restricts the practice of optometry in mercantile establishments, according to the witness, he alleges that the Board of Optometry has interpreted state laws in a way calculated to find fault with any doctor who chooses to practice in a commercial location. The actions of the board, in his view, have caused doctors to leave otherwise viable practices and caused other practitioners to shy away from entering into them. Because Massachusetts law specifically prohibits employment of optometrists by parties other than optometrists or ophthalmologists, his firm enters into subleasing agreements with optometrists in order to provide optician and optometric care in one location. According to the witness, none of the investigations by the state board have focused on standards of care, but usually deal with the terms of lease, the number of locations, the kinds of doorways that optician and optometrist have to a common area or between the doctor's office and the optical shop, forms of advertising and how services are represented. The witness testified that the board has questioned rents under the leases as being too high and accusing the optician of profiting from the practice of optometry, which is

unlawful. The board has also questioned some rents as being too low, accusing the optician of indirectly profiting from the practice of the optometrist and indicating that the optician may even be exercising some degree of control over the optometrist's professional prerogatives. The lease was also questioned by the board because it requires that the doctor be open for business for certain hours. According to the witness, the master lease with commercial locations generally requires that the opticianry be opened for business during certain hours. The board allegedly has further questioned the lease because it contains a relatively short termination clause, advising the witness that this gives the optician an ability to control the optometrist. Finally, the witness added that the board has stated that the connection between optometrists and opticians is "inappropriate", but has not indicated what situation the board would find acceptable. Feldman, Tr. 79-82. In testimony, NAOO witnesses representing five major chain opticianry corporations advised that the evolution of conveniently locating vision care facilities in areas of high traffic such as shopping malls and operating these facilities under flexible time periods such as evenings and weekends has not only increased the business purposes of their professional employees but also services the needs of the consumer. It is claimed that these innovations have been accomplished without any diminution in quality of care. NAOO (Washington, D.C.) HX-J-8(a) at 2. In a statement generally urging the Commission to remove restrictions on commercial practice, one of the principal associations representing

opticians makes the point that if prescribers are permitted to own, control or profit from ophthalmic dispensing services through business interests in dispensaries, then opticians should have the corresponding right to make readily accessible to the public the services of refracting doctors. It is argued that laws and regulations which restrict this right are unfair. The association also claims the consuming public benefits from competition within the retail eyewear delivery system, and from competition with those prescribers who have decided to dispense. OAA, R-H-80 at 10-11.

54. State officials commenting on the prohibition or restriction of practice in a commercial location testified both to specific state requirements as well as the rationale for such restrictions. Generally, the practice of optometry in a high traffic area such as a mall was not deemed, of itself, to be a widely objectionable practice. In fact, private practitioners in many states have practices in such areas. Beier, Tr. 2103. The principal objection is practice inside a commercial location such as an opticianry or department store. State officials opposing relaxation of restrictions on practice in mercantile locations are generally of the view that prohibiting the practice of optometry in a mercantile establishment is necessary because the consumer is entitled to receive eye care in a professional atmosphere where professional, not business, standards are enforced. Strulowitz, Tr. 16. Indication was also given that practice in a mercantile establishment, i.e., inside a dispensary or department store, differed from practice in a shopping mall in

that in a department store, for instance, optometry would be intermingled with the sale of general merchandise and entrepreneurship will take over with the result that the visual examination and procedures performed by the optometrist will no longer be separated from the sale of glasses, tints, etc. Such situations were distinquished from side-by-side arrangements wherein the optometrist does not control the patient once the examination is completed and the patient departs from his office. Van Patten, Tr. 2259-61. Others echoed the view that if practice inside a mercantile location such as a department store is permitted the result will be an attempt on the part of the mercantile location to control such things as the hours of service of the optometrist. Robinson, Tr. 2993. Representatives from some states indicated that although optometric practice in a mercantile location in, for example, a side-by-side arrangement, is permitted, rules and regulations promulgated by state boards may still regulate signs, displays and other modes of advertising to preclude misrepresentation or deception regarding the relationship between an optometrist and the lessor or commercial concern next door. Sidney W. Beckett, Washington State Board of Optometry, R-E-26 at 1.

55. Private practitioners supported the views of many of the state representatives who commented on this restriction. It was asserted that practice in a mercantile environment poses problems similar to those involved in corporate (i.e., employer-employee) and franchised practices. As one practitioner stated the position, "[t]he rendering of health care in a feed store, a

furniture store, a department store next to a shoe store, to me this is a totally repugnant proposal to a thinking, reasoning person seeking health care." McCrary, Tr. 173. Others viewed the consequences of a relaxation of the ban as permitting the placement of emphasis on economic gain over patient welfare, Pickel, R-H-96 at 2, and as an attempt to place professional health care on the same level as mass merchandising, Dr. Jerry L. Leopold, R-H-142 at 1. Not all private practitioners viewed the mercantile prohibition in the same light, however, some seeing the supposed evils of corporate employment as being paramount and suggesting that permitting optometrists to lease space in mercantile establishments would permit commercial practice but without the alleged abuses that occur in employment situations. Dr. Edmund M. Herb, R-H-87 at 1.

56. Associations representing the retailing industry generally commented on the restrictions on the practice of optometry in mercantile locations by indicating that ophthalmic goods and services, like other consumer products, ought to be available on a competitive basis. If consumers prefer to purchase these goods in a noncommercial setting, that choice should be available as it is today. However, if customers choose to purchase in a commercial setting, that choice too should be available. Robert J. Verdisco, Vice President, for Government Relations, National Mass Retailing Institute, R-D-5 at 1. Current restrictions were also criticized as sweeping too broadly and adversely affecting the average consumer's access to vision care while providing no measurable increase in quality. Tracy

Mullin, Senior Vice President, Government Affairs, National Retail Merchants Association, R-D-7 at 1.

(d). §456.4(a)(4) of the Commission's proposed rule seeks to prohibit enforcement of any law, rule or regulation which imposes a trade name ban.

57. The staff report asserts that such bans serve to impede the growth of commercial practice, generally prohibiting an optometrist from practicing under any name other than the one shown on his or her license or certification of registration. The report observes that these restrictions generally do not prevent an optometrist from working for another optometrist and holding themselves out under the name of a professional corporation. Thus, according to the report, these restrictions have a distinct discriminatory impact on nonprofessional corporations. The staff asserts that the discriminatory impact here is not that a professional corporation is able to use a traditional trade name but rather that individual optometrists can hold themselves out under a firm name which does not contain their individual name so long as that firm is a professional corporation or the name of a licensed optometrist who employs that individual optometrist.[7] The staff report observes that trade name bans may indirectly restrict corporate practice and

[7] The staff report advises that the issue of trade name bans arose during the Eyeglasses I rulemaking and states the conclusion that trade name bans were not preempted by the trade regulation rule because the intent of the rule was to eliminate burdens on the dissemination of information and not to alter state regulations regarding permissable forms of business practice. R-B-2-1 at 24.

the development of large commercial chains. Bans on the use of trade names may prevent providers from operating multiple store operations and developing goodwill based on the name and reputation of the firm. The staff also believes that trade name bans may inhibit effective mass-media advertising by large firms and, thus, indirectly restrict commercial practice even in those states where the commercial practice of optometry is otherwise permitted. According to the report, over time a trade name can provide consumers with important information concerning the type, price and quality of goods and services offered for sale in a trade name practice and that trade name bans, like advertising bans, restrict the free flow of commercial information. If the use of trade names does facilitate advertising which is often important to the success of large-scale commercial practices with numerous branch operations, these bans may have the indirect effect of precluding commercial practice. The report advises that twenty-one states prohibit by statute the use of trade names by optometrists. These statutes provide that practicing optometry "under a name other than one's own name" shall constitute grounds for revocation or suspension of one's license to practice. In eight other states, the statutes do not refer explicitly to trade names but provide that the practice of optometry under a "false or assumed name" shall be grounds for suspension or revocation of one's license to practice optometry. An additional twelve states prohibit the use of trade names by optometrists through state board of optometry regulations. Thus, only nine states and the District of Columbia

permit or are silent on the use of optometric trade names. R-B-2-1 at 23-27.

58. NAOO argues that consumers, over time, become familiar with trade names and identify those names with particular products and services and attribute certain levels of quality and price to such names. Trade name identification is found in the medical marketplace and, NAOO suggests, such identifying names as "Cataract and Implant Surgeons of Maryland", "Washington Eye Associates" or "Eye Surgery Associates" constitute such trade name identification, and are to be found in local telephone directories. Similarly, NAOO contends that such proper names as the Mayo Clinic, Cleveland Clinic or Stanford Medical Center are examples of institutions about which consumers are aware of the quality of services available, while few could name any physician who practices at those institutions. It is also contended that Health Maintenance Organizations (HMO) such as Kaiser-Permanente and others provide an example of trade name practice which, over time, develop a reputation for the quality, price and availability of care provided. It is argued that while patients who subscribe to an HMO almost certainly know the name of the institution responsible for their care, they may not know the name of the individual physicians who practice on the staff of the HMO. NAOO states that trade names are an integral part of the business strategies of its member firms and that in every state such firms offer dispensing services under their respective trade names. In most states, however, the optometrists with whom these firms are affiliated may not practice under the same trade

names. These bans increase the costs associated with the effective marketing of an optometric practice, decreasing the ability of an optometric practice to expand inside its existing market or grow into new markets. Such bans often increase the operating costs of the optometric practice by forcing the optometrist who affiliates with a vision care firm to practice in a side-by-side configuration. Finally, it is argued that current laws have the effect of permitting the use of trade names benefitting private practitioners by not banning all trade names, and that existing prohibitions competitively harm optometrists who affiliate with vision care firms. R-H-78a at 68-69.

59. The economic effects of trade name bans, according to NAOO are two-fold. They dramatically increase the cost of advertising since, as the number of practitioners practicing under a common trade name increases, significant economies of scale can be achieved. It is also argued that trade name bans increase the operating costs of optometrists who affiliate with vision care firms by requiring them to sometimes practice in a side-by-side configuration with a vision care firm, resulting in a needless duplication of business services. In the case of advertising, it is argued that trade name bans deter optometrists from engaging in the market research and testing of advertisements targeted to an audience that is likely to purchase their products or service. Although individual optometrists practicing under separate names could affiliate for the purposes of conducting market research and produce advertising copy, the likelihood that such common efforts will occur is significantly

increased when the practitioners can affiliate under a trade name. In connection with major media advertising, on television for instance, advertising which would be prohibitively expensive for a single practice may be well within reach for a group of optometrists practicing under a common trade name. R-H-78a at 70-74.

60. It is argued that trade name bans have the same consequences as bans on employer-employee restrictions in some states, i.e., that in some jurisdictions trade name bans result in optometrists affiliated with commercial practices being required to physically separate their practice from that of the vision care firms from which they lease space. This physical configuration results in increased operating costs and prevents vision care firms from informing the public that eye examination services are available from an optometrist. R-H-78a at 74-75.

61. Only the proposed rule provision concerning restrictions or prohibitions on employer-employee and other business relationships garnered more comment, both pro and con, than the provision concerning trade name bans. From the viewpoint of those opposing the proposals, if employer-employee affiliations between optometrists and commercial vision care firms are the threat to quality vision care they are alleged to be in this profession, trade name usage, especially by commercial optometrists, is a menace of nearly equal magnitude. Conversely, commercial vision care firms and optometrists feel that trade names are a highly useful, necessary, valuable adjunct to the advertising and practice of commercial vision care. Concerning current

restrictions on trade names the International Franchising Association comments that the restriction such bans place on advertising is similar to matters considered in recent controversies involving the real estate brokerage company, Century 21, and the Hyatt Legal Services operation. These two matters involved, among other things, requirements that the individual names of professionals be disclosed in connection with the use of trade names. Insofar as franchise arrangements are concerned, the association argues that recent legislation at the national level affirms that certain prohibitions are incursions on the Lanham Act permission of the right of a trademark licenser to advertise the trade name to the public. Zeidman, Tr. 595.

62. A number of state officials testified as to the existing laws and regulations in their states. States having trade name bans believe their continued enforcement is required to avoid creating the situation of the "anonymous" doctor who can function with uncaring abandon, having little or no professional accountability to the patient. It was argued that a trade name frees an optometrist from dependence on his personal reputation to attract patients and even allows him to assume a new trade name if negligence or misconduct casts a shadow over the old one. Further, by using different trade names at locations under common ownership, a chain operation could give the public the false impression of competition. Dr. Dennis Kuwabara, Hawaii Board of Examiners in Optometry, R-E-20 at 6. Similar concerns were voiced by other state representatives who indicated the belief that an optometrist should maintain his name and individuality,

Corwin, Tr. 1782, and expressing the fear that trade name usage can be a device for shedding a reputation for poor quality care through adoption of a new trade name, thereby confusing and deceiving the consuming public. Beier, Tr. 2098-99. Others indicated that a change in trade names would be a device to hide allegations of malpractice from the public, Honaker, Tr. 705, and impair the ability of consumers to make informed decisions in obtaining optometric care. Dr. Arthur Gorz, Wisconsin Optometric Association, Tr. 1091. Some states, while prohibiting an optometrist from practicing under a name other than his own will nevertheless permit an optometrist or group of optometrists to name their practice. North Carolina, for instance, will permit two or more optometrists to call themselves "John Smith Optometric Associates" so long as John Smith's name appears in conjunction with the term "Optometric Associates." The witness from this state explained that a group of optometrists could also use the term, for instance, "Smith Optometric Vision Center", but could not use the term "Smith Vision Center." According to the witness, this construction of state law is intended to prevent opticians from describing themselves as vision centers when they are not. Robinson, Tr. 2993-94.

63. Private practitioners characterized the use of trade names as detrimental to the profession. Use of a trade name in advertising was described as selling a product rather than a service, telling the consumer that the product may be good for everybody and taking away the professional judgment of the individual practitioner. Easton, Tr. 143. It was further argued

that trade names make it very difficult for the public to identify an individual doctor who may be responsible for providing less than quality care. Alderette, Tr. 1739.

64. Several witnesses cited the Supreme Court decision in Friedman v. Rogers[8], upholding a Texas prohibition on the use of trade names against a challenge under the First Amendment as an indication from the highest court of the land that such names are an inherent source of mischief. The former chairman of the Texas Optometry Board who was serving a chairman at the time the lawsuit was undertaken appeared during the public hearings and quoted from the language of Justice Powell's decision which determined that the Texas statute under challenge was a constitutionally permissible one in furtherance of the state's interest in protecting the public from deceptive use of optometrical trade names. The majority opinion states that rather than stifling commercial speech, the Texas statute ensured that information regarding optometrical services will be communicated more fully and accurately to the consumer than it had been in the past when optometrists were allowed to convey the information through unstated and ambiguous associations with a trade name. Friedman, Tr. 2393. Dr. Friedman also pointed out that since the time of the decision the Texas legislature has determined that a trade name ban is no longer necessary as a protective device and the ban was eliminated. Tr. 2394. Finally, the witness testified that since the elimination of the trade name ban, very few practices in Texas are now using trade

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8 440 U.S. 1 (1979)

names. He indicated that the current statute permitting use of trade names requires that a doctor must also display his own name in conjunction with the trade name. Tr. 2406. Based upon the experience in Texas, Dr. Friedman observed it seems appropriate that the Texas legislature arrived at its decision after monitoring the situation in Texas carefully and at close range. He observed that other states have enacted statutory prohibitions against trade names similar to the former Texas statute and asked whether these states, having determined that the bans are necessary, should not be allowed to monitor the needs of their own citizens. Tr. 2394.

65. In the Friedman v. Rogers decision the Supreme Court identified three areas in which the use of trade names can be deceptive or misleading. First, a firm employing a trade name may experience a turnover of optometrists within the firm with the consequence that the reputation of the firm using the trade name may be based on the skills of optometrists no longer practicing with that firm. In the second instance, an optometric practice can assume a new trade name if the old one becomes associated with negligent practice or misconduct. Finally, trade names may be used to create a false impression of competition among shops under common ownership.[9]

66. State officials and private practitioners repeatedly cited these examples as reason for continuing enforcement of existing trade name bans. Others questioned the premise of the Commission's proposal in light of the Supreme Court decision.

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[9] Id., at 13.

John M. Coady, D.D.S., Executive Director, American Dental Association, R-D-10 at 3. (It is unclear from Dr. Coady's submission whether states may have enacted similar bans relating to the practice of dentistry.) The decision was also used as the basis for arguing that the Commission's stance in this matter is anti-professional. One who commented for the written record, citing the Friedman decision, argued that the final goal of professionalism of any vocation is to increase the personal commitment of the practitioner to a refinement of his knowledge and skills. Not to allow the state to use its police power in respect to achieving increased responsibility in professional practice must be seen as a detrimental intrusion by federal government into operations rightfully belonging to the state. Norris Class, Professor Emeritus, University of Southern California, R-F-2 at 2. The proposal was also characterized as sweeping too broadly in barring enforcement of trade name bans. The chairman of the Wisconsin Optometry Examining Board advised that it is not enough to have a law which requires only that the identity of an optometrist be disclosed to a patient at the time an eye examination is performed or ophthalmic goods or services dispensed. The consumer makes a choice of optometrists long before that point in time, it was argued, and the ability to make an informed choice requires that the indentity and location of the optometrist's practice be disclosed in a manner which permits a member of the public looking, for example, at the Yellow Pages to determine where that particular optometrist practices. Dr. Lloyd A. Milawitz, R-E-7 at 2.

67. Individual witnesses appearing in support of the rule proposal did not attempt to argue the particular merits of the Friedman decision, pointing instead to other considerations which the Commission should weigh in deliberating the trade name provision of the proposal. The witness representing the International Franchising Association stated that recent barriers created by state or local jurisdictions to impede the growth of franchising are quite broad in range and generally fall under the subject of commercial practice restrictions or advertising restrictions. He observed that generally these barriers have as their purported justification a variety of quite legitimate and salutary goals, "...protection of the consumer against deception and the like." Zeidman, Tr. 592. He argued, however, that the real question is whether the justifications are in fact adequate to support what are quite clearly anti-competitive consequences either in purpose or in effect of some of the restrictions themselves. Tr. 592. In discussing the concept of franchising, the IFA accepted the Commission's definition of franchising as set forth in the Trade Regulation Rule: Disclosure Requirements Concerning Franchising and Opportunity Ventures.[10] According to the witness the first characteristic of a franchise is that the franchisee sells goods or services which meet the franchisor's quality standard and in cases where the franchisee operates under the franchisor's trademark or trade name or advertising or other commerical symbol designating the franchisor's mark or which are identified by the franchisor's mark. Tr. 590. Trade names

[10] 16 C.F.R. 436 at 436.2.

benefit franchisees and provide "shorthand" information to consumers about the type, range, quality and price of goods and services available from the company using the trade name, according to IFA. Firms thus have an enormous incentive to develop and maintain the integrity of the products and services provided under their trade name because the entire package they offer is being judged continuously by consumers on the basis of the samples they purchase. Insofar as franchisors are concerned, they have a strong incentive to promote rather than cut corners on high quality service. Franchise agreements are often five or ten years in duration or longer, and offer renewals for similar periods. Franchisors are unlikely to risk long-term perceptions of low quality by customers for a short-term profit. Additionally, IFA states that franchisors face potential liability claims concerning the professional conduct of its franchisees, notwithstanding the otherwise arm's length commercial nature of the relationship. It is illogical to assume that it is in the franchisor's interest to promote low quality service. HX-J-14 at 11. IFA also asserted that under franchise arrangements, most national and regional chains mount extensive advertising and promotion campaigns, and that some of franchising's symbols have the highest recognition level among consumers. System-wide campaigns provide much greater advertising support than a single businessman could afford. IFA also noted that franchisees benefit from the economies of scale which are possible through collective buying power. HX-J-14 at 10. Finally, in response to the allegation that trade names can

easily lead to deception because the trade name can be changed at will, the IFA witness testified that in the franchise context it does not happen. The franchisor has put a very substantial investment in the value of the name. The last thing the franchisor is going to do, according to the witness, is change that name because the first name has become devalued. The witness concluded by advising that name change is an extremely uncommon phenomenon and he could not imagine any public policy based upon an assertion that name change is a problem that needs to be dealt with. Zeidmen, Tr. 623-24.

68. Representatives of commercial optical firms urging removal of trade name bans testified that they were unaware of any state jurisdiction which does not require an optometrist's name to be prominently displayed at a point in the professional's office and that if a prospective patient wants to inquire as to the name of the doctor, he or she will do so and the inquiry will be fully answered. It was argued that prospective patients and potential customers rely upon the trade name for a certain level of service, a certain level of expectation. Rozak, Tr. 358. It was also argued that in connection with advertising, particularly broadcast media advertising, use of a trade name is important since, in a 15-30 second radio or television commercial, the average prospective consumer is not going to be able to identify a particular optometrist when the advertising is intended to cover commercial locations which may number from 5 to 20 in an area. Rozak, Tr. 358-59. Using one commercial firm and its affiliated optometrists in the Chicago trade area as an example,

it was asserted that the use of a trade name to advertise six locations enables the commercial firm to reduce the cost of an eye exam to the consumer over what it would cost to advertise without a trade name. The cost of six separate sets of print advertising, published six times a year to permit identification of the optometrists in each of the six locations, would substantially increase the cost of eye examinations when compared to trade name advertising which would permit all locations to be covered under one advertisement. Butler, Tr. 359. Although individual advertising permits the prospective patient to identify the doctor at a particular location, it was observed that the same information becomes available when the patient arrives at the door of the location, the doctor's name is on the door of the office, he wears the name (presumably on a name tag) and his diploma is in his office. Butler, Tr. 359-60. The owner of a commercial optometric practice which uses a trade name where permitted by law in a practice with 50 associated optometrists observed that he has a very large business at stake and cannot afford the risk of substandard eye examinations. Ellis, HX-J-48(c) at 3. His optometric practice is affiliated with the commercial dispenser represented by the witness E. Dean Butler, and his statement reinforces Mr. Butler's testimony that the cost of an individual eye examination in the Chicago area would increase substantially if individual practice locations must bear the cost of print advertising, if trade name advertising is unlawful. HX-J-48(c) at 8. Another commercial practitioner who practices under a trade name and is a member of the Texas

Optometry Board addressed the allegations that quality care suffers when practice under a trade name is prohibited by observing that the State of Texas has a basic competency law which consists of 10 basic findings which must be performed on all new patients. According to the witness, the Texas State Board utilizes field investigators to check unsuspecting optometrists to ascertain that they are at least doing the minimum required by state law. As a State Board member, he advised he is in a position to know that there are no more violations of the basic competence rule by trade name practitioners as compared to private practitioners. Davis, HX-J-48(e) at 3.

69. Summary Finding, §456.4(a)(1)-(4). A review of this rulemaking record demonstrates that none of the participants in the proceeding, including representatives of state governments and state boards of optometry, as well as practitioners of optometry, ophthalmology and opticianry, asserted, testified or in any way attempted to demonstrate or prove that the prohibitions and restrictions which are within the provisions of §456.4(a)(1)-(4) of the Commission's proposal may not constitute unfair acts or practices. The record does demonstrate that the subject prohibitions and restrictions are defended as being an appropriate exercise of the states' legislative and regulatory authority to insure the maintenance of quality standards for vision care and health, See, for example, Vesta M. Roy, President of the Senate, State of New Hampshire, R-E-12 at 1. The prohibitions and restrictions being considered under the rule are in the public and consumer interest and constitute valid,

substantive public health care policy. See Bill Morris, State Senator, State of Kansas, R-E-17 at 1. Others observed that while state laws and regulations may have aspects that unreasonably limit competition, the rulemaking proposal raises serious questions as to whether a trade regulation rule will fairly discriminate between state rules that limit competition and those that serve beneficial purposes. See Wesley J. Howard, Assistant Attorney General, Consumer and Business Fair Practices Divison, State of Washington, R-E-5 at 2-3.

CONCLUSIONS, RESTRICTIONS ON FORMS OF COMMERCIAL PRACTICE, §456.4(a)(1)-(4).

A. Commercial practice restrictions of the type subject to this rulemaking proposal are broadly intended to insure the quality of vision care provided by optometrists to the citizens of the various states. Forms of commercial practice are seen by the states to threaten the quality of vision care because the structure of the practice of commercial optometry burdens the commercial optometrist with economic and profit considerations which may mitigate or supplant professional judgment in the practice of the profession. Many of the alleged abuses which have given rise to restrictions on commercial practice may also occur in the professional or private practice of optometry as well. While this record affords no basis for concluding that practices such as assembly line examinations, over-prescribing, failure to ensure the quality of care by employee-optometrists, lack of proper supervision of employees in branch offices, and similar practices are widespread in professional optometry, the

structure of private practice does not, of itself, make professional optometrists immune from many of the same factors which are alleged to taint commercial optometry. Certainly, the profit motive is present in both commercial and professional practice. In the case of restrictions placed on the employment of optometrists and other business relationships, the salient difference between these arrangements and those found in the private or professional field is the access of the state to the optometrist. Where optometrists directly own or operate practices that may engage in substandard care or be in violation of established standards of professional conduct, the optometrist is controlled under the licensing laws of the state and, where appropriate, action against these optometrists to revoke or suspend a license or take other disciplinary action may be commenced. In contrast, where an optometrist is employed by a corporate or lay entity, or who may be a lessee or franchisee of a corporate or lay entity, engages in substandard care or nonprofessional conduct, the state may still proceed against the individual optometrist. However, if the conduct has been induced by the professional procedures established by the employer or result as a consequence of the financial arrangements arising under a lease, franchise agreement or other arrangement, the state usually is unable to proceed against the corporate or lay employer, the lessor or franchisor under the statutes, rules or regulations governing the optometric profession. See Findings 17,18,38.

B. Professional optometry is sheltered from the effects of

commercial competition in jurisdictions which have adopted commercial practice restrictions, at least to the extent of the particular restrictions imposed. This record provides no basis for reaching economic conclusions, however, on the specific effect particular commercial practice restrictions may have on competition.

C. While some major corporate chains employing optometrists and/or engaging in leasing and franchising arrangements with optometrists have undertaken efforts to assure that acceptable quality of care levels are maintained within their organiziations, the record does not disclose how widespread such efforts may be within the entire universe of commercial optometry. Moreover, corporate chains admit they find it less difficult to assure quality of care standards are met by their employed optometrists, than by those who may operate under a corporate standard, but in a leasing or franchising arrangement rather than an employment relationship. Evidence presented by the representatives of commercial optometry concerning steps taken to assure quality of care in that branch of the profession is limited in scope, supplemented only by rather general assertions that there is parity of care between commercial and professional optometry. Therefore, no general conclusions concerning the quality of care issue in this proceeding can be reached based upon this limited body of evidence. This view should be qualified, however, with the observation that testimony of the opponents of this rulemaking in characterizing the entire practice of commercial optometry as being insensitive or uncaring

of quality of care matters is excessive and not supported by the record. If this characterization is to be accepted in its entirety, one must assume that those entering the field of commercial optometry surrender their ethical and professional convictions at the door of their employer or the corporation with which they enter into a business relationship. Nothing in this record permits that over broad conclusion. On the contrary, the record is punctuated with statements of praise by all sides in this proceeding for the quality of recent graduates of the optometry schools in this country and agreement that graduates of these schools entering both the professional and commercial fields after graduation and licensing have experienced the same quality of training and are possessed of the same level of qualifications. Further, this record offers no evidence to support a view that commercial practitioners are less well educated than their professional counterparts, are lacking in professional credentials, are employed in substandard environments or performing examinations with substandard testing equipment or routinely failing to meet minimum requirements where such are established by state law or regulation. To the extent that quality of care issues are addressed in this record, such issues are not the direct conse-quence of these aforementioned factors. See Findings 25,27-31,37,39.

D. While this record abounds with accusations that commercial optometry engages in so-called assembly line practice, this rulemaking record contains no body of evidence which may be used to compare, on average, numbers of patients seen, for

instance, in a day by individual private practitioners and by commercial practitioners. To be sure, substantial discussion is set forth on the record as to alleged differences in the length of time of examinations rendered by commercial and professional optometrists. Moreover, individual witnesses involved with commercial optometry have given testimony that commercial optometrists may receive compensation based upon the number of examinations given in a day or the number of contact lens prescriptions written, or by payment of bonus on number of examinations and commission on the sale of contact lenses. Others involved with commercial optometry, however, appear to offer only salary as compensation or, in other cases, a minimum guarantee in fees. No evidence was offered to indicate whether one form of compensation was more prevalent than the others. Moreover, the record is lacking in evidence to indicate, by way of comparison, the forms of compensation which may be employed by professional optometrists who employ other optometrists, either in their own offices or in chain practices through branch offices. See Findings 30,33,34.

E. Viewed within the context of present day eye care as practiced in the marketplace, the provisions of §456.4(a)(1) largely raise questions in this proceeding concerning the control of optometrists by opticianry, i.e., the arm of the eye care industry that fills prescriptions and dispenses optical products. While the restrictions to which the rule provision are addressed also prevent the direct employment of an optometrist by a drug store, for instance, department store, or, as one witness pointed

out, a feed store, these are not the entities appearing in this record to argue the case for commercial optometry. The leading industry advocates are corporate chain employers, franchisors and lessors who may do business on a large regional or national scale. Where permitted to compete with professional optometry these corporations provide a formidable presence in the marketplace. Undoubtedly, individual professional practitioners perceive them as an economic threat to their own practices. Whatever the economic advantages to professional optometry may be in keeping current commercial practice restrictions in place, however, there appears to be little argument that many, if not all, these restrictions were originally adopted for sound and practical professional reasons. These reasons are essentially embodied in the quality of care issue which is the fundamental issue of this proceeding. Issues of price of optical products to the consuming public and the availability of optometric care and optical products are, as a practical matter, secondary issues to the quality of care issue. It is in the context of proposed §456.4(a)(1) that the principle issue of this proceeding must be settled before complete attention can be given to the remaining restrictions addressed by §456.4.

F. Branch office restrictions and restrictions which inhibit or prevent locating an optometric practice in so-called mercantile locations, particularly high-visability, high-traffic areas are not as prevalent as those restricting employer-employee or other business relationships. It is not uncommon in jurisdictions where branch offices and/or practice in a

mercantile location are permitted, to find both commercial and professional optometry having multiple office locations with some situated, perhaps, in shopping malls or similar areas. At the same time, however, optometrists who, in one jurisdiction, practice in a mall or sublease space in a department store, may be foreclosed from both of these methods of operation in another jurisdiction. State legislatures or state boards appear to have had no uniformity of view on these matters, with some believing that in order to effectively limit commercialism in optometry it is necessary to do more than merely make illegal employer-employee and other business relationships. Looked at from another viewpoint, however, these restrictions can be viewed as a genuine reflection of the desire on the part of state legislatures and state boards to enhance the quality of care by removing whatever temptations may flow from high-visibility, high-volume practices. Unlike employer-employee and other business restrictions which are esentially brakes on the formation and growth of commerial optometry, restrictions on mulitple offices and practice in mercantile or commercial locations affect both commercial and professional optometry. In practical effect in today's marketplace these restrictions are, in all likelihood, more inhibiting to commercial optometry than to private practitioners. It is indeed a fact that some private, professional practitioners engage in chain optometry and optical dispensing where permitted to do so by local law, and may locate these practices in those areas most convenient to access by the consuming public. Only a portion, an undetermined percentage of

professional optometry has chosen to practice the profession in this form, however. Commercial, corporate optometry is more clearly frustrated by these restrictions, especially those organizations engaged in offering optical and optometric services on a regional or national scale. To state the obvious, legislatures and boards of optometry are, by their nature, attentive to the local needs of their citizens as they see them. In exercising their authority, these bodies have, in many instances, chosen to limit branch offices or practice in mercantile and commercial locations, where such activities have not been banned altogether. In jurisdictions where limitations are imposed, situations have been created which prevent a chain practitioner from having, as an example, more than two offices in a particular state although the chain may have a large number of offices, employing a substantial number of optometrists, spread over a large regional area. From a business standpoint, the frustration of the chain practitioner who contends that more convenient and economical service can be offered the citizens of a particular state if more offices can be opened in the state, is understandable. See Findings 45,46.

G. Some of the reasons offered for continuation of restrictions on practice in branch offices and in mercantile or commercial locations are not entirely persuasive or of great assistance in any comprehensive evaluation of these restrictions. Continuity of care was offered as one of the reasons for banning or restricting branch offices, for instance, to ensure that patients see the same practitioner on each visit to an office.

The question must be asked, however, whether continuity of care is more important to the optometry profession than to other health care fields? It is not necessary to stray from this record to take note of the fact that health care in general is undergoing substantial change at the present time and, to some extent at least, views on the requirements of continuity of care has been reevaluted and adjusted in such new forms of health care practice as Health Maintenance Organizations. In ordinary diagnostic and treatment situations at least, this record affords no basis for concluding that continuity of care is more essential for optometry than for any other health care profession. At the same time, the states and the profession have strong reasons to avoid creating situations in which multiple offices cannot be properly administered to assure the quality of diagnosis and treatment, including such matters as sanitation, maintenance of equipment, conformance to professional standards, and similar matters. Undoubtedly the states have an interest in and responsibility for assuring that individuals and others do not practice optometry in such fashion that their capability to assure quality of care in all its aspects is not exceeded. I cannot conclude, based upon this record, that branch office restrictions including total bans are the only means available to individual jurisdictions to accomplish these objectives. At the same time, it is recognized that bans and limitations are undoubtedly the most easily administered type of controls and, presumably, the least expensive to enforce. Individual jurisdictions also have an interest in assuring that optometric

care is rendered in a professional setting. As noted elsewhere in this report, the Supreme Court has affirmed the interest of the individual states in this area by permitting states to impose geographical restrictions on optometry to "...free the profession, to as great an extent as possible, from all taints of commercialism..." Williamson v. Lee Optical of Oklahoma, 348 U.S. 482, 491 (1955). The question therefore becomes whether states have options other than geographical restrictions with which to effectively blunt perceived commercialism in the profession. It is obvious that "commercialism" in the context of the Supreme Court opinion is not necessarily the sole province of commercial, corporate or chain optometry. While this record affords no specific guidance as to possible regulatory alternatives available to the states, it is nevertheless apparent that some have not found it necessary to impose geographical restrictions in order to protect their citizens from the negative effects of commercialism. See Findings, 47,48,51,52,54,55.

H. Trade name bans appear to have their most profound effect on corporate and chain practices and, in many ways, are closely interrelated with the prohibitions on employer-employee and other business relationships inasmuch as organizations which come within the ambit of the business relationship restrictions may most often be affected by trade name restrictions, as well. The record makes clear that utilization of a trade name by corporate or chain organizations is a valuable marketing tool, permitting easy identification of a particular organization by consumers, facilitating joint advertising by optometrists affiliated with a

particular organization and perhaps, in a given set of circumstances, being equated in the consuming public's mind with a certain type or level of service that may include, among other things, such factors as price of service, rapidity of service, quality of service. In various areas of competition between commercial and professional optometry, the latter may often engage in professional practice under a form of trade name, such as that of a professional corporation or the name of the licensed individual or individuals owning the practice. Undoubtedly, while some commercial optometrists could hold themselves forth to the public in a similar manner, little benefit is gained through use of these individual trade names if, for instance, they are associated by lease or franchise with the "XYZ Vision Service", a corporation or chain entity. The value of the trade name to these practitioners is as an indication of their commercial affiliation. Commercial optometry therefore views trade name restrictions as another limitation on its ability to compete with professional optometry. On the basis of this record, it can be concluded that competitive inequities are created between commercial and professional optometry where these bans have been adopted and enforced by the individual states. See Findings 57-62,67,68.

I. Any action to preempt trade name bans must be weighed against the Supreme Court decision in Friedman v. Rogers case, confirming the authority of states to invoke such bans as a means of eliminating deception in the marketplace. Trade name bans,

perhaps moreso than bans or restrictions on the geographic location of optometric practice, place this rulemaking in the middle of a conflict over application of a state's authority to act as a matter of public policy. In Friedman v. Rogers, the Supreme Court took particular note of the fact that concerns of the Texas legislature about the deceptive and misleading uses of optometrical trade names were not speculative or hypothetical but were based on experience in the state with which the legislature was familiar when it adopted the trade name ban. (440 U.S. 1, 13). This record is not of assistance in determining what actions, other than trade name bans, states may reasonably and effective utilize to eliminate misleading and deceptive use of trade names. It is not necessary to refer to the record, however, to conclude that states may pursue individual cases of deception. Likewise, the record is not needed to reach the conclusion that total trade name bans are a highly effective and convenient means of accomplishing this goal with a minimum of enforcement effort. The record does not offer guidance as to other possible state alternatives which may exist between these two extremes. See Findings 64-66.

2. Effects of Commercial Practice Restraints.

70. The Statement of the Commission's Reasons for the Proposed Rule set forth in the NPR[11] advises in part that the staff assessed the impact on price, quality and availability of vision care of the restrictions which are the subject of §456.4(a)(1)-(4) of the proposal. The ultimate issue addressed is whether higher prices and diminished access to vision care result from these restrictions and, if so, whether such consumer injury is counterbalanced by positive effects on quality of care.[12] Staff sponsored research studies were performed and submitted for the record to address the questions of quality, price and availability of vision care. The NPR further advises the staff recommendation that the Commission engage in rulemaking proceedings regarding commercial practice restrictions is based primarily on the results of these studies, which contradict the claim that the entry of commercial firms into the market lowers the overall level of quality of vision care. At the same time, the results show that average prices are significantly higher where commercial practice is restricted. Therefore, the Commission has reason to believe that these restrictions may be unfair acts or practices within the meaning of Section 5 of the FTC Act.[13]

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11 50 Fed. Reg. 598 (1985), Section A at 598.

12 Id., at 599.

13 Id., at 599-600.

(a). Quality of Vision Care.

71. The primary evidence placed into the rulemaking record in support of the proposal, on the question of quality of vision care are studies prepared by the Commission's Bureau of Economics, ("BE Study")[14] and the Bureaus of Consumer Protection and Economics relating to cosmetic contact lens fitting, ("CL Study" or "CLS").[15]

(i). The BE Study.

72. This work was designed to compare relative price and quality of optometric services available across regulatory environments and kinds of practice.[16] The objective of the study was to assess the independent effects of advertising and commercial practice on the price of eyeglasses and exams, on the thoroughness of examinations, on the accuracy of eyeglasses, on the workmanship of eyeglasses and on the degree of unnecessary prescribing. Ronald S. Bond, FTC, Bureau of Economics, HX-J-11(a) at 2.[17] The Commission hired survey researchers to

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[14] Staff Report on Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry, Bureau of Economics, September, 1980. R-B-2-31.

[15] A Comparative Analysis of Cosmetic Contact Lens Fitting by Ophthalmologists, Optometrists and Opticians, Bureau of Consumer Protection and Bureau of Economics, December, 1983. R-B-5-1.

[16] Note 14, supra, at 1. Issues relating to relative price will be discussed in another section of this report. The Commission's notice of proposed rulemaking set forth four questions (1-4) concerning the substance of the BE Study. (50 Fed. Reg. at 602). The responses to these questions received on the rulemaking record are subsumed in the findings set forth herein.

[17] The introductory section of the BE Study captioned "The Issues" states in part that "[t]he study does not purport to measure the absolute level of quality of optometric services footnote (cont)

purchase eye examinations and eyeglasses in cities with a wide variety of legal environments. Cities were classified as markets where advertising was present if there was advertising of eyeglasses or eye exams in the newspapers or the Yellow Pages. Cities were classified as markets with commercial practice if eye examinations were available from large interstate optical firms. Bond, HX-J-11(a) at 3. Before going into the field, the survey researchers spent a week at two colleges of optometry, (College of Optometry of the State University of New York and the Pennsylvania College of Optometry) being trained to identify important procedures common to complete eye exams. To provide a baseline for judging the accuracy of the prescriptions purchased in the field, both colleges also performed eye examinations on each member of the survey team. After training, the surveyors went into the field and purchased examinations, prescriptions, and, in most cases eyeglasses. After each examination they completed debriefing sheets on which they noted all of the various procedures the optometrist had performed. The debriefing sheets provided the basis for evaluating examination thoroughness. The prescriptions and the eyeglasses provided the basis for judging accuracy and workmanship. Finally, a subset of the subjects went to their examinations wearing eyeglasses that the schools of optometry had already determined were correct. Those subjects asked each optometrist they visited whether or not a new pair of glasses was needed. The optometrist's response

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available, nor can the study be used to compare optometry with other professions providing primary eye care." Note 14, supra, R-B-2-31 at 1.

became the basis for evaluating over-prescribing. Bond, HX-J-11(a) at 3.

73. The staff states, concerning the BE Study, that "...our measure of the thoroughness of an exam is a measure of inputs or procedures employed. It is not a direct measure of the ability of the practitioner to detect visual pathologies or to deal with extreme problems of visual acuity." Bond, HX-J-11(a) at 4.

74. The surveyors who were examined are described as visually healthy but myopic individuals with relatively routine optometric needs. Bond, HX-J-11(a) at 4.[18] Staff rejected as impractical the idea of using subjects with visual pathologies, advising that most individuals with active pathologies would already have been under treatment and, even if individuals with untreated active pathologies could not have been asked to forego treatment until

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[18] The testimony by representatives of the Southern California College of Optometry commented on the age range of the subjects in the BE Study, ranging from 26 to 51 years, (BE Study, R-B-2-31 at 43), asserting that this age group eliminates preschool and school age children and young adults with visual problems. It was also observed that the study eliminates from consideration the elderly patient who universally requires vision care and presents a segment of the population most likely to manifest ocular pathology and systemic health problems. The elderly frequently require special care and testing techniques, including low vision evaluation, and when appropriate, referral to other health care practitioners. It was argued that since selected patient types represented a segment of the population which only requires the most elementary level of optometric care and competency, little differentiation of the optometric subgroups with regard to quality and thoroughness of care would have been noted in the BE results. The design of the study appears to have as its goal the proof that the quality of care provided by the advertising optometrist is equal to that provided by the non-advertising optometrist. The selection of this particular simplistic limited patient type, it was urged, was the best to produce the results found in the study. Dr. Richard L. Hopping, President, Southern California College of Optometry, Tr. 1596.

after the study was completed. Staff reports that because healthy individuals were used, it is not known whether an examining optometrist would have detected a pathology had it existed. What is known, according to staff, is whether the optometrist conducted specific tests designed to reveal such problems. Bond, HX-J-11(a) at 4.

75. Staff states that all of the analysis in the report is of a multivariate nature. Multivariate statistical techniques are the standard economic tools for dealing with situations where the variables of interest may be affected by a number of factors, according to the staff. The price and quality of optometric services are very likely to be determined by a number of forces other than state regulation, and if the effects of those variables are not taken into account, the conclusions of the analysis can be seriously misleading. Bond, HX-J-11(a) at 4.

76. The BE Study concluded that analysis of the measures of quality of care suggested that neither restrictions on commercial practice nor restrictions on advertising raised the level of care available in the market. The data collected on the accuracy of the prescriptions, the accuracy and workmanship on the eyeglasses and the extent of unnecessary prescribing all suggested that large chain firms perform no worse than optometrists who practice traditionally. In addition, the data suggest that the eye examinations purchased from optometrists in cities both with and without commercial firms were, on average, of about equal thoroughness. However, there was substantial variation in thoroughness among optometrists in both kinds of markets. Both

in cities with and without commercial firms, some optometrists offered more-thorough and some optometrists offered less-thorough exams. In cities with commercial practice, it was the commercial firms that tended to offer the less-thorough exams. But the percent of optometrists offering less-thorough exams was about the same whether or not commercial firms were present. Hence, eliminating commercial practice would not appear to raise the average thoroughness of exams available in the market. Bond, HX-J-11(a) at 5.

77. The study, insofar as it relates to quality of care, was summarized as suggesting restrictions that prohibit commercial practice do not seem to raise the average level of care available in the market. The study reported that commercial firms provide prescriptions and eyeglasses that, on average, are at least as accurate as those provided by traditional practitioners. The frames and lenses purchased at commercial firms evidenced a level of workmanship equal to that available elsewhere. The study also reported that optometrists at commercial firms engaged in no more unnecessary prescribing than other optometrists. The study concludes that examinations were, on average, of about the same thoroughness in markets with and without commercial firms. Although less-thorough exams were available in both kinds of markets, the percentage of optometrists offering less-thorough exams was not higher in markets with, than in markets without, commercial firms. Bond, HX-J-11(a) at 6-7. According to the report, however, it was concluded that in nonrestrictive cities, the decision to advertise or practice commercially appears to be

associated with a decision to give a less-thorough, less costly examination. Advertising optometrists and chain optical firms in nonrestrictive cities are less likely to perform certain important tests related to the assessment of eye health. BE Study, R-B-2-31 at 25. A staff witness, when asked whether the removal of restraints might add an enhancement of quality, testified that the BE Study compared environments in which restraints existed to those environments where restraints did not exist, and found the level of quality to be statistically indistinguishable in the two. Kwoka, Tr. 511. Further, on the quality issue, the study finds that, on average, commercial optometrists did give exams of lesser thoroughness than traditional practitioners. This is with regard to the thoroughness index used, however. But the conclusion did not hold with regard to dimensions of service, particularly the accuracy of the prescription, workmanship of glasses, unnecessary prescribing, etc. Kwoka, Tr. 514-15. This matter is addressed more expansively in the report which points out that if a consumer is interested in having a thorough eye examination, the data suggest that more thorough examinations are likely to be obtained from nonadvertisers. But even with nonadvertisers, consumers in nonrestrictive cities appear to have an advantage. In nonrestrictive cities the decision not to advertise or practice commercially appears, on average, to be associated with a decision to offer a more-thorough examination. In restrictive cities, no such association can be made. Nonadvertisers appear to give more-thorough examinations in nonrestrictive than in

restrictive cities. But the data reveal substantial differences in the thoroughness of examinations not only between, but also within, cities and types of optometrists. The report points out that comparing prices for nonhomogeneous services may be misleading and it is therefore necessary to analyze the relation between price and quality. R-B-2-31 at 23.

78. The BE Study is criticized on a number of grounds as being insufficient to substantiate the action which the Commission proposes in the NPR. Although the rulemaking record is replete with opinion testimony, pro and con, relating to the quality of care issued generally, a specific body of testimony was offered, particularly by members and representatives of the American Optometric Association (AOA) intended to refute or discredit the conclusions reached in the study. Much of the criticism of this study on the quality issue was tendered as responses to the questions, numbered 1 and 2 in the NPR, which are concerned with the use of a relatively routine visual problem, myopia, as the basis for testing the surveyors, and whether the use of "process" rather than "outcome" tests is inappropriate methodology. The NPR also asks whether there are reasons to believe that the procedures and tests performed to detect eye disease were not performed adequately by those optometrists surveyed.

79. <u>"Process" versus "Outcome" Tests</u>. Placed into the record in oppostion to the BE Study is a survey prepared and conducted on behalf of AOA by Robert R. Nathan Associates, Inc.

(RRNA)[19] This survey undertakes to address, among other things, the question of whether the use of "process" tests in the BE Study rather than "outcome" tests is inappropriate methodology. The survey report advises that the methodology employed in the 1980 BE Study primarily judged the quality of eye examinations based on a tabulation of examination procedures or tests used by optometrists, whereas the RRNA survey measured the quality of eye care based on the outcome of the eye examination for specific eye conditions. Statement of Robert R. Nathan Associates, Inc., HX-J-66(a), Vol. I., Ex. 3 at 3. The RRNA survey was conducted by sending each of 11 patients to 10 optometrists, five commercial and five noncommercial, for eye examinations. The survey was conducted only in New York City, a market in which commercial practice is "prevalent", as characterized by RRNA, and had as its focus only the comparison of quality of eye examinations given by the two groups of optometrists. According to RRNA, for each of the eye conditions present in the survey subjects there exists a clear, correct diagnostic path. It was possible to determine whether the examining optometrist had correctly diagnosed the condition based on his discussion with the patient and the prescription issued. Joseph R. Gunn, III, Vice President, RRNA, Tr. 2586. Unlike the BE Study, this work was not designed to test results across regulatory environments, but only to test a market in which there are no commercial restrictions. Stephen A. Schneider, RRNA, Tr. 2758. During testimony, it was stated that

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[19] Ophthalmic Practice Rulemaking Statement and Exhibits - Robert R. Nathan Associates, Inc., Vol. I., Ex. 3, HX-J-66(a).

the RRNA survey does not give an exact measurement of the effects of commercial practice restrictions because no measurements of a restrictive market were taken to provide a baseline. Schneider, Tr. 2822. According to the survey report, the primary purpose of the survey was to collect data on the number of optometrists who detected the vision problems of the survey subjects. HX-J-66(a), Vol. I., Ex. 3 at 17.

80. The RRNA survey differs from the BE Study in that optometrists who were surveyed were evaluated on the basis of detection of the vision problems (outcome) of the survey subjects, while the BE Study evaluated the apparent completeness of procedures (process) employed to evaluate the ability of the practitioner to discover all relevant facts about the patient's eye condition.

81. The RRNA survey was not criticized on the basis that outcome, of itself, was less preferable than the process method utilized in the staff's work, although the survey itself was criticized for several other reasons.[20]

82. According to the RRNA survey report, the study results revealed that 60 percent of the optometrists in private practice settings detected the vision problems of the participants whereas 32 percent of those in commercial practices detected these same vision problems. HX-J-66(a), Vol. I., Ex. 3 at 17. The report states that the difference in detection rates between the two

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[20] See Rebuttal Statement of Dr. Thomas J. Maronick, R-K-19; Rebuttal Statement of Gary T. Ford, R-K-20; Rebuttal Statement of National Association of Optometrists and Opticians, R-K-1.

groups tests out as being "significant". HX-J-66(a), Vol. I., Ex. 3 at 17.[21]

83. Responding the the NPR, the California Optometric Association (COA) argues that question 2 misstates the issue and illustrates the Commission's confusion and lack of understanding of what optometrists do and how their conduct affects the health of their patients. The issue should not be whether the use of process tests, as opposed to outcome tests, is the appropriate measure of quality of care. Rather it should be whether quality of care may be measured without consideration both of processes used and the outcome of the processes. COA argues that the BE Study's survey subjects had simple conditions and requested only simple services. Thus the cases presented did not establish the proper conditions to evaluate which processes could or should have been used. The BE survey considered only time spent without any evaluation of the conditions of the patient at the time of the exam, examiner experience, and the propriety of the performance of the process. Most important of all, COA argues, the BE Study made no attempt to evaluate how well a given process was performed. Without consideration of those factors no scientific conclusion can be reached about the quality of the examination. A proper clinical evaluation of quality of care necessarily

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[21] The "process" results as reported in the BE Study as estimates of average thoroughness of eye examinations indicated that all optometrists had an average score (using FTC index) of 58.5 in restrictive cities and 61.6 in nonrestrictive cities. Nonadvertising optometrists (using FTC index) had an average score of 58.8 in restrictive cities and 70.0 in nonrestrictive cities. R-B-2-31 at 8. The record does not appear to provide any correlation between the BE and RRNA results.

requires an evaluation of the outcome. Obviously mere performance of process (test or procedure) does not ensure that it was performed correctly. One must also evaluate the clinical judgments that were made as a result of the performance of the process. COA observed that no physician would make a judgment about the quality of care given by another physician without having considered all the factors discussed above. According to COA, no less an analysis can be made with regards to optometry or virtually any other profession. Because the surveys (both BE and CLS) failed to conduct such an analysis they are invalid and their conclusions as to quality of care should not be accepted. COA, R-H-98 at 5-6.

84. Myopia versus Other Vision Problems. The restriction of the survey sample to individuals with myopia was uniformly criticized by AOA witnesses. The study reports that picking subjects who were representative of the population as a whole was considered ideal but not feasible for two reasons. First, the use of dissimilar subjects would have increased substantially the expected variation in the price and quality of eye examinations and eyeglasses. Uneconomically large samples would then have been required to determine if, on average, differences between advertisers and nonadvertisers exist. Second, it was impractical to use subjects with visual pathologies. (See Finding 74.) It was decided that groups of subjects of different ages and with different but relatively routine, optometric needs would be utilized. R-B-2-31 at 43. It was argued by AOA witnesses that the decision not to pick subjects who were representative of the

population as a whole violates fundamental rules of conducting good research and, further, that the decision of the staff not to include a random sample of eye/visual conditions seen in the routine optometric practice resulted in an unrepresentative sample which required only the lowest and most basic level of skills and expertise necessary in the provision of optometric care. Dr. Richard L. Hopping, Southern California College of Optometry, Tr. 1594-95. The first reason cited in the study for not picking subjects who were representative of the population as a whole, i.e., use of dissimilar subjects would have increased the variation in quality of exams and glasses, is challenged as being contrary to accepted research theory. It is argued that if one is to generalize quality differentials across types of optometrists, one should insure the greatest amount of variability possible across these optometrists in terms of their being able to perform examinations. By limiting the variability, the overall results are inevitably biased in favor of practices which are least likely to provide high quality care for complex cases. RRNA, Vol. I, Ex. 1 at 76.

85. It is the staff's position that while the eye condition tested for was relatively simple, using a "process" procedure to gather data to test the thoroughness of examinations rendered to survey subjects overcomes the need for a survey using more heterogeneous subjects. According to the BE Study:

> The initial, and in many ways the most complex, part of an eye examination is the evaluation of the patient's general visual and ocular health status. This is performed through a battery of tests, questions, and procedures, ranging from well-known and easily-recognized tests...to some more obscure tests... The purposes of these procedures

> are twofold: (1) to determine the reasons and required therapy for visual problems, and (2) to detect, at the earliest possible stage, signs of eye disease or injury or other systemic problems that might require medical attention. If a possible ocular disease or injury is detected in the course of an eye examination, the patient is ordinarily referred to an ophthalmologist for exact diagnosis and possible treatment.
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> In this experiment, subjects were thoroughly trained in components of an optometric examination and filled out checklists of the procedures performed in each examination they took. It should be noted that this measure of the thoroughness of the optometric examination does not preclude the possibility that some procedures, while apparently performed, were in fact not performed correctly. In one important instance -- ophthalmoscopy -- the subjects were instructed to record the time spent in the procedure, and not merely whether or not it was undertaken, in order to more nearly determine thoroughness. But in most instances, no additional information about the validity of the procedures could be obtained. Hence our definition of thoroughness measures apparent completeness of imputs (procedures) employed, and not directly the output, the ability of the practitioner to discover all relevant facts about the patient's eye condition. R-B-2-31 at 58.

The staff pointed out that the thoroughness index used by BE is not a measure of minimum quality. The subjects noted whether or not each optometrist performed a large variety of tests. Ronald S. Bond, R-K-18 at 9. It is further observed that "...although none of our subjects had truly serious pathologies, we do know whether or not optometrists performed tests that would have revealed the presence of pathologies, had they existed." Bond, R-K-18 at 10.

86. The RRNA survey addressed the use of myopia as the visual problem in the BE Study, describing myopia, or nearsightedness, as a refractive problem most prevalent in persons between 12 and 17 years of age. The survey report states that to obtain more reliable results on the completeness of visual examinations, a variety of eye conditions that are

detected using a range of visual tests were included in the RRNA study. These included anisocoria, astigmatism, vertical eye muscle imbalance and retinal abnormalities. The eye conditions used in the study occurred independently or in conjuction with other conditions. Myopia occurred in some of the subjects' eyes in addition to the primary conditions that are the focus of the RRNA study. HX-J-66(a), Vol. I, Ex. 3 at 9. Based upon the results of the RRNA survey, the conclusion is offered that eye examinations conducted in commercial settings were less likely to detect a range of eye conditions. Ex. 3 at 20.

87. The RRNA survey also sought to collect what is described as secondary data to determine the percent of optometrists who took medical history information as a part of the eye examination and on the average length in minutes of eye examinations in the two settings, i.e., private and commercial. According to the report, 73 percent of the eye examinations taken in private practice settings included questions about the patient's medical history, while 47 percent of the exams taken in commercial practice settings included medical history questions. The average length of an eye examination in a private practice setting across all subjects was 31 minutes. For the commercial practice settings the average length was slightly less than 14 minutes. HX-J-66(a), Vol. I., Ex. 3 at 18. The conclusions adduced from these findings are that eye examinations conducted in commercial settings were less likely to include medical history information and were considerably shorter in duration. Ex. 3 at 20. The overall conclusion is that the results of the

RRNA study of private and commercial optometry in New York City provides strong evidence that eye examinations given by commercial optometrists are neither as complete nor of as high a quality as those given by their private counterparts. Ex. 3 at 20. It is further asserted that this evidence is consistent with the statistically significant finding in the BE Study that eye examinations given by commercial optometrists were less thorough than those given by their counterparts in nonrestrictive markets. Ex. 3 at 20, note 1.

88. The RRNA survey is criticized on a number of grounds, including the sampling procedures and patient selection utilized, the use of the New York City trade area as a sampling frame, and the sampling methods used to identify the private optometrists who were included in the sampling frame. Dr. Thomas J. Maronick, R-K-19 at 1. The conclusion is reached, based upon rebuttal analysis of the research work, that the RRNA study is of questionable validity and reliability and that great caution must be used in ascribing any weight to the findings. Maronick, R-K-19 at 1.[22] Other specific criticism of the research design and execution reached the conclusion that the potential for significant bias in the research is so great that the study results cannot be relied upon for purposes of rulemaking. Gary T. Ford, R-K-20 at 10-11.[23] It is also asserted that the four eye

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[22] See also Rebuttal Statement of Joseph Mulholland and Renee Kinscheck, R-K-21 at 1-6 which discusses composition of sample frames for private optometrists in RRNA study.

[23] See also Rebuttal submission of National Association of Optometrists and Opticians, Analysis of RRNA survey by Dr. Alan R. Beckenstein, R-K-1, App. A.

conditions are not representative of disorders seen in the population as a whole, making the study incapable of reaching generalizations with regard to the population. Dr. Joseph Seriani, R-K-26 at 1 of his RRNA Analysis. NAOO, on the other hand, contends that the survey attempted to show that such levels-of-service issues as the amount of time spent with the patient were more critical than vision care needs as evaluated by the accuracy of the prescription or the appropriateness of referral. According to NAOO, the RRNA survey, in fact, sustains NAOO's contention "...that there is no difference in quality of care, only the level of services, among vision care firms and salon practitioners." NAOO, R-K-1 at 8-9.

(ii) The Contact Lens Study.

89. The question of quality of care was also addressed by the staff sponsored Contact Lens Study. This work was initially intended to compare contact lens wearers fitted by ophthalmologists, optometrists and opticians.[24] A total of 502 contact lens wearers were examined during the course of the study. Gary D. Hailey, HX-J-6(a) at 2. These subjects were identified using two national consumer panel firms to assist in accomplishing the task by means of a screener questionnaire mailed to households in 18 urban areas to identify the desired number of subjects. The questionnaire asked if any member of the household had been fitted with contact lenses within the past three years and, if so, if he or she were still wearing the

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[24] Note 15, supra, R-B-5-1 at 17.

lenses. If the answer to both questions was in the affirmative, household members were offered an opportunity to be an examination subject. Those agreeing were subsequently contacted by the panel firms and examination appointments scheduled. CLS, R-B-5-1 at 19-20. Study subjects arriving at field examination facilities were first interviewed by FTC staff members and questioned about who fitted the subjects' lenses, how long ago the lenses were fitted, how much the lenses (and related goods and services) cost, whether the lenses caused any discomfort, etc. The interview was taped and the answers recorded on a Patient Interview Form. Subjects were instructed not to tell the examiners anything about their contact lens history, especially the name of the practitioner who fitted the lenses. A series of examination procedures were performed by contact lens technicians or an assistant or by one of the optometrist-examiners or ophthalmologist-examiners, testing for visual acuity and whether individual subject's visual acuity could be improved if lens power was increased or decreased. The best available visual acuity and the amount of change in lens power, if any, needed to achieve that acuity were recorded on the Examiners' Form. R-B-5-1 at 20-21. After vision tests were completed, subjects removed their lenses and the physical condition of the lens was checked and graded for cleanliness, warpage and damage and results were recorded on an Assistants' Form. After subjects removed their lenses each was given biomicroscopic and keratometric examinations independently performed by each of the three examiners without consultation between the examiners. The

biomicroscope was used to examine the surface of the eye for a variety of potentially pathological conditions and the keratometer was used to take K-readings (measurements of the steepest and flattest curvatures of the corneal surface) and to evaluate corneal distortion. Results of each examination were graded according to a grading manual and recorded on the Examiners' Form. Because some of the conditions which were evaluated by the examiners were time-related, an FTC staff member recorded the order in which the three examination procedures were performed. R-B-5-1 at 21-23.

90. The field examinations were performed in the 18 urban areas between June 2, 1979 and February 25, 1980. Of the 502 contact lens wearers examined, further screening and missing observations reduced the final sample to as low as 402 wearers for parts of the quality of fit analysis and 388 wearers for the price analysis. R-B-5-1 at 23.

91. Soon after the field examinations were finished, the staff mailed an Original Fitter Questionnaire to the practitioners whom each subject had named as the source of his or her contact lenses. The main purpose of the questionnaire was to obtain information which would enable the staff to determine whether the subject had been fitted by an ophthalmologist, optometrist or optician. The questionnaire also sought data from each fitter's records including the subject's contact lens specifications and his or her original and most recent K-readings which were to be compared to data from the field examinations.

R-B-5-1 at 25. See note 52 at 25 for explanation of information received on K-readings.

92. The contact lens wearer study was designed to produce information that would enable the staff to compare the contact lens fitting performance of ophthalmologists, optometrists (both commercial and noncommercial) and opticians. The report of the study concludes that about three times as many study subjects were fitted by optometrists as were fitted by either ophthalmologists or opticians. R-B-5-1 at 32. The report indicates that regression estimates of differences in the mean summary of quality scores fitted by opticians versus those fitted by other fitter groups reveal no statistically significant differences among the subjects fitted by opticians, optometrists and ophthalmologists. R-B-5-1 at 34-35. Conclusions were also reached on the percentage of optican-fitted subjects exhibiting any measurable degree of a particular condition differing from that of fitter groups to which it was compared. R-B-5-1 at 36-37.

93. The contact lens wearers study also compared price and quality of contact lens fitting by commercial and noncommercial optometrists. According to the report, for purposes of analysis of the data, optometrists were divided into three groups. Commercial optometric practices are defined as those that employ several optometrists, use a trade name, advertise heavily or are located in a department or drug store. Noncommercial optometrists are defined as solo practitioners who practice in nonmercantile settings and who do not advertise or use trade

names. This classification was based on information obtained from the subjects and the fitters and from an examination of a nationwide optometric directory and relevant Yellow Page volumes. For example, optometrists who worked for large firms or who purchased display ads in local Yellow Pages were classified as commercial optometrists. Optometrists who were members of the American Optometric Association and who did not purchase Yellow Page advertising were classified as noncommercial optometrists. A third group was labeled as Unclassified Optometrists and included optometrists about who there was insufficient information to permit classification as commercial or non-commercial, such as an optometrist the staff could not locate in their source materials or, in other instances, optometrists who were not listed as members of AOA, but for which there was no information indicated that they were commercial providers. The unclassified group also includes optometrists who practice in health maintenance organizations, the military or other settings which are neither commercial nor noncommercial. R-B-5-1 at 30-40, notes 64,65.

94. The report of the study indicates that regression estimates of differences in the mean summary scores of subjects fitted by commercial optometrists versus those fitted by other fitter groups reveals that subjects fitted by commercial optometrists had better scores than those fitted by ophthalmologists, opticians or noncommercial optometrists, but that those differences are either not statistically significant or only marginally significant. Commercial optometrists did score

significantly better than optometrists who could not be classified as either commercial or noncommercial practitioners. R-B-5-1 at 42. The report also advises that the percentage of commercial optometrist-fitted subjects exhibiting any measurable degree of a particular condition did not differ to a statistically significant extent from that of the fitter group to which it was compared. In every case in which there was a significant difference, the commercial optometrists' score was better. R-B-5-1 at 44.

95. The overall conclusion reached by the survey concerning the quality of care issue is that the findings of the study call into question claims that restrictions on contact lens fitting opticians and commercial optometrists are necessary to protect the public. Among the contact lens wearers examined in this study, the quality of contact lens fitting provided by opticians and commercial optometrists was not lower than that provided by ophthalmologists and noncommercial optometrists. R-B-5-1 at 47.

96. The CL Study surveys only so-called successful contact lens wearers but not unsuccessful wearers. That is, the screener questionnaire which was sent to consumer panel members at the outset of the survey asked members if they had been fitted with contact lenses within the past three years and, if so, whether they were still wearing the lenses. If the answer to both questions was "yes" the panel members were offered an opportunity to be an examination subject. R-B-5-1 at 19. As a consequence, respondents to the questionnaire who, for instance, responded "yes" to the question of whether they had been fitted within the

past three years, but "no" to the question of whether they were still wearing the lenses, were not offered the opportunity to participate in the survey. A Commission staff member testifying on the results of the survey agreed that a staff memorandum, HX-J-6(b), dated September 6, 1978, a period when the survey methodology was under consideration, R-B-5-1 at 17, indicates that the FTC staff believed at that time it should survey the question of unsuccessful wearers so that at least the staff would be able to respond to any questions in the area of unsuccessful wearers. Hailey, Tr. 218-19. Under questioning, Mr. Hailey advised that groups consulted on the design of the methodology, i.e., groups and organizations in the fields of optometry, ophthalmology and opticianry, felt it would have been a good idea to do some testing of the unsuccessful wearers. Hailey, Tr. 216. The witness stated this is the reason the questionnaire sent out to "survey subjects" (apparently meaning individuals receiving the initial screening questionnaire) asked questions of those who were no longer wearing their lenses and attempted to gather data on unsuccessful wearers. Tr. 219. An appendix to CLS discusses the former wearer issue, pointing out the recommendation that former wearer data would supplement data on current wearers. "It was hypothesized that many former contact lens wearers were 'failures' due to the lack of skill of their fitters. If we could gather reliable information about former wearers as well as current wearers, we would be better able to compare the overall quality of contact lens fitting by different groups of fitters." R-B-5-1, App. B at B-1. The report continues by

pointing out the difficulty of developing a methodology for testing and the reasons it is believed that limiting the analysis to current wearers does not mean the CLS findings about relative contact lens fitting quality are based only on data from satisfied wearers with healthy eyes and well-fitted lenses. R-B-5-1, App. B, B-1 to B-6.

97. The NPR asked two questions (5-6) concerning the methodology employed in the CL Study to determine whether there is any reason to believe that the distribution of former contact lens wearers among different fitter groups is significantly different than that of current (successful) wearers. The NPR also seeks to determine whether there is any evidence to indicate that the quality results would have differed if the study's subjects had included wearers who were aphakic or who suffered from unusual medical or visual problems.

98. A series of criticisms of the CL Study were directed to the methodology employed and conclusions reached on the quality of care issue. These can be summarized as follows: (a) The CLS was not truly designed for the purpose for which the FTC is now trying to use it. The study was primarily designed to address the impact of state laws restricting contact lens care by opticians, but is being improperly used as part of the effort to nullify state laws regulating the commercial practices of optometry. (b) The CLS was defective because it involved only cosmetic contact lenses and did not include extended-wear lenses and patients with more difficult eye or vision problems, such as post-cataract surgery patients. The lenses and conditions which

were not included involve complex fitting and patient-care considerations. The study does not provide helpful information with respect to a significant portion of the contact lens wearer population. (c) The CLS data were collected in a non-random fashion that produced unrepresentative samples. (d) The CLS is based on data collected during 1979-1980 from patients in 18 urban areas who had been fitted with cosmetic contact lenses. The sample size and distribution of the patients included as subjects in the survey were far too small to produce valid, representative results. The survey does not provide a reliable basis for major public policy decisions in the health care field. (e) An arbitrary, unreliable method was used to classify optometrists as commercial or professional providers. (f) the CLS is incomplete and unreliable because it effectively excluded unsuccessful wearers. The CLS does not use data concerning unsuccessful wearers and does not deal with the physiological damage unsuccessful wearers may thereby have sustained. (g) The proper care of a contact lens patient includes several follow-up visits during the period of adaptation to the lenses following the initial examination and fitting to ensure that no adverse problems occur that affect eye health and vision, and so the provider can also determine if further adjustments or changes in the initial lenses may be needed to prevent unsuccessful wear. A reading of the CLS would seem to indicate that it yielded no data on this subject. However, data on follow-up care was collected by the staff, but for unstated reasons was not included in the report. (h) After the initial period of adaptation, the contact

lens patient should return for regular checkups to ensure that no problems have developed that might result in the patient becoming an unsuccessful wearer. Instructions for such regular examination are a significant quality indicator. Data relating to such instructions were collected by the staff, but were not included in the CLS. (i) The procedures used to perform eye and vision examinations for the survey were incomplete and unreliable. Contrary to CLS assertions that the survey's examination procedures closely resembled those used by contact lens fitters to perform follow-up examinations, the procedures were incomplete and different from those generally used during follow-up: [1] a refraction without the lenses on, used to determine "spectacle blur," was not performed; [2] the original keratometer (K) readings, used to determine corneal molding, were not available at the time of the examination; [3] most patients had not worn their lenses for at least four hours before the examination; and [4] the examiner was not allowed to question the patients about their subjective reactions to the lenses. (j) A major clinical defect in the CLS is that lens wear time on the day of examination was inadequate to provide valid examination results for a significant majority of the subjects of the survey. The period of time the majority of the patients wore their lenses was far too short for many potential problems associated with improper contact lens fitting to be noticeable. AOA, R-H-81 at 35-46.

99. Several representatives of commercial optometry testified as to the quality of care rendered in commercial

establishments concerning the fitting of contact lenses. The record indicates that at least some commercial practitioners may fit all types of contact lenses as are fitted in optometric offices generally throughout the country, including lens fitting in so-called problem-type situations that may require additional time to complete the fit because of the difficult visual problems presented. Some commercial practitioners may also make known their willingness and ability to take on difficult contact lens fitting problems to the optometric and ophthalmological communities in which they practice. Zaback, Tr. 1916-17. Many commercial practitioners indicated that their fee for contact lens fitting generally covers a period of six months (with a range of 3 months to one year). These fees are intended to cover problems developed after the initial fitting, including visual problems or problems with the lenses themselves. These commercial practitioners emphasized the need for follow-up care in the management of contact lens patients, advising that follow-up should be considered a measure of quality of contact lens care. The record is unclear as to whether the fees charged by commercial practitioners includes the cost of contact lenses provided patients after the initial fitting if visual problems develop while the initially fitted lenses are being worn. There is indication that some will "do whatever is necessary to resolve the patient's problems, if any develop". See NAOO Washington Panel, Tr. 347-50; NAOO Panel 1(a), Tr. 1916,1948-49,1959-60, 1969,1970,1978-79; NAOO Panel 1(b), Tr. 2034-35,2077-78. (Noncommercial practitioners appear to sell contact lenses as a

package, as well, including examination, dispensing and follow-up care. See Dr. Douglas McBride, Montana Optometric Association, Tr. 2272-74; Dr. Harvey P. Hanlen, Pennsylvania Optometric Association, Tr. 2339-41; Dr. Warren Wheeler, Oregon Optometric Association, Tr. 2222; Friedman, Tr. 2407-08.)

100. As part of its presentation on behalf of the AOA, RRNA submitted an assessment of the CLS. According to RRNA, after the CLS had already been executed, the focus of the analysis was changed and directed away from the question of whether opticians provided eye care comparable to that provided by other practitioner groups. Instead, the principal question of interest became whether significant price and quality differences exist between commercial and noncommercial optometrists. RRNA, HX-J-66(a), Vol. I, Ex. 2 at I. Introduction.

101. Commenting on the CLS methodology for quantifying the ocular health of successful contact lens wearers RRNA asserts that the study did not control for additional events beyond the control of the fitter that affect the ultimate ocular health of a contact lens wearer. RRNA suggests a sequence of events involving examination of a patient and fitting of contact lenses by the examiner, a different practitioner from the same group as the original or a different practitioner belonging to a different group, with follow-up care and checkups provided by entirely different practitioners belonging to entirely different provider groups. Based upon the suggested sequence of events RRNA speculates that between the time of the CLS subject's lens fitting or most recent checkup and the CLS survey interview and

examination, the subject may have experienced physiological ocular changes. A subject may have been on medication the day of the examination or may have been pregnant or using birth control pills. The report of the survey does not indicate events in a patient's history that may have contraindicated the subject's inclusion in the study. HX-J-66(a), Vol. I, Ex. 2 at 5. RRNA states that in contrast to the difficulties of quantifying the ocular health of contact lens wearers and attributing the health to the fault of contact lens fitters, quantifying input measures of eye care quality is a relatively straight-forward task. The CLS collected information indicating whether survey subjects had received contact lens fitting follow-up care, whether instructions had been provided on the importance of regular checkups, and whether they had returned for regular checkups. RRNA observes that an analysis of these data was not presented in the final report of the staff. HX-J-66(a), Vol. I, Ex. 2 at 5.

102. RRNA asserts that the data collected for one purpose in CLS is being used for another purpose, and that the survey was not designed to provide information for determining whether states should have the legal right to restrict commercial forms of optometric practice. RRNA alleges that internal Commission documents make plain that a comparison of commercial and noncommercial optometrists with respect to examination scores was not designed to be a part of the contact lens study and that more than a year after data collection for CLS was completed, a staff decision was made to extract information from CLS data to provide input into a rulemaking record regarding commercial practice. At

that time a decision was made to classify optometrists as commercial or noncommercial providers. HX-J-66(a), Vol. I., Ex. 2 at 7-8 and notes 1-3. Although special efforts were made by staff to ensure that the survey generated a representative sample of opticians, no steps were taken to ensure a representative sample of commercial and noncommercial optometrists. In addition, because the CLS survey used a non-probability sampling procedure, the accuracy of the sample estimates cannot be determined. RRNA further asserts that internal Commission documents demonstrate an intention to collect a representative sample of opticians and that because the CLS survey was not designed to obtain sample data adequately representing commercial and noncommercial optometry, the final report on analysis of data collected from field examinations submitted to the Commission by the contractor doing the analysis expressed concern relating to the relatively small sample size involved in the survey and the restrictions the sample size placed on the ability of those analyzing the data to detect differences, if any, between fitter groups. HX-J-66(a), Vol. I., Ex. 2 at 10-11.

103. RRNA argues that the original population of interest was defined to be ophthalmologists, optometrists and opticians who had fit contact lenses for patients choosing to wear their lenses for cosmetic reasons only. The final focus of the present use of the CLS is on differences between commercial and noncommercial optometrists. Therapeutic lens fittings that can be provided by optometrists were not included in the CLS analysis. In addition, data pertaining to unsuccessful fittings

were collected, but not analyzed or presented in the final report. The final report seems, according to RRNA, to present the view that the unsuccessful wearer data collected by the FTC staff are unreliable as a basis for analysis. HX-J-66(a), Vol. I., Ex. 2 at 13.

104. A number of other aspects of the design and implementation of CLS are challenged, including design of the patient interview form, examination procedures, practitioner classification scheme and the fact that alleged error occurs when a subject included in the sample does not participate. As to the so-called nonresponse error, of 1,871 subjects identified in the screening questionnaire, only 502 were eventually examined. RRNA alleges this to be a nonresponse rate of 73 percent, contending that the seriousness of such an alleged error is that the direction of difference, i.e., nonresponding subjects may be quite different from those responding, is usually unknown and its magnitude cannot be estimated reliably. HX-J-66(a), Vol. I., Ex. 2 at 13-14,18.

105. Measurement errors are also alleged by RRNA in that the length of time the lens had been worn by survey subjects on the day of the examination (weartime) had the strongest influence on the summary scores. As the weartime increased, summary scores decreased. HX-J-66(a), Vol. I., Ex. 2 at 18. Dr. John Kennedy, a practicing optometrist who served as one of the examiners during the CLS appeared during public hearings, and generally criticized the study. Accepting the AOA evaluation of CLS, Dr. Kennedy noted that apparently over 78 percent of the individuals

examined in the study had worn their lenses for less than four hours prior to being examined. The pre-examination weartime can be a critical factor in determining the existence of a number of eye health problems resulting from improper contact lens care. According to the witness, this does not mean that no problems will be found, and, in fact, the CLS did find problems in some who wore their lenses for less than four hours. Some conditions are more long standing and not as time related. However, many problems that would develop after four, six or eight or more hours of wear would not be discovered in the subjects who wore their lenses only one, two or three hours prior to being examined. The witness concluded that, as a result, many subjects who exhibited minor problems may have exhibited more severe problems had their lenses been on longer and some subjects who showed no problems may have exhibited signs of some problems after four or more hours of wear. HX-J-26 at 8. Noting the fact that a majority of the subjects had their lenses on less than four hours at the time of the evaluation, the witness stated this fact could have significantly effected the results obtained for several visual conditions. The shorter the wearing time, the less likely the conditions would be detectable or fully manifest. From a health care perspective, Dr. Kennedy advised, the results of the study examinations cannot be regarded as providing meaningful or reliable results. HX-J-26 at 12.

106. Testifying to the question of weartime, a member of the Commission's staff recalled receiving a letter from AOA approximately six months before the first field exam for CLS was

conducted in which AOA suggested that patients should have worn the lenses on the day of examination for a minimum of four to five hours before they were examined. The witness agreed, however, that the staff did not instruct patients to wear their lenses for at least four hours before they came in to be examined. The witness also indicated that the instructions sent to the survey subjects by the FTC staff merely advised them to bring their lenses to the examination site. He further agreed that some survey subjects who may suffer from troublesome conditions associated with improper fitting may not have exhibited symptoms of these conditions if the subjects brought their lenses to the examination and put them on shortly before they got there. Hailey, Tr. 227-29. The Commission's witness testifying as to the statistical treatment of weartime stated he was advised by the CLS staff that weartime was not that important an issue. Mulholland, Tr. 865-66.

107. According to the CLS, R-B-5-1 at 22, each survey subject underwent a keratometric examination by each of the three examiners to obtain measurements of the steepest and flattest curvatures of the corneal surface and to evaluate corneal distortion. During the post-examination data collection phase of the CLS the Original Fitter Questionnaire mailed to the practitioner who survey subjects had named as the source of their contact lenses, sought, among other things, the subject's original and most recent K-readings. The CLS report observes that change in K-readings over time was one of the measures of eye health which the associations' (AOA and others)

representatives agreed should be included in the study. Any significant change from the original K-readings is a strong indication that the lenses did not fit properly and should be replaced or modified. Staff intended to use that data to compare groups of subjects classified by fitter type, but much of it was of questionable reliability. The three field examiners rarely agreed on the correct K-readings for a subject. Only about 70 percent of the questionnaires that were mailed to the subjects' original fitters were filled out and returned. Many of the readings on those questionnaires were incompletely recorded, or recorded in nonstandard fashion. "Although the results of the K-readings comparisons would have been of interest, the absence of those results is not of great importance. The relative presence (or absence) of the seven potentially pathological conditions provides a comprehensive measure of the relative health of a contact lens wearer's eye." R-B-5-1 at 22-23,25, note 52. Dr. Kennedy testified that although keratometry measurements may determine gross distortions in corneal curvature, their value is most often related to a comparison of current K-readings with the original K-readings. The inability in the study to compare the original K-readings with the current readings severely limits the value of this procedure in determining problems related to contact lens wear. He further stated that the FDA protocols for investigative contact lens clinical studies require that this comparison be done. HX-J-26 at 12.

108. RRNA, as part of its criticism that the CLS is being used for a purpose other than that for which it was designed,

argues that the classification of optometrists for the CLS may be erroneous. Pointing to record material indicating that survey subjects did not know the credentials of the providers of their contact lens fittings, RRNA argues that the Original Fitter Questionnaire did not contain questions appropriate to permit the original fitters to provide the needed information themselves. It therefore became necessary for the staff to devise the classification method previously described. It is urged by RRNA that, in many cases, it is likely that the classifications made by FTC staff of the original fitters do not reflect the form of the fitter's practice at the time he provided the sample subject's fit. The classifications were made during 1981 using Yellow Pages from 1979, 1980 and 1981. RRNA observes that the majority of fittings (79 percent) were provided from 1975 through 1978. Contemporaneous editions of the Yellow Pages were not used to classify the fitters of 79 percent of the CLS subjects. HX-J-66(a), Vol. I., Ex. 2 at 17-18.

109. Dr. Kennedy has also criticized the CLS, stating the fact the examiners were not allowed to question subjects about their contact lens wearing history, or about subjective problems, severely limits the ability to relate signs found, lens condition, etc. to actual problems relating to the initial fitting of the lenses. HX-J-26 at 12. The Commission's witness, Mr. Hailey, stated that examiners were not allowed to review the case histories before they examined a patient. This witness advised there was concern about the identity of fitters coming from the same locality as the examiners and felt that examiners

should not know who fitted a particular subject since the fact the examiner might know the fitter may have, in some way, biased or prejudiced the survey. Tr. 246. The witness also believed that survey subjects were instructed they should not tell the examiners anything about their contact lens history and examiners were told not to ask survey subjects questions about whether the lenses were causing discomfort or other problems, because the staff wanted the examiners' objective measurements of certain conditions rather than having their answers influenced by subjective information from the patient. Tr. 247-48. While the staff asked some of the questions concerning possible discomfort or other problems in their interview form, the answers to these questions were not available to the examiners. Tr. 248-49.

110. Dr. Kennedy states that an important area of quality contact lens care that was not discussed in the analysis of CLS relates to patient instructions on lens care and maintenance and the providing of needed follow-up care. According to Dr. Kennedy, continuing successful wear requires that patients be fully aware of the need for proper lens handling, cleaning and care. Failure to follow appropriate procedures for lens insertion, removal and handling of lens cleaning and care can result in significant problems of discomfort, blurring of vision and discontinuance of wear. Although information on these aspects of care were apparently collected by the staff, they were not used in the analysis or findings of CLS. The doctor also criticized the survey because it was limited to relatively simple cosmetic daily wear contact lens patients. The number and types

of contacts lenses availabale and prescribed today, according to the witness, provide for much more complex fitting circumstances. The availability of extended wear lenses has necessitated the evolution of a whole new area of contact lens care, and with this has come increased risks for the development of eye health and vision problems. The availability of toric soft lenses for astigmatism creates a more complex fitting procedure than the fitting of spherical contact lenses. Bifocal contact lenses also present unique fitting and wearing characteristics that require more thorough evaluation and care. The advent of rigid gas permeable lenses of many different types and the expanded number of daily wear soft lenses available present a different situation than existed only a few years ago in the contact lens field. The CLS did not evaluate contact lens practitioners' capabilities in these more complex areas of lens care. Therefore, according to the witness, the study's ability to reflect present-day reality is severely crippled. Dr. Kennedy concluded, based upon his observations as a result of participation as one of the examiners in the study, that the Commission should not rely on the limited results of the study as the basis for any policy decision in this area of health care. HX-J-26 at 12-14.[25]

111. The summary quality score set forth in the CLS is not associated exclusively with poorly fitted contact lenses,

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[25] A separate criticism which repeats several matters argued by RRNA and Dr. Kennedy was filed by Dr. Barry Barresi, Associate Professor and Director, Center for Vision Care Policy, College of Optometry, State University of New York, HX-J-13(a), and Tr. 529-79.

according to RRNA's analysis. The examination procedures did not allow for the examiners to observe the contact lens on the eye of the subject, and the examiner was not asked to evaluate whether the presence of one of the corneal conditions may have been due to factors other than the lens. RRNA concludes that, as a result, very little evidence was produced to support the inference that other causal factors were not responsible for the associative variation between fitter groups and summary quality scores. Intervening events between the initial fitting and the CLS survey examinations are of paramount importance. Did a patient return for regular checkups; did he follow the fitter's instructions on lens care procedures; did he adhere to the fitter's recommendations regarding lens wearing time; could physiological ocular changes have occurred since his last examination and fitting? Were any patients using birth control pills? Had any consumed drugs on the day of the exams? In short, RRNA asks, were their histories examined for events that would have contraindicated their inclusion in the study? HX-J-66(a), Vol. I., Ex. 2 at 23-24. RRNA also argues that the data show significant decreases in quality scores as weartime increases and states that given this is so it is obvious that the number of observations in the data is too small to find statistically significant differences between contact lens fittings provided by commercial and noncommercial optometrists using only the subjects whose weartimes were sufficient to allow the manifestation of potentially pathological eye conditions (more than four hours). Ex. 2 at 26-27.

112. RRNA offered additional information which it claims is demonstrated by an analysis of the CLS data concerning quality of care. According to the RRNA report, if quality eye care is defined to include important services such as contact lens fitting follow-up care, instructions on the importance of regular checkups, and the provision of regular checkups, noncommercial optometrists provide significantly higher quality eye care than their commerical counterparts. HX-J-66(a), Vol. I., Ex. 2 at 37. Based upon an RRNA analysis of responses to questions in the Patient Interview Form of the CLS, it is alleged that the data demonstrates that noncommercial optometrists instructed more patients on the importance of regular checkups than did commercial optometrists. It is also asserted that noncommercial optometrists provide more follow-up care and that more of their patients return for regular checkups. RRNA concludes that these three dimensions differentiate the higher quality eye care provided by noncommercial optometrists from the care provided by commercial optometrists. Ex. 2 at 37-40.

113. Rebuttal materials filed by or on behalf of the staff address several of the arguments and conclusions raised by the AOA presentation concerning the quality issue. These are:
(a) Classification of Optometrists - The staff states that since the rulemaking involves trade name usage, branch offices, commercial locations and corporate employment, the classification scheme focused on whether or not optometrists were engaged in these activities. In order to be classified as "commercial", optometrists had to be engaged in one or more of these

activities; no optometrists were classified as "commerical" optometrists merely because they advertised. Furthermore, the vast majority of "commercial" optometrists were either chains, or optical companies offering optometric services. Staff states that every effort to be conservative was made in the classification approach and that if there was any doubt about whether an optometrist was truly commercial or a private practitioner, that optometrist was placed in the "unknown" category. More importantly, the staff suggests, while doing the classification of each optometrist, staff did not know how that optometrist had scored on the quality index and there is thus no reason to assume bias in the classifications. Rebuttal Statement of Joseph P. Mulholland, R-K-23, App. B at 1. (b) Weartime - Addressing the AOA/RRNA arguments that suggest that some eye conditions resulting from poor fit may not be evident until subjects had worn their lenses for a number of hours on the day of the examination and that since relatively few subject wore their lenses for the suggested four hours minimum wearing time, the CLS quality results are thereby invalidated, staff believes such arguments are invalid. According to the staff, the eye conditions to which AOA/RRNA refer make up only a part of the full list of eye conditions contained in the summary quality score. In addition, those conditions cited as requiring minimum weartime were given relatively low weights by the FTC's optometric consultants, indicating that their medical consequences were less important than many of the remaining eye conditions. Four of the seven eye conditions in the CLS exam do

not require any minimum amount of wearing time on the day of examination for detection and these eye conditions tend, on average, to be assigned a greater importance weight than those remaining eye conditions claimed by critics not to require a minimum weartime for detection. Staff concludes that even if the three conditions requiring minimum weartime were deleted from the CLS the remaining condition categories are clearly relevant for the information on quality differences. Staff further states that the quality scores on the remaining eye conditions provide the basis for concluding that commercials are at least as competent at contact lens fitting as are noncommercials. Staff further urges that flawed reasoning underlies the RRNA observation that average quality score for subjects with a weartime greater than four hours was significantly lower than the corresponding average for subjects that wore their lenses for four hours or less, arguing an analytical conclusion to the matter. In this regard the staff offers the final conclusion that since the commercial practitioners' performance in relation to eye conditions for which no minimum weartime level is required is at least as good as the noncommercial practitioners' performance, there is no reason to suppose that the CLS quality analysis would have led to different results if all subjects had worn their lenses for some minimum length of time before being examined. R-K-23 at 4-7. (c) Former Wearers - Staff observes that while former wearers could not be included in the main body of the CLS because it was impossible to devise a means to evaluate the quality of fit of contact lenses that had not been

worn for months or years, the issue was nonetheless discussed extensively in Appendix B of the report, included with a classification of as many fitters as the staff was able to identify based upon the information available to them. Staff admits that while all fitters for whom they had sufficient information were classified in the Appendix, there was necessarily a large unclassified group, and discusses the history of its classification efforts. R-K-23, App. B at 1-5. Staff also challenges the AOA analysis of the CLS data which led them to the conclusion commercial optometrists had a far greater proportion of patients who had stopped wearing their lenses than did other types of providers. AOA, R-H-81 at 40. Staff concludes that analysis of the data used to support the AOA analysis actually buttresses the staff position that tests using former wearer groups are unreliable and that a more appropriate approach to the long term successful fits issue is to analyze the current wearers group, where the information is much more extensive and reliable. Such an analysis, according to staff, indicates that there is no significant difference among fitter groups in their ability to provide successful, long lasting contact lens fits. R-K-23 at 8-11. (d) Follow-up Visits - the argument that follow-up visits are indicative of higher quality of care is disputed by a staff-sponsored submission as not being unambiguously the case. Rebuttal Statement of Valerie Cheh, R-K-16 at 1. The alternative hypothesis, it is asserted, is that follow-up visits are actually a measure of how poorly the contact lens was fit, not a measure of good quality care, and that an

analysis of the data evaluating correlation coefficients between the number of follow-up visits and the outcome quality scores reported in the CLS is inconsistent with the hypothesis that follow-up care is more often obtained by customers who have problems with their contact lenses. Thus, it is concluded that the number of follow-up visits is not a good indicator of quality. R-K-16 at 2.

(b) Price of Vision Care.

114. The BE Study and the Contact Lens Study are the primary evidence placed into the rulemaking record by the staff to compare the relative price of optometric services available across regulatory environments and kinds of practice and to support the contention that higher prices result from the imposition and enforcement of commerical practice restrictions.

(i) The BE Study.

115. To gather pricing information on vision care, the BE Study undertook to classify cities (in reality Standard Metropolitan Statistical Areas [SMSAs]) which were distinguishable by the type of mass media advertising observed on eye examinations and eyeglasses as well as by whether or not large chain optical firms operated in the market. Mass media advertising was monitored in the Yellow Pages and in newspapers. No attempt was made to obtain measures of radio and television advertising by optometrists or local optical firms. In the most restrictive cities, essentially no advertising of either eyeglasses or eye examinations was observed. In the least restrictive cities there was price advertising of eyeglasses and at least nonprice advertising of eye examinations. R-B-2-31 at 2.

116. To evaluate the effect of large chain optical firms on the price and quality of optometric services, cities were further classified by whether or not large chain optical firms sold eyeglasses and eye examinations. In nonrestrictive cities large chain firms sold both eye examinations and eyeglasses. There were no large chain firms in restrictive cities. It was antici-

pated that large chain firms might enjoy economies of scale in both purchasing and distribution. Such economies could lead to lower prices not only from the firms themselves, but also from optometrists competing with them. R-B-2-31 at 2. Restrictive cities, by definition, did not include either optometrists who advertised in the media or optometrists who worked for large chain firms. Except for a few optometrists who advertised on site, all were necessarily nonadvertisers. Nonrestrictive cities included three major types of optometrists: nonadvertisers, advertisers and large chain firms. R-B-2-31 at 2-3.

117. The BE Study uses data collected by actually purchasing eye examinations and eyeglasses. Purchases were made in both restrictive and nonrestrictive cities. Data were also collected from optometrists practicing in large chain optical firms in cities where they are permitted to operate. R-B-2-31 at 39. Two sets of price data were analyzed -- the total price of the examination and eyeglasses and the examination price separately. According to the report each set of analysis shares a common problem, i.e., prices from different SMSAs reflect, in part, differences in the cost-of-living; this has nothing to do with the particular price patterns under study in this experiment. In the survey methodology, in order to control for this effect, some deflator is required to adjust the prices encountered in the twelve SMSAs visited. The report indicates that references to "prices" in the discussion of analysis means <u>adjusted</u> prices. R-B-2-31 at 48,51.

118. The study reports that total price and examination price appear to be lower, generally, in markets where large advertising firms compete and lower yet when the service is purchased from the advertisers themselves. Since these data represent classes of practitioners, the market-wide price effects will depend on the relative market shares of, for example, large chain firms and nonadvertisers. That is, according to the report, if the former account for a relatively large fraction of total optometric examinations, the average prices in those markets will be considerably lower than where they are prohibited. The report observes as noteworthy the result that price declines are most evident in those markets with price advertising of eyeglasses and nonprice advertising of examinations in the presence of large chain firms. SMSAs with various slightly weaker forms of advertising show substantially smaller impacts on price with sometimes lower levels of statistical significance. The possible greater effect of price advertising raises interesting economic questions concerning the information content of nonprice advertising and is reflected in the distinction many states draw in regulating price and nonprice advertising of optometric goods and services. These results also reveal that prices of nonadvertisers' examinations in advertising markets (while lower than in other markets) remain above the larger chain firms' prices. Neither the presence of considerable advertising nor the commercial practices employed by the chain firms drive these prices to equality. R-B-2-31 at 57.

119. The BE Study also evaluated the relationship between price and quality. It is observed that the presence of advertising and commercial practice may lead to substantial reductions in the price of eye examinations and eyeglasses. The chain firms themselves offer the lowest prices, but even nonadvertising practitioners in the presence of chain firms are forced to lower price somewhat. The ability of optometrists to advertise price, rather than simply availability (that is, non-price advertising), appears to have special force in altering market prices. The report indicates that in the evaluation of eye examination quality, looser restrictions do not cause erosion of quality throughout the market. Looser restrictions do seem to result in greater frequency of less-thorough examinations by advertising optometrists, but this does not imply that the absence of restrictions has caused market quality to erode. Rather, the absence of restrictions has permitted an alignment of thoroughness with the form of practice. Those inclined towards thorough examinations maintain traditional forms of practice. Those who would give less-thorough examinations are more likely to practice as advertisers or to affiliate with commercial practice. Both coexist. In restrictive markets these different practices are not eliminated but simply obscured by the inability to advertise or engage in commercial practice. The report also states that whereas thoroughness of eye examination does vary across type of optometrist, other dimensions of quality do not. The accuracy of the prescription, the accuracy of the eyeglasses, and the workmanship of the glasses are essentially the same

regardless of provider or regulatory environment. In almost all instances, it is likely that at a minimum the consumer wants to be checked for the need for new eyeglasses, and it would appear that this service and the resulting product (eyeglasses) are not substantially different under any circumstances. It is in the area of quality of optometric service that consumer preferences and the thoroughness of practice vary. R-B-2-31 at 89. Finally, the BE report advises that given such differences in both price and at least one dimension of quality, the question is raised as to how quality-adjusted price varies across markets. The data reveal that within types of optometrists as well as within markets and across markets, there are strong positive associations between the thoroughness of practice and the price. But even after allowing for this association, price in nonrestrictive markets is clearly less than in restrictive markets. The conclusion is that advertising and commercial practice are powerful devices in lowering market prices without reducing overall market quality. Consumers gain in this manner as well as by being better able to judge the thoroughness of the service to be rendered from the form of optometric practice. R-B-2-31 at 90.

120. The overall summary conclusion of the BE survey on the matter of price is that the total prices charged for eye examinations and eyeglasses are significantly lower in the least restrictive cities. Large chain optical firms, advertising optometrists, and even nonadvertising optometrists all charge less in these cities than optometrists in the most restrictive

cities. The lowest prices are those charged by large chain optical firms and other advertising optometrists. R-B-2-31 at 4.

121. The NPR sets forth two questions (3-4) relating to the design and statistical analytical technique employed in the BE study, asking for comments on the possible effect of the court decision in Bates v. State Bar of Arizona, 433 U.S. 350 (1977) as well as whether the multivariate statistical technique used in the study could lead to inappropriate conclusions about the impact of restrictions on price.

122. In testifying to the design of the BE study concerning price, a Commission witness stated that one of the prior hypotheses the Bureau of Economics had when the study was laid out was that the existence of nonprice advertising of eye examinations in a market would be expected to have an independent effect on the market price for eye examinations. It was also hypothesized that the existence of price advertising for eyeglasses may be expected to have an independent effect on the market prices for eyeglasses. Bond, Tr. 487. The witness explained that the BE study analyzes the effect of state regulation independent from the effect, presence or absence, of advertising on price. The witness further testified concerning the term "state regulation", that in states where there was no advertising in the survey sample, there were regulations that would seem to prohibit advertising. It is possible that in some states where there was advertising in the sample there were regulations that were not being enforced. The market cells used in the survey, however, were not defined in terms of statute or

regulation or law. That approach had been considered, but when looking for the presence or absence of advertising, it was found that the market did not always comport with what one would expect from a reading of state regulations. Where advertising was prohibited, for instance, one may still find advertising. Bond, Tr. 487-89. Based upon the survey, the witness stated he believes price advertising has a much more significant impact on the price of optometric goods and services than nonprice advertising. Bond, Tr. 491. Another Commission witness testifying to the BE study stated the conclusion that the study, buttressed by some independent work he had done, indicates that without commercial firms, prices are distinctly higher, leading to excessive payments for ophthalmic care by some consumers and reduced availability to ophthalmic care by others. Kwoka, Tr. 499. Stated another way, the witness advised that the BE study, and his own research, conclude that the greatest impact resulting from nonrestriction had to do with price, and that there was in fact no measurable impact on quality. Kwoka, Tr. 510.

123. The use of variables to adjust the price data contained in the BE Study was repeatedly mentioned in individual statements of testimony and witnesses pointed out instances in which average prices actually charged in cities classified in the study as most restrictive were in fact actually less than the average price charged in the least restrictive cities. See William Erxleben, Tr. 1414; Conner, Tr. 657.

124. The primary and more generally comprehensive objections to the BE Study of price were filed principally by AOA

and RRNA and go to the methodology and analysis utilized in the preparation of the report, together with a general criticism of the overall design of the study. On the question of design, AOA argues that it is essential to the validity of a survey study that it be designed with the purpose of eliciting information relevant to the question at hand. The BE Study was intended to measure the effect of advertising and commercial practice on the price and quality of routine eye examinations and eyeglasses. Throughout the Study the emphasis is primarily on advertising linked with a secondary concern with commercial practice. Nowhere is it claimed, according to AOA, that the presence or absence of commercial practice, itself, has been studied or measured -- nor was it the purpose of the study to do so. AOA, R-H-81 at 23-24.

125. According to the description of the experimental method set forth in the BE Study, R-B-2-31 at 39-40, markets for the survey were selected based on the use of the Yellow Pages during the initial screening and, subsequently, newspapers were scanned to obtain additional information on the types of advertising permitted on eyeglasses and eye examinations if an SMSA appeared to be a likely candidate for inclusion in the survey. The newspaper searches generally began in May 1977 and continued through December 3, 1977. AOA/RRNA argue that since the study was undertaken prior to the impact of Bates the BE Study is irrelevant and wholly unlinked to the present-day realities of optometric practice. R-H-81 at 24. It is observed that there is indication in the record that prior to the Bates

decision, some chain optometric firms may actually have operated in states with advertising restrictions. It is further argued that because the BE Study fails to report whether some of the 31 states eliminated from consideration in the BE Study methodology contained commercial firms operating in states with advertising restrictions, and failed to survey such markets, the study cannot isolate the effects of advertising restrictions from the effects of commercial restrictions. RRNA, HX-J-66(a), Vol. I., Ex. 1 at 63-64, 66-67. Citing language in the BE Study to the effect that since price advertising of eyeglasses and eye examinations may now be legal in all states, the BE Study's findings concerning price differentials in cities with only nonprice forms of advertising are not relevant to the BE inquiry, AOA argues that the study is nearly a decade stale, and is irrelevant and does not report the realities of the current market place for examinations and eyeglasses. R-H-81 at 23-24.

126. The BE Study is further criticized for use of the Yellow Pages to classify markets. It is argued that because the survey failed to explicitly consider state regulations, heterogeneous populations were grouped into broad categories (e.g., restrictive and nonrestrictive cities). RRNA argues that since the sample cells (markets) are heterogeneous rather than homogeneous, grouping across the cells runs the risk of producing meaningless results by possibly affecting the price and quality variables. The argument is illustrated by the fact that the cities of Washington, D.C., Seattle, Minneapolis, Baltimore, Portland, Columbus and Milwaukee are all considered as "nonre-

strictive" by the BE Study. However, record information of the comparison of state laws indicates that Washington, D.C., Minneapolis and Baltimore permit the corporate employment of optometrists, while Seattle, Portland and Columbus prohibit such employment. HX-J-66(a), Vol. I., Ex. 1 at 67-68.

127. The survey is also criticized as not reflecting the contemporary state of the marketplace citing the fact that only print advertising was scrutinized in the 1977 period, whereas the scanning of television and radio advertising was not done. It is suggested that local optical practices, both corporate and noncorporate, are better able now (1985), as opposed to in 1977, to media advertise in their local markets. Price reductions in eye care due to this increased advertising availability cannot be measured by or accounted for in the context of the BE Study. HX-J-66(a), Vol. I., Ex. 1 at 66.

128. In connection with the BE Study survey of advertising, it is urged that the study is incomplete and outdated for present day purposes for failure to consider markets where advertising is present and chain firms are absent. It is argued that these markets should have been sampled in order to draw conclusions relevant to separating the effects of advertising from commercial restrictions. HX-J-66(a), Vol. I., Ex. 1 at 68.

129. Both the modeling and analytical phases of the BE Study are discussed in extensive detail in the RRNA presentation, listing several perceived failures of consideration in the modeling and posing a series of objections relating to evaluation and analysis of the BE Study data. Noteworthy among the

objections in the modeling area are those relating to the field procedure employed by survey subjects to assist in gathering data concerning price. Citing the Commission's own data that 85.9 percent of consumers are aware of the fact that one does not have to purchase eyeglasses from the examining refractionist and that consumers may ask for copies of prescriptions after an eye examination, as well as data indicating that approximately 30 percent of consumers surveyed actually engaged in comparison shopping for eyewear[26], the FTC Study methodology requiring certain survey subjects who received certain prescriptions to buy the eyeglasses from the examining optometrist is viewed as being invalidating. It is argued that because FTC prescription release requirements allow patrons to purchase eyewear from optometrists, opticians or M.D.s who do not necessarily perform the examinations, then for customers who shop in this manner the actual prices they pay for eye wear may be lower than the BE Study allows. In 1985, consumers can select optometrists for examination on the basis of advertising in both restrictive and nonrestrictive markets. To reflect present market conditions, in RRNA's view, the survey must take into account both the effect of the Bates decision and the Commission's prescription release rule. One cannot be confident that the prices faced by the subjects in the 1977 experiment are similar to those actually faced by consumers in 1985. Data collected from a study that had subjects act in a

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26 Final Report FTC Eyeglasses Study: An Evaluation of the Prescription Release Requirement, Public Sector Research Group, Market Facts, December 17, 1981, R-B-6-1 at 4; Table III.14 at 36.

manner different from the way in which consumers may be expected to act today cannot be used to project the actual prices paid or quality received by real consumers in different market environments in 1985. HX-J-66(a), Vol. I., Ex. 1 at 82-83.

130. The design is also criticized as it relates to the actual purchase of eyeglasses in that the so-called "blurred" vision subjects were directed to purchase a particular unisex metal frame, if possible, in order to assure comparability of the resulting eyeglasses and to minimize cost variation. R-B-2-31 at 4, item (4). It is argued that this procedure is questionable since it seems highly unlikely that all optometrists would have the "particular unisex frame" in stock. When alternatives were proposed to subjects they were required to use their best judgment in picking out a frame. In order for the data collected on eyeglass frames and lenses, whose prices were often quoted as a whole, to be rationally used, the frames must be of homogeneous cost and quality. The BE Study should have, as a reliability test, had the frames examined by a practitioner in order to verify that the frames were, as the BE Study states, comparable. HX-J-66(a), Vol. I., Ex. 1 at 84. It is also argued that inasmuch as the BE Study concluded that over half the frames examined by an optometrist were of high quality, the fact there is a variation in quality violates the requirement that the unisex frames gathered by the subjects be comparable and any prices that incorporate these eyeglass frame prices cannot be used for comparison purposes. HX-J-66(a), Vol. I., Ex. 1 at 93.

131. According to RRNA, given that the long-term goal of large chains is to generate good will and increase their prices (as recent data indicate, in RRNA's view) and assuming that consumers are unable to adequately pre-judge the quality of care received, the data provide evidence to suggest that there is an imbalance in the market. Consumers may be led to believe and are convinced that chain firms charge lower prices and offer higher or equally good care as do nonchain practices. RRNA believes the data and materials gathered by the FTC staff, as analyzed and discussed by RRNA, show that the opposite is actually the case; chain firms charge more, do not pass economies of scale on to consumers in terms of lower eye care costs, and provide a lower quality of eye care. According the BE Study, "other factors, including consumer misinformation play significant roles in this market." HX-J-66(a), Vol. I., Ex. 1 at 165. AOA also argues that the record lacks empirical evidence substantiating broad assertions that consumers do, in fact, ultimately benefit from the lack of state regulatory restrictions, claiming that some of the material presented by RRNA suggests that economies which may be attained by chain firms are not passed on to consumers. R-K-4 at 3-5.

132. The California Optometric Association filed the results of a survey prepared for use by it before the California legis-

lature. COA, HX-J-67(a), unnumbered Appendix.[27] The survey, begun in December, 1982, purports to compare price and quality of eyeglasses dispensed by corporate optometric practices in the Metro-Atlanta, Georgia area. The summary results of the survey indicated that: (1) The mark-up in materials (lenses and frames) is not significantly different between corporate optometric practices and private commercial or professional optometric practices.[28] (2) Analysis of the 30 study examination

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[27] Consumer Study of Optometric Practices in Metro-Atlanta Area. Conducted by: John H. Thomas and Associates, Atlanta, Georgia (undated). The survey, which was not specifically prepared for this rulemaking, was submitted without providing other interested parties to the proceeding the full data underlying its preparation. See Tr. 2571-74,2575-79. The ability of the staff and other interested parties to fully examine witnesses appearing to testify to the results of the survey was thereby restricted. In the evaluation of this survey material, it is my determination that the conclusions reached can be given no greater weight than other opinion testimony because of the lack of a complete data base for use by others in the proceeding.

[28] Unlike the BE and CL studies, it should be noted that the practice of optometry was broken into three groups in the COA survey, rather than two. These are: (1) Corporate Optometric Practice - practice by a licensed optometrist who is affiliated with a corporate chain, national in scope. This affiliation may be in the form of a "side-by-side" office arrangement or in close proximity. The corporate optometric practice provides eye examinations and prescriptions and refers the patient to the corporate affiliate for dispensing eyeglasses. The corporate chain advertises and markets its services and is conducted in a commercial setting. (2) Commercial Optometric Practice - practice by an independent licensed optometrist who chooses to advertise and market his profession similar to the corporate optometric practice; however, the practice is not affiliated with a corporate chain. Commercial optometric practice is generally local in scope, but is conducted in a commercial setting. (3) Private Professional Practice - practice by a licensed optometrist generally in one location and not affiliated with any other entity. The private professional practice provides a total patient service of eye exams, prescription and dispensing ophthalmic lenses and frames. The private professional practice seldom, if ever, advertises and is conducted in a traditional manner. HX-J-67(a), unnumbered Appendix at 33.

prescriptions for variance from the benchmark prescriptions showed no statistically significant differences among the types of practice. (3) The cost of an eye examination alone is less at the corporate optometric practices than at either private commercial or professional practices. (4) The amount of time taken to conduct an examination by the corporate optometric practice on the average was half or less the amount of time taken by commercial or professional practices studied. (5) The cost per examination minute was nearly one-third less in both commercial and professional optometric practices than in the corporate practices studied. (6) A review of all eyeglasses actually dispensed as compared to the written prescriptions, revealed that in terms of deviation from prescription, professional and commercial optometric practices demonstrated better accuracy than did corporate optometric practices. HX-J-67(a) at 34-35.

133. In response to the general assertion that the BE Study is obsolete because it does not take into account the Bates decision and the subsequent effects the decision may have had on markets studied, staff observes that when the data for the BE Study was collected, advertising of ophthalmic goods and services was restricted in some markets. Inasmuch as the BE Study took into account observations both in markets where advertising restrictions were in place and markets where advertising was quite similar to that observed today, i.e., advertising without restriction, the study cannot be deemed obsolete because of the Bates decision. Bond, R-K-18 at 5. According to the staff, the

only type of advertising that was not found during the survey with much frequency in any of the cities considered in the study was advertising of the price of eye examinations. Staff does not believe its estimates of the effects upon price of chain firms are affected by that fact. The statistical technique used to estimate the independent effect of chain firms upon price first calculated the total difference in price between the most and the least restrictive environments. Since almost no price advertising of eye exams was observed, almost none of the difference between the most and least restrictive environments could have been due to such advertising. Therefore, according to the staff, the effects of chain firms could not have been confused with the effects of price advertising of eye examinations. Presumably, the staff concludes, price advertising of eye exams would lower prices in markets both with and without chain firms. Bond, R-K-18 at 5.

134. Staff agrees that the BE Study does not provide information on the effects of specific state laws, pointing out that it was initially intended that specific state restrictions would be considered. However, there was no simple way to classify states because the statutes and rules varied substantially and it was unlikely that the effects of specific laws could be isolated. States were classified on the basis of whether or not eye examinations were available at optical firms inasmuch as the intent of restrictive laws and regulations was to prohibit the availability of eye examinations from optometrists who practiced in a commercial setting, without regard to the

specific language of such laws and regulations. Further, for cities with commercial practice, observations were confined to those where eye examinations were available from large interstate optical firms since such firms offered the best opportunity to observe optometrists operating in a commerical setting. Bond, R-K-18 at 7.

135. Staff challenges the contention that because television advertising was not considered in the BE Study their conclusions may be invalid in contemporary circumstances. Markets with television advertising are likely to have Yellow Page and newspaper advertising as well, according to the staff. Since both Yellow Page and newspaper advertising was surveyed, it is doubted that cities were misclassified even though television advertising was not surveyed. Staff contends it seems doubtful that an optometrist or an optical firm would choose to advertise on television and not to advertise in either the Yellow Pages or the newspaper. Bond, R-K-18 at 7.

136. In response to the criticism that the field sampling procedure that required survey subjects to purchase eyeglasses at the place where they purchased exams may have biased price data upward, staff argues that many people prefer one-stop shopping enabling them to have their eyes examined at the location where they purchase their eyeglasses. Virtually all optometrists sell eyeglasses, suggesting that they expect to sell eyeglasses to many of their patients, according to the staff. Since many people prefer to do one-stop shopping and since most optometrists offer both eye examinations and eyeglasses, it seems reasonable

to focus the study upon the price and quality of both. Bond, R-K-18 at 10. Concerning criticism raised relating to the inability of survey subjects to purchase the designated unisex eyeglasses frame at all of the places they visited, staff contends that the methodology employed in the study minimized variation and avoided bias. It is true that survey subjects were unable to purchase the designated frame at all places they visited, the staff concedes. Nonetheless, the frames and lenses that the subjects did purchase were examined by the staff's consulting optometrists to assess quality. After identifying trademarks had been covered, both consulting schools of optometry were asked to evaluate the quality of the eyeglasses. The analysis of the data revealed that there were no systematic differences in quality of workmanship among eyeglasses purchased at different types of practitioners. Bond, R-K-18 at 12.

137. The staff rebuttal challenges the RRNA reanalysis of the BE Study price data which led to the conclusion that markets with chain firms do not have lower prices. RRNA found that the presence of chain firms did not lower the prices charged by traditional practitioners, reaching this conclusion by analyzing data that included only visits for which separate examination prices were available, while excluding other data and variables used by the staff in its analysis. Staff finds nothing wrong with analyzing the effects of restrictions upon exam prices, but argues that it is wrong to discard the evidence concerning the combined price of eyeglasses and exams. Many, if not most, people would prefer to shop for the two together rather than

separately, according to staff, and the analysis of the combined price is therefore important. Bond, R-K-18 at 13.

138. Responding to the conclusions reached in the survey submitted by COA of prices and quality in the Metro-Atlanta area, NAOO contends every valid survey that has examined the relationship between commercial restraints and vision care prices paid by the consumer demonstrates there is a direct relationship between the degree of restriction and the price of goods and services. The COA/Atlanta survey is not credible, according to NAOO, because it fails to focus on the cost and quality of vision care in a restrictive versus nonrestrictive environment, and focuses only on differences between practitioners in the same market. The study does not focus on the price paid by a consumer for goods and services but an allegedly contrived "cost per minute" for examinations and the "markup" on the ophthalmic products. NAOO also states that at the time the survey was conducted in Atlanta, lay corporate employment of an optometrist was illegal in that area. NAOO, R-K-1 at 5-6, App. C at C-1. According to NAOO, COA would have the Commission believe that consumers who pay more for an eye exam that took twenty minutes longer to conduct are better off than those who paid less and were examined for a shorter period of time, even though the results of the exam were comparable. NAOO argues that the length in minutes of an exam is not necessarily correlated with quality, nor is a longer exam always desired by patients. Finally, NAOO urges that "markup" is a meaningless measurement since there is no standard markup and that cost of materials must be factored together with

payroll, utilities, rent, taxes, advertising, etc. for comparisons to be made. R-K-1, App. C at C-1,C-4-5. Staff argues that there is doubt about the markup comparisons in the survey because, unlike the BE Study, where an effort was made to purchase standard frames so that accurate cost comparisons could be made, no such attempt was made in the Atlanta study. Instead, subjects were allowed to select whatever frames they wanted, with the apparent result that the sample frames varied widely in cost. Staff also points out that markup in the survey was defined as the difference between the retail price and the single-item wholesale price and excluded volume discounts. The survey indicated a wide spread in markups within each provider group and therefore, in staff's view, provides little useful insight into the prices charged by different provider groups. Because of the variation in wholesale cost and spread in markups of the frames/lenses purchased, a different set of purchasers may well have provided an appreciably different set of results. Rebuttal Statement of Joseph Mulholland and Renee Kinscheck, R-K-21 at 608.

(ii) The Contact Lens Study.

139. The CLS, which was completed following the publication of the BE Study, states that whereas the BE Study compared the price and quality of eye examinations and eyeglasses provided by commercial and noncommercial optometrists, the CLS carried that analysis one step further by comparing the price and quality of contact lens fitting by these two kinds of practitioners. CLS Report, R-B-5-1 at 39. The CLS concludes that restrictions on

opticians and commercial optometrists may increase costs to consumers by limiting the choices available to them. Members of those groups often practice in convenient locations, such as shopping centers, and many are open nights or weekends. Restrictions may also result in higher prices for contact lens fitting by limiting consumers' access to relatively low-cost providers or by reducing competition in the marketplace. R-B-5-1 at 47-48. The pricing data which is used for the comparisons and conclusions reached in CLS was developed based on information which the staff obtained from the oral interview with patients (survey subjects) when they came to the field examination locations to have their eyes examined. Hailey, Tr. 244-45. A series of questions was asked of survey subjects concerning the price of their contact lenses and what that price included, such as follow-up care, an initial care kit, insurance. However, some of the wearers interviewed were unable to answer all of the questions. The CLS price analysis is therefore based upon the responses of only those wearers who were able to answer all the questions concerning cost. R-B-5-1, App. C at 1. Inasmuch as various items were included in the prices given by different survey subjects, a uniform package price including the cost of the lenses, the eye exam, follow-up care and initial lens care kit was established. The package price formulated for CLS did not include the price of insurance. R-B-5-1, App. C at 2-3. Of the 435 wearers utilized in the quality-of-fit analysis, 388 were able to answer all the questions concerning cost. The CLS price analysis is based on the information obtained from those

388 wearers. Tests for differences in price among the provider groups were based on a regression analysis of the data the results of which implies, according to CLS, that the average price charged by commercial optometrists for both hard and soft lenses was significantly lower than that charged by any other fitter group. In relative terms, commercial optometrists charged from 15 to 55 percent less than other fitter groups for hard lenses. The corresponding range of percent differences for soft lenses was 30 to 56 percent. R-B-5-1 at 3-5.

140. The CLS advises that the meaning of the regression results is somewhat ambiguous due to the possible existence of nonfitter influences on price that are not taken into account in the regression equation. The most relevant potential influences are specific market elements operating in each city that influence the prices that fitters charge. The wide variance in the distribution of wearers fitted by the optometrist groups indicates that the omission of city-class-specific influences may be important. (Differences in the costs of operation were accounted for by adjusting the price variables by a cost-of-living index specific to each city in the sample.) Of most importance, according to the report, is the competitive environment in which contact lens fitters practice. One key aspect of competition is the degree of advertising allowed in the market. The CLS, citing the BE conclusion that the existence of advertising in a city tended to lower prices charged by all eyeglass providers, states that if, as appears probable, the existence of advertising also lowers contact lens prices, it is

necessary to hold constant the effect of advertising when making price comparisons across cities. The CLS states it is particularly important to control for advertising when making comparisons involving commercial optometrist groups since members of that group advertise heavily and are almost certain to be found only in cities where advertising restrictions are minimal.

141. Using a 4-city subset of data and estimating the price regression equation for the subset, the CLS tests for the existence of price differences among fitter groups in a set of cities in which, by assumption, all fitters operate in a similar competitive environment (at least to the extent that it is affected by advertising). The findings suggest, as stated by CLS, that commercial optometrists on the average appear to charge significantly less than other contact lens fitters. That finding must be qualified, the report states, due to the inability to control fully for certain factors other than type of fitter that may have influenced prices. R-B-5-1, App. C at 9-13.

142. Staff testimony relating to the CLS advised that the estimation of the types of costs which result with the limitation of choice imposed on consumers by state restrictions is a difficult matter and was beyond the scope of the CLS. Mulholland, HX-J-19(a) at 6. Instead, the analysis focused on the most easily identified cost component - the actual amount of money paid for the contact lens fitting by subjects in the sample. The staff advised that while this approach is more straightforward, it does tend to underestimate the total costs that can be attributed to commercial practice restrictions. HX-

J-19(a) at 6. According to the staff, the alternative tests imposed on the CLS data, HX-J-19(a), Tables A-2 to A-4, further establishes the CLS finding that commercial optometrists do indeed charge less than other provider groups for contact lenses. Staff states this result is really not surprising and supports the conventional view of commercial optometrists as relatively low cost providers in the vision care market. It is consistent with results of the BE Study. The pricing pattern is also consistent with the position of those vision care provider organizations that support commercial practice restrictions; these groups maintain that the alleged lower quality offered by commercial optometrists is due to the lower prices they charge. Mulholland, HX-J-19(a) at 9.

143. The CLS analysis of contact lens fittings supports the view that commercial practice restrictions are unnecessary and costly, staff reasons, because optometrists operating in commercial settings were found to provide a quality of fit equal to that of other vision care provider groups. Such laws can impose considerable costs on consumers by denying to consumers the greater convenience and lower prices offered by commercial optometric providers. HX-J-19(a) at 9. Based upon the tests on the CLS data done subsequent to the CLS report, a staff witness stated that, at the time of the public hearings, contrary to the language of the CLS report, he was confident that commercial firms do charge less than noncommercial optometrists. According to the witness, he found the statistical terminology quite robust. "We were finding the same results, the same pattern in

all of those different equations. So based on that and based upon that sort of history of how we did it, I am now confident that for the sample that there was an indication that commercial practice providers did charge less." Mulholland, Tr. 794-95. In this regard, the witness acknowledged that he now disagrees with the qualified conclusion of the CLS, because the additional tests he performed indicate it is clearer now that advertising is not a factor that was creating bias in the results. Tr. 814-15. The witness testified further, in this regard, concerning the subject of sample size used in the alternative tests, stating that sample size are most to the point in price analysis, because when he was doing the alternative tests he was getting down admittedly to a small sample size. The witness advised that the alternative testing was mostly in the nature of a sensitivity analysis and that such analysis verified his conclusion that commercial optometrists were still seen charging significantly less than the other groups, and particularly the ophthalmologists and the non-commercial optometrists. Tr. 805-06.

144. On the overall question of costs, the staff witness testified that search costs play a major role in affecting the real costs of ophthalmic goods and services. Advertising, such as that done by large commercial chains, location in a mercantile area, extended shopping hours all contribute to the lowering of search costs to consumers. Tr. 813. Another staff witness defined search costs as covering both the gathering of information and of moving to the site where the service or good can be obtained. Kwoka, Tr. 516. To illustrate the fact of

lowered search costs the witness Kwoka stated that optical goods sellers with optometrists in their employ offer convenient "one-stop shopping", which lowers search costs for those individuals seeking both an optometric exam and eyeglasses. HX-J-12(a) at 3. While the consumer is free to move elsewhere, there is an opportunity to conserve on that particular time and expense. The views would have application to a dispensing optometrist, however, and these observations are not unique only to corporate practice. Tr. 516.

145. In connection with the witness Mulholland's testimony relating to the alternative tests he conducted after completion of the CLS report, these continued to demonstrate that commercial optometrists exhibit lower prices than other fitter groups and that the 1979 sample shows an increase in price advantage. Indicating the two year interval between the Bates decision and the 1979 sample, Mr. Mulholland concluded the increase in price advantage may be due to the fact that commercial optometrists are in a better position to exploit economies of scale associated with advertising than are less commercially oriented competition. The import of this view is that commercial optometry, no longer faced with pre-Bates restrictions, used advertising to increase price advantage. Mulholland, HX-J-19(a) at 9.

146. In meeting the issues relating to price presented in the CLS, AOA argues that the survey fails to support the proposed rule with meaningful or reliable data with respect to the price issues. The adjusted price data produced by CLS, which the staff

itself felt compelled to qualify, is stale and fundamentally unreliable. The patients had purchased their contact lenses (and related services and products) at various times in 18 different urban areas generally over the half-decade period from 1975 through 1979. Unsupportable and inappropriate adjustments to the price data were made by the staff in an effort to try to make the data comparable. According to AOA, not only is the adjusted price data outdated, but the helter-skelter dispersion of the small number of price observations over so many different years and cities, necessitating debatable statistical adjustments and estimates, reflects the highly deficient design and implementation of the survey. AOA, R-H-81 at 46. In AOA's view, the adjusted price data is also unreliable for other reasons. The data set is based on patient recall during the oral interviews and some survey subjects may have purchsed their lenses as many as 4 or 5 years before they were interviewed. AOA observes it appears that no attempt was made to collect actual price data from the original fitters. The survey also did not fully take into account whether the costs that were being compared were comparable services. Thus, according to AOA, the survey fails to validly relate the relative thoroughness of the doctors' eye examinations, or the number of the follow-up visits included by the fitters in the package price, to the prices charged. The different prices may reflect the different nature and amount of services provided to the different subjects. Further, the adjusted price data is unreliable in AOA's view because it is being used in a field where there have been major

developments affecting prices in the intervening years. These developments include a very significant increase in the number of competing companies manufacturing soft contact lenses from 1976-1978, the development of less expensive sterilization systems needed for soft contact lenses, and the development of new types of contact lenses, such as the extended wear lenses. R-H-81 at 47. AOA also again raises the spectre of Bates in connection with the data on price collected after that decision, arguing that when the data was collected the effect of Bates had not been felt fully and that the data is clearly of little relevance to today's substantially changed circumstances. R-H-81 at 48.[29]

147. Opponents of the rulemaking submitted substantial criticism of the CLS price analysis, arguing first that the uniform package price arrived at for the purpose of analysis was flawed in several respects. For instance, it is asserted that when survey subjects did not know whether a particular item had been included in the price they paid and did not provide a separate charge for the item in question, the staff assumed the item was included in order to complete the data package for the uniform package price. Survey subjects sometimes responded that insurance had been included in their lens prices, but were unable to differentiate its cost from the total. In these cases, it is alleged the CLS data shows that the staff estimated the cost of insurance and subtracted the estimated amount from the subject's price response. Instead of employing this methodology to arrive

[29] The CLS data base includes observations on prices paid by survey subjects both before and after publication of the Bates decision.

at price, the contention is that the actual prices paid by the survey subjects could have and should have been obtained from the fitters to ensure accurate, reliable results. RRNA, HX-J-66(a), Vol. I., Ex. 2 at 27-28. The cost of living adjustment intended to reflect variations in the year of purchase and city of purchase among subjects is challenged as having been based upon an index which the Commission's Bureau of Economics found to be inadequate in a Report on another matter prepared after the filing of the CLS report. HX-J-66(a), Vol. I., Ex. 2 at 28. RRNA contends that the report gives no indication that the staff investigated whether prices charged by different practitioners measured different levels of eye care service, including, for instance, the amount of patient follow-up care. RRNA points to Question 14 on the CLS Patient Interview Form which asked about follow-up care they had received, and observes that no discussion of the analysis of the responses is found in CLS. Further, RRNA argues, although the uniform package price includes follow-up care, the derivation of the package price did not control for differences in the average number of follow-up exams provided by each practitioner group. RRNA included within its presentation its own analysis of the responses to Question 14 of the Patient Interview Form which it believes demonstrates that patients fitted by noncommercial optometrists returned for more follow-up visits on average than patients fitted by commercial optometrists on average. RRNA concludes that the difference between follow-up visits between patients of the two groups of providers is significant and provides a basis for the conclusion that

noncommercial optometrists provide more follow-up care than do commercial optometrists. HX-J-66(a), Vol. I., Ex. 2 at 29-30.

148. On the question of data analysis, RRNA contends that the effect of the Bates decision and other structural changes in the contact lens field (presumably increased use of contact lenses), cannot be assumed to be uniform across all observations. The role these effects played in generating the observed associative variation between the CLS survey and provider group data should have been investigated by the staff. HX-J-66(a), Vol. I., Ex. 2 at 32-33.

149. RRNA considers the regression analysis in which the CLS attempts to take into account the presence of advertising in a market to assess competition to be questionable, arguing that although it is agreed that the presence of advertising in a market is one indicator of competition, there is far less certainty that commercial optometry and advertising are strongly correlated. The alternative tests conducted by Mr. Mulholland of the Commission staff are also characterized as being of questionable validity as being both statistically in error and for failing to ensure that the price responses used in his analysis were accurate. Based upon its argument that the price measurements in CLS between commercial and noncommercial practitioners are nonhomogeneous due to differences, for instance, in follow-up visits, RRNA concludes that Mr. Mulholland's alternative tests and analysis introduced no additional controls or adjustments to account for the nonhomo-

geneous nature of eye care provided by the commercial and non-commercial optometrists. HX-J-66(a), Vol. I., Ex. 2 at 33-36.

150. Responding to the contention that CLS measures a non-homogeneous package of goods and services in the uniform package price, since no comparison of follow-up care was made, staff observes that the RRNA reliance on services (follow-up visits) is irrelevant. In the final analysis, the staff argues, customers are concerned about how well their lenses fit - not the amount of effort expended by an optometrist at supplying that fit. This being so, the CLS focused on analyzing the most important aspect of fit quality: The absence of pathologic eye conditions that are caused by poor fits. Using this criterion, commercial optometrists were found to provide fits of at least equal quality to noncommercial optometrists. As a consequence, according to the staff, there is no basis for inferring that noncommercial optometrists provide "more" quality to consumers simply because they offered a large number of visits. Mulholland, R-K-23 at 1. The statistical arguments of RRNA upon which it bases the conclusions that the alternative tests conducted by Mr. Mulholland are of questionable validity are themselves challenged. Staff observes that RRNA does not deny the accuracy of the estimated prices, nor the test statistics that are derived from them. Rather, RRNA implicitly contests the significance levels that can be attributed to each. Staff contends that reevaluation of the alternative tests indicate that all comparisons show a significance level of five percent or lower, meaning that in no case is there a greater than five percent

chance that it is incorrect to infer that commercials charge less than noncommercials. Mulholland, R-K-23 at 2.[30]

(c). Availability of Vision Care.

151. It is urged that one measure of the availability of vision care is the frequency with which eyeglasses are purchased in a given period of time. Staff Report, R-B-2-1 at 84.[31] The 1980 Staff Report suggests that the likelihood of obtaining eyeglasses in a given year is greater in states with lower prices and that consumers purchase eyeglasses with greater frequency in the states termed less restrictive or having less professional control. Another factor, according to the staff, which could affect the accessibility or availability of vision care is the location or convenience of obtaining ophthalmic goods and services. If location restrictions decrease the accessibility of vision care, these restrictions may decrease the frequency with which vision care is obtained. Some consumers may receive no care at all, it is argued, or may receive care less frequently than they otherwise might. This is particularly true with respect to the elderly, whose mobility problems are greater than those of the population as a whole. R-B-2-1 at 85-86. Referring to the results of the BE Study, staff believes these suggest that commercial practice restraints do not, for the most part, protect

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[30] See Finding 86, supra, at (d) Follow-up visits, for discussion of whether follow-up visits are a positive quality measure. Cheh, R-K-16 at 1.

[31] The NPR, Section A, refers to the "availability" of vision care. The staff report, however, discusses the "accessibility" of vision care. For the purposes of these findings, these two terms are treated as being synonymous.

consumers from lower quality care. Furthermore, BE found that prices were significantly higher in cities where commercial practice was restricted and that for the same price, consumers receive a higher quality eye examination, as measured by the study, in nonrestrictive cities than in restrictive markets. While it is true, the staff advises, that for higher prices consumers received a longer, more thorough eye examination from higher-priced optometrists, it is believed far from clear that the overall costs of commercial practice restrictions are offset by increases in quality. For some individuals the choice may be between a less-thorough eye examination at a lower price or no examination at all. R-B-2-1 at 88. John E. Kwoka, Jr., one of the co-authors of the BE Study, testified that where no restriction on the employment of an optometrist exists, consumers benefit by the ability of optical goods sellers with optometrists in their employ offering convenient "one-stop shopping." This arrangement lowers search costs for those individuals seeking both an optometric exam and eyeglasses, but does not require them to purchase both at the same location if they do not wish to do so. HX-J-12(a) at 3. The ban on restricting practice in a mercantile location prevents an optometrist from leasing space in an optical goods dispensary and from setting up his practice side-by-side with a retail optician, or in a high-traffic area like a shopping center, department store or drug store. The witness observed, however, that mercantile locations can significantly improve market efficiency. Convenient locations conserve on customers' time for search and purchase of optometric

services, as with any good or service. This is one reason why shopping malls and department stores exist in the first place, and the premiums their floorspace commands are measures of the value of customer convenience and time savings. Side-by-side or, even better, according to the witness, same-premises provision of optical goods and examinations are similarly advantageous to consumers. And to the extent mercantile location increases seller volume, cost savings may be better achieved. HX-J-12(a) at 3-4. Trade names, the witness states, can convey information to consumers about the price and quality of goods and services. This is especially important when consumers cannot fully evaluate a product or service before purchase. It is in the seller's own interests to provide and maintain higher or less variable quality to the degree that they have investments in brand names, long-term advertising, and reputation. The witness believes it apparent that consumers understand the market value of a firm's established reputation and respond to it. It is pointed out, however, that brand names do not necessarily connote higher quality, but in many cases it is lower variability to quality, or even price itself that is implied. HX-J-12(a) at 5-6. Finally, restrictions on the number of branch offices an optometrist may operate directly control the production and delivery of services, according to Mr. Kwoka. Such restraints may prevent the practitioner from using his own time most efficiently, and reduce the cost savings from time-saving optometric or management techniques. In fact, the witness advised, to the extent that branching restrictions reduce total volume, almost all the

volume-related efficiencies are jeopardized. Further, branching restrictions can hinder entry and expansion into geographical areas needing additional optometric services. They limit the economic return to trade names, and may thereby diminish their value in terms of quality and predictability of quality. And they may retard the development of sophisticated quality control techniques. Techniques applicable to a single outlet may be extended to other outlets at little additional cost, but if branching is prohibited, these economies may not be fully realized. HX-J-12(a) at 6-7. In summary, employment bans and branch office restrictions restrain the production and delivery of services and would show up in the price of services that consumers finally pay. Trade name bans and mercantile location restrictions, in the staff's view, have the effect of inconveniencing consumers and providing less information than otherwise would be the case. Those bans have the effect of reducing the level of competition in markets, with the effect of maintaining or elevating the price above the level that is the minimum necessary for an efficient and competitive environment. Kwoka, Tr. 512.

152. The American Association of Retired Persons testified in support of the removal of restraints on optometric practice. The President-elect of the association stated the belief that commercial practice restraints do not have any significant positive impact on the quality of vision care, but increase price and reduce accessibility of quality vision care. John Denning, Tr. 51. According to the witness, AARP believes that the more

accessible eye wear outlets are, the better off older consumers will be. Removing restrictions in various states would result in the expansion and proliferation of eye wear outlets and would increase the options available to consumers and lower prices through increased competition. Tr. 53. A member of the AARP Board of Directors testified that the association's interest in these rulemaking proceedings relates to older Americans who are the largest single age group of eye care purchasers. Edmond Eggen, Tr. 1453-54. In 1977, older Americans were spending $698 a year out-of-pocket on health care as an average. By 1985, the amount had risen to $1,660 a year, a 138 percent increase. Currently, older Americans are spending approximately 15 percent of their total incomes out-of-pocket on health care. The witness pointed out that older Americans are very interested in obtaining quality eye care at reasonable, affordable prices. This is particularly true for the older persons on a fixed or limited income. For them, expenditures for eye care can represent a serious financial drain on resources that are required for basic support and maintenance. Tr. 1454.

153. Consumers Union (CU) furnished a report of a study prepared by the California Consumer Affairs Department which, among other things, estimated that the restrictions on commercial practices in California impose substantially higher costs on California consumers without providing better quality health care. The witness for CU advised that restrictions on practice are not the way to control quality of care, describing such restrictions as being solely price enhancement devices. Harry

Snyder, Tr. 1053-54. Contending that removal of restrictions in California would result in the lowering of prices for optometric services in California, the witness pointed out that recent changes in many public assistance programs and in private insurance plans have shifted costs of vision care directly onto the consumer. Decrease in cost will mean a greater number of consumers will be able to afford vision care and the eyeglasses they need. Tr. 1055.[32]

154. NAOO contends that the data presented with its comments on the rulemaking proposal demonstrate that economies of scale are attainable with respect to virtually every expense in a vision care practice. Certain variable costs (such as payroll) do not increase at the same rate as revenue when sales expand. Other variable costs decrease in per unit cost as quantities purchased are increased. Fixed costs such as initial capitalization decline per office as the number of offices increases. Occupancy cost as a percentage of revenue declines as the volume of a practice grows. Clearly, the inefficiency of low-volume practice cannot be contested, according to NAOO. The association also argues that the business practice restrictions that this proceeding proposes to preempt clearly promote inefficiency and high prices. When those restrictions do not exist, NAOO member firms can and do provide quality vision care at prices lower that when those restrictions do exist. Moreover, to

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[32] See Rebuttal Statement of California Optometric Association for discussion of perceived shortcomings in the California Department of Consumer Affairs Study on commercial practice restrictions. R-K-12 at 1-2 and attachment.

the extent that higher prices cause consumers to forego or defer obtaining vision care, those consumers have been harmed. NAOO argues that the evidence is unequivocal that as price increases, consumption of vision care services decreases, citing to data ascribed to the Office of Technology Assessment estimating the frequency with which contact lenses are obtained or replaced as a function of household income. This data appears to demonstrate that as income rises the frequency with which contact lenses are initially purchased or replaced also rises. NAOO states the survey notes that if the demand for a product is sensitive to changes in income levels, it generally is sensitive to price changes of that product. R-H-78(a) at 30-31.

155. The president of a regional optical company operating retail locations in six western states observed that it was difficult for his company to expand its optical service into small towns in states in which employment of optometrists by a corporation was prohibited. The witness stated that as a new optical business is building in smaller towns it is sometimes difficult to persuade an optometrist to live in the smaller towns and become part of the community. The witness advised, however, that if his company were able to employ an optometrist, guarantee the doctor a minimum salary, then optometrists could be enticed to small towns and there would be sufficient business to support the optical and optometric practices. Ingalls, Tr. 2184-85. (Apparently in smaller communities where the employment option is not available to the optical company, it is not profitable to offer only optical services without an optometrist present in the

community or where an optometrist may have an office in the community but is not there on a full time basis each week.)

156. Opponents of the rulemaking proposal made no organized presentation on the question of availability of vision care services. While there were repetitions of opinions to the effect that in various environments in which forms of bans on commercial practice exist, competition is healthy and vigorous, Michael J. Tiernan, California Association of Dispensing Opticians, Tr. 1263-64, or that competition is "sufficient" in a particular region, James Fallis, California Society of Ophthamic Dispensers, Tr. 1486, with few exceptions, however, presentations by those opposing the rule and relating to the availability issue were made in the form of rebuttal. Some witness presentations point out that availability is regarded differently in various areas of the country. In Wyoming, a state which generally precludes commercial optometry, the Assistant Attorney General testified when asked whether circumstances are satisfactory in terms of the population being completely served by the practice of optometry that most major communities in Wyoming sit near population centers in adjoining states. Those living in southern Wyoming can drive to Denver, Colorado. For the eastern part of the state, it's Rapid City, South Dakota. For western Wyoming, Salt Lake City is nearby. And on the northern border, it's Billings, Montana. Allen C. Johnson, Tr. 2001. The witness for the North Dakota State Board of Optometry, a state in which some commercial restrictions are imposed, agreed that the popu-lation of this large state was not evenly distributed. Optometric services

tended to be available in the population centers, particularly Fargo, Grand Forks and Bismarck. Commercial optical companies do business in the population centers in the state, and consumers from outlying rural areas and smaller towns must travel to the larger cities for service. Louise Zuern, Tr. 1574-77. In commenting on the testimony of John E. Kwoka, Jr., and comments of NAOO concerning availability, the rebuttal statement filed by RRNA asserts overall that one important criticism applicable to both Kwoka's and NAOO's contentions is the lack of empirical evidence substantiating broad assertions that consumers do, in fact, ultimately benefit from the lack of state regulatory restrictions. While singling out various assertions set forth in the NAOO written presentation, R-H-78, relating to the attainment of economies of scale by chain dispensing firms, RRNA questions whether such economies are actually attained by chain firms to a greater extent than nonchain private practitioners. A further question is posed as to whether economies of scale, if obtained to a greater extent by vision care firms, are actually passed on to consumers in the form of lower than average prices. RRNA argues that both the Kwoka and NAOO statements avoid claiming that such economies are actually incurred and passed on to the consumer. RRNA also argues that evidence presented by it during the proceeding suggests to the contrary. RRNA, R-K-4 at 3-5. Mr. Kwoka's testimony relating to the effects of employment restrictions is challenged on several grounds, including assertions that his conclusions are hypothetical, unbuttressed by supporting data and by reference to testimony of other witnesses

which may be regarded as indicating that at least some chain-affiliated commercial opticians may occasionally find it more economical to purchase from independent suppliers rather than through a chain buying arrangement. R-K-4 at 5-10. As to the convenience for consumers of so-called "one-stop shopping" testified to by Mr. Kwoka, RRNA points to his testimony indicating that reduction in search costs which may be achieved by consumers in "one-stop shopping" arrangements may not be confined to commercial optometrists but may also be achieved by consumers patronizing professional (noncommercial) optometrists. Further, RRNA argues that Kwoka does not estimate the reduction of search costs due to the post-Bates use of advertising by both commercial and noncommercial optometrists. R-K-4 at 10. Kwoka's testimony on the contention that the ability of an optometrist to locate in a mercantile setting conserves on a customer's time for search and purchase of optometric service is also disputed. It is argued that commercial optometrists located in mercantile establishments offer inferior care and that the record does not establish that consumers are willing to accept this allegedly inferior care as a trade-off for the convenience of shopping in a mercantile location. R-K-4 at 13-15. On the issue of trade name restrictions, RRNA again asserts that Kwoka's views are not substantiated with empirical evidence. RRNA argues specifically that Kwoka assumes customers can equate a trade name to actual quality and that this assumption is inaccurate in the optometric market. RRNA contends that consumers lack comprehension of the difference between a complete and incomplete examination, and

states that two optometric trade names can be of equal value across two different firms while the quality of care delivered by them is divergent. RRNA concludes that trade names cannot, therefore, signal a standard level of quality to consumers. RRNA believes there is no evidence that chain firms can reasonably guarantee that an eye examination in California will be identical to one performed in North Carolina and that Kwoka's theory that trade names reflect a standard level of care would suggest that the examination given at one branch would be roughly equivalent to an examination given at another. It is suggested that evidence in the record demonstrates that what is alleged to be Kwoka's theory may have no basis. R-K-4 at 15-20. RRNA also points to testimony on the record indicating that large regional chain firms engage in infrequent price advertising, arguing that one might expect large chain firms to generally advertise lower prices if economies of scale due to trade names are passed on to consumers. R-K-4 at 20-21. Mr. Kwoka's views on branch office restrictions are challenged as having no studies underpinning them and that no study demonstrates that in states where branch office restrictions exist, consumers are underserved. Further, no evidence is presented, according to RRNA, which demonstrates that in states where restrictions are absent, consumers are better served than are consumers who reside in states where branch office restrictions are enforced. R-K-4 at 22. Other nonregulatory factors including the population density or average income of a community, local crime rates, the number of optometrists per capita in a geographic area, and other

optometrists per capita in a geographic area, and other environmental factors must be considered in order to begin to understand the reasons underlying a group of consumers being underserved, according to RRNA. R-K-4 at 22-23.

CONCLUSIONS, EFFECTS OF COMMERCIAL PRACTICE RESTRAINTS, §456.4.

A. Disposition of this rulemaking rests on the conclusions which can be drawn from two principle bodies of evidentiary material placed into the rulemaking record, namely the Commission's surveys reported on by the Bureau of Economics (BE Study) in 1980, and the Contact Lens Study (CLS) reported on by the Bureaus of Economics and Consumer Protection in 1983. Witnesses appearing to testify on behalf of each of these surveys were examined at length during the course of public hearings. The surveys were the subject of extensive written and oral comment before and during the public hearings as well as rebuttal filed following the public hearings. Based upon this record, it may be concluded that both of these evidentiary submissions are deficient in some material respects. Neither completely survived the challenges directed at them. Of crucial importance to the viability of this rulemaking, however, is the accuracy, reliability, and comprehensiveness of these two submissions. As noted in the NPR, and affirmed during the course of this proceeding, the undertaking to preempt state bans on commercial practice is based primarily on the results and conclusions of these studies.

B. The BE Study undertakes to compare relative price and quality of optometric services available across regulatory environments and kinds of practice, using the premise that for

services as potentially complex as those offered by professionals, the assumption of equal quality may not be warranted. No attempt was made, therefore, to measure that absolute level of quality of optometric services available. Inasmuch as the issue framed by the NPR is whether higher prices and diminished access to vision care result from restrictions imposed by the states and are counterbalanced by positive effects on quality of care, the entire question of quality, whether quality is affected by state regulation, whether there is a disparity of quality between commercial and noncommercial providers, is the core issue of this proceeding. The Contact Lens Study is offered, among other reasons, as support for the conclusions of the BE Study on both quality and price issues. As to the quality of care issue, based upon full consideration of this entire record, I must conclude that neither of the studies individually or as a body of collective evidence provides the Commission substantial evidence upon which an overall determination can be made as to whether state restrictions have positive effects on quality of care. The highly theoretical nature of the BE Study and the methodology of both studies are not, in my view, sufficiently elastic to afford the basis for reaching conclusions on this quality question. That can be applied with any degree of confidence to the universe of visual problems and pathologies occurring in the population as a whole, or as encountered by commercial and noncommercial optometric practitioners throughout the country.

C. The thoroughness measures of the BE Study are reported and compared as between restrictive and nonrestrictive cities to

reach specific conclusions as to the comparative levels of thoroughness in these environments and as between commercial and noncommercial practitioners. Much of the testimony and criticism on this record is directed at the methodology which led to the compilation of the thoroughness estimates, particularly that portion of the methodology involving eye examination itself. As stated in the findings, survey subjects were myopic, required to observe major components of an eye examination performed on them and report back their observations. The thoroughness scores were developed from these reports. As the BE Study report advises, the measurements here are inputs, not outputs, and only indirect inferences can be drawn as to whether an examiner would have found pathology, had it been present. See Finding 85. Thoroughness is evaluated on the basis of the extent to which all components of an eye examination were administered by individual examining optometrists. See Finding 75. While this methodology may permit the development of relevant thoroughness estimates for comparative purposes, I am unable to accept it as providing a definitive measure of quality of care that is useful to this proceeding, for a number of reasons. First, while survey subjects were able to report on whether components of the eye examination were apparently performed, nothing on this record permits the conclusion that these subjects were in position to evaluate whether all of the components were performed either completely or accurately. In this regard, the BE report advises as to the observations by survey subjects that "...this measure of the thoroughness of the optometric examination does not

preclude the possibility that some procedures, while apparently performed, were in fact not correctly performed." See Findings 83,85. Second, prescriptions received by the survey subjects were subsequently evaluated against the clinical records of the individual subjects to assess the accuracy of the prescription. Eyeglasses were purchased from optometrists by some subjects and evaluated against the prescriptions issed them. However, all of the survey subjects were described as visually healthy, but myopic, with relatively routine optometric needs. Based upon the evidence offered by AOA/RRNA on the outcome of examinations for a number of visual conditions and pathologies other than myopia, I do not believe this record will support the conclusion that the results of the BE Study can be projected with certainty to all visual conditions and pathologies which may be encountered by examining optometrists. See Findings 72,74,84,86,88. Third, the Commission itself was apparently sufficiently concerned about the process tests employed in the BE Study to solicit comments concerning process and outcome tests. Based upon this record, however, it does not appear that the most direct and appropriate question concerning these tests was posed by the Commission in the NPR. The question should not be whether there is reason to believe that the tests performed to detect eye disease were performed correctly or not, but rather whether survey subjects were qualified to report on the tests which were performed. If, in fact, survey subjects were unable to report whether tests were either complete or accurate, then no determination of any kind regarding quality, of even "thoroughness" in its most objective

sense, can be adduced from this record. As demonstrated during the examination and evaluation of the AOA/RRNA report relating to outcome results, difficulty is also encountered in attempting to assess quality and thoroughness questions by this methodology, as well. While the BE report clearly spells out the limitations under which the staff was operating which, apparently, precluded it from engaging in broadscale outcome tests, the outcome methodology, in my view, is superior to that employed by the staff, i.e., process tests, for the purpose of evaluating the issues in this proceeding. See Finding 74. In all likelihood, the persuasive argument of the California Optometric Association that evidence of quality of care can be adduced only by consideration of both the examination processes employed by an optometrist and evaluation of the outcome of the processes, is most accurate on this point. See Finding 83. The BE survey permits the evaluation of outcome, by prescriptions rendered, optical products purchased, only insofar as they pertain to the myopia of the survey subjects. In my view, any attempt to extend this methodology to other visual conditions can only be done on the basis of speculation.

D. The Contact Lens Study, standing alone or in tandem with the BE Study, affords no basis for general conclusions on the quality issue. This survey undertakes to examine successful but not unsuccessful wearers of cosmetic contact lenses. See Finding 89. Without reference to the statistical and analytical comments directed to this body of work, several important parts of the methodology bear on the ability to use the findings of this

survey to reach broad conclusions on the quality of care issue. First, the survey is restricted only to successful wearers and does not take into consideration unsuccessful wearers in reaching its conclusions. While the staff has explained the difficulty encountered in obtaining usuable former wearer data in CLS, and advised that among the successful wearers group were those who experienced poor vision, discomfort and other problems, which satisfied the staff in reaching quality conclusions, I do not believe these conclusions sufficient to support the undertaking in this rulemaking. See Findings 96,113. The question of whether there may be a disparity in the quality of contact lens fitting between different fitter groups cannot be directly addressed, in my view, without some usable data on former wearers. In this regard, CLS provides hypotheses, not substantive data analysis. To reach broad quality conclusions based on the CLS data, absent information about unsuccessful wearers, one must accept the staff's hypotheses and reject those offered by opponents of the survey. See Finding 96. This record provides no basis for making such an election, particularly on the important quality issue. Second, while the survey undertook keratometric examination of survey subjects by each of the three examiners, the keratometry or K-readings were not utilized in the survey report as imput for the conclusions reached. The CLS report advises that earlier K-readings were unavailable from a large number of initial fitters and were omitted from the study. Unrebutted testimony by Dr. John Kennedy, who acted as one of the survey examiners, corroborates the CLS observation that any

significant change which may occur between recent K-readings and the original readings is a strong indication the lenses did not fit properly and should be replaced or modified. However, when this information proved to be unavailable, CLS took the position that "...the absence of those results is not of great importance. The relative presence (or absence) of seven potentially pathological conditions provides a comprehensive measure of the relative health of a contact lens wearer's eye." Dr. Kennedy's testimony, that the inability to compare original K-readings with the current readings severely limits the value of this procedure in determining problems related to contact lens wear must be regarded as authoritative. His testimony that the FDA protocols for investigative contact lens clinical studies require that the K-reading comparison be done merely adds emphasis to the importance of this information for purposes of quality evaluation. See Finding 107. Further, without regard to the possible biasing effect on data questions concerning case histories of survey subjects may have had, the inability of the optometric examiners to determine whether lenses were causing discomfort and how such discomfort may have been related to the initial fitting, methods of lens care, etc. must be regarded as circumscribing the quality findings. See Finding 109. The unavailability of the K-readings to the examiner or to the CLS surveyors and the inability of the optometric examiners to directly attempt to assess possible causes for discomfort or other problems, substantially diminishes the quality assessments. Third, the importance of weartime prior to the CLS

examination has been contested throughout the proceeding. Opponents of this proceeding have vigorously argued that pre-examination weartime can be a critical factor in determining the existence of a number of eye health problems resulting from improper contact lens care. See Finding 105. CLS survey subjects were not advised to wear their lenses for a suggested 4-5 hours prior to their examination, however, and according to one member of the CLS staff, some survey subjects who may suffer from troublesome conditions associated with improper fitting may not have exhibited symptoms of these conditions if they brought their lenses and inserted them shortly before the examination. See Finding 106. The staff does not agree that this fact invalidates the quality results, however, pointing to the fact that the eye conditions affected by weartime make up only a part of the full list of eye conditions contained in the summary quality score, and that these lists were given relatively low weights by the CLS optometric consultants. See Finding 113. The content of this record does not afford the basis, in my view, for arriving at a conclusion as to where the balance should be struck as between the effect of these two viewpoints on the value of the summary quality scores. Nevertheless, the record clearly indicates the effort of part of the optometric community to persuade the staff to include weartime as a factor in assessing quality of fit prior to the commencement of CLS. In addition, Dr. Kennedy gave testimony which, in my view, was not seriously challenged either by cross-examination or rebuttal, that many survey subjects who exhibited minor problems may have exhibited more severe problems

had their lenses been on longer and some subjects who showed no problems may have exhibited signs of some problems after four or more hours of wear. See Finding 105. The fact this record offers only a statistical evaluation of the survey analysis, with no independent optometric assessment in this specific instance of the validity of Dr. Kennedy's medical views, limits the extent to which the summary quality scores may be relied upon. Finally, CLS contains no data on follow-up care. Although the Patient Interview Form was designed to collect information on follow-up care, the CLS report failed to provide any analysis of the data collected. Virtually all of the optometrists appearing at the rulemaking hearings advised that follow-up care was part of their contact lens package, i.e., examination, lenses and follow-up, which were sold to consumers. Both professional and commercial practitioners emphasized the need for follow-up care in the management of contact lens patients and the record appears to indicate general agreement between the two branches of the profession that follow-up is a quality component of contact lens care. See Finding 99. Although the absence of this data from the record is unexplained, the argument that follow-up visits are indicative of higher quality of care was disputed in rebuttal filed on behalf of the staff as not being unambiguously the case. RRNA offered its own analysis of the data collected on the follow-up questions, concluding it demonstrated that noncommercial optometrists offered more follow-up care than commercial optometrists and equating the difference between the number of visits offered to an indication of the higher quality

care offered by noncommercial optometrists. See Finding 112. The rebuttal filed on behalf of the staff suggests, however, that a statistical analysis of the data supports a different view to the effect that follow-up visits more correctly reflect how poorly contact lenses were fit or that patients are having problems with their contact lenses. See Finding 113. Inasmuch as the record demonstrates agreement by the optometric community that follow-up is a quality component which was not analyzed by the CLS, although some data apparently was available, such fact mitigates the reliability of the quality conclusions reached in the survey.

E. Both the BE and Contact Lens studies undertake to report on the quality issue in relative terms, i.e., comparing the relative quality of services offered by commercial and noncommercial optometrists. In view of the conclusions set forth above on crucial aspects of the methodology employed to assess quality in these evidentiary offerings, all of the conclusions reached in BE and CLS on relative quality are called into question. Given the theoretical nature of these two works, the valid criticisms set forth on the record and the scope of the undertaking in this rulemaking, I am unable to conclude that substantial evidence has been offered to support the BE and CLS conclusions which have been reached on relative quality of service offered by commercial and noncommercial optometrists.

F. The summary conclusion of the BE Study concerning the price of vision care is unqualified in stating that the prices charged for eye examinations and eyeglasses are significantly

lower in the least restrictive cities and that large chain optical firms and both advertising and nonadvertising optometrists charge less in these cities than in the most restrictive cities. See Finding 120. Despite all of the objections lodged both to the conclusion itself and the methodology employed in reaching the conclusion, I believe the summary conclusion to be largely accurate on the basis of the data and analysis on which it is based. There is no argument that the data was some eight years old at the time public hearings were conducted in this proceeding and was gathered at a point in time contemporaneous with the Bates decision. There is also no argument that advertising which was utilized was limited to the print media and did not include radio or television advertising. See Findings 115,125,127. The record does not provide adequate basis, however, for invalidating BE because of these facts. The AOA/RRNA presentation assumes there has been a change in the marketplace since the 1977 period, but no actual evidence to this effect has been offered on the record. See Findings 125,127-129. Moreover, inasmuch as the survey took observations both in markets with and without advertising restrictions, and almost no price advertising for eye examinations was observed, I am in agreement with the staff's conclusion that almost none of the difference in price between the surveyed environments could have been due to such advertising. See Finding 133. The effects of Bates on this survey is not quite as pervasive as may first appear. RRNA presented extensive comment and its own reanalysis of the BE data while offering further data of its own. See

Finding 131. Based upon my review of the RRNA material, together with the BE presentation, it is my view that RRNA is urging rejection of the BE conclusions, insofar as they pertain to the price of vsion care, because the BE Study is not the study that RRNA would have performed. In view of the foregoing, because of the deficiencies I believe exist in Commission presentations on the quality issue, the conclusions reached in BE on the relationship between price and quality are called into question as well. The summary conclusion reached on price, however, appears viable and supported by the record. See Findings 134-138.

G. The pricing conclusion reached in the Contact Lens Study was more tentative in tone than that found in the BE Study. This work concludes that restrictions on opticians and commercial optometrists may increase costs to consumers by limiting the choices available to them. Restrictions may also result in higher prices for contact lens fitting by limiting consumers' access to relatively low-cost providers or by reducing competition in the marketplace. See Finding 139. To an extent, the CLS pricing conclusions "piggyback" on the BE Study by adopting the summary pricing conclusion of BE as a premise for assessing pricing in CLS. See Finding 140. The tenor of the overall findings reached in CLS is accounted for, in part at least, by the secondary finding that commercial optometrists on the average appear to charge significantly less than other contact lens fitters. This secondary finding was qualified in the report, however, due to the inability to control fully for certain factors other than type of fitter that may have

influenced prices. See Finding 141. During public hearings one of the authors of CLS testified that, based upon additional tests he had performed, he disagreed with the qualified conclusion because the tests indicated that advertising, which affected the factors for which earlier analysis was unable to fully control, was not a factor that was creating bias in the results. See Findings 141,143. The record does not disclose whether this view is also the view of the Bureau of Economics. However, the testimony offer by this witness, demonstrating that advertising did not have a biasing effect on the data is sufficient, I believe, to accept the secondary conclusion without qualification. See Finding 142. Although the survey sample for pricing is smaller than the full sample used for CLS (approximately 75 percent of total sample), (See Finding 139), I am not persuaded that the sample size was too small to reach meaningful or significant conclusions. The argument that the analysis is biased in the sense that noncommercial optometrists provide more services than commercial optometrists, based upon the comparison of follow-up visits is substantially undercut, in my view, by repeated testimony that follow-up visits are usually built into the package price for examination and lenses. A substantial number of optometrists, both noncommercial and commercial testified that follow-up was provided without limitation on the number of visits for periods of 3-12 months. It must be concluded, therefore, that follow-up visits were included in the prices which made up the CLS package, even though they were not specifically broken out as a cost component. See Finding 99.

Despite the objections interposed by AOA/RRNA as to the method used to compute that package price for contact lenses, I am unable to determine from this record where this package, as a measurement of price between commercial and noncommercial optometrists, is seriously deficient. See Findings 139,142,146,147. Again, as in the case with BE, while this may not have been the package of comparatives that AOA/RRNA would have chosen, such fact does not void the CLS conclusions. See Finding 150. In addition, although the cost-of-living adjustments applied to the analysis may have been found inadequate in another Bureau of Economics work, this record affords no specific evidence to clearly indicate the adjustments are inadequate here. See Finding 147. The other Bureau of Economics work was not submitted for consideration here, and no conclusions can be drawn from the AOA/RRNA assertion in this regard. Finally, as was the case with BE, I cannot conclude that the effects of the Bates decision invalidates this work, particularly in view of the fact that CLS includes observations occuring at least two years after that decision. See Finding 145. In view of the foregoing, I find substantial support on the record for the overall CLS conclusions on price.

H. Both the quality and pricing conclusions reached in CLS rest on the classification of optometrists into three groups, commercial, noncommercial and unclassified. See Finding 93. This grouping was criticized as being inexact because an arbitrary and unreliable method was used to classify optometrists. RRNA believes it likely that classifications do

not reflect the form of the original fitter's practice when CLS survey subjects were initially fit, and points to the fact that noncontemporaneous Yellow Pages were used in the classification process. See Finding 108. Absent supporting evidence on this record and some sort of wholesale change in the form of fitter's practices occurred throughout the CLS survey area between 1975-78, the periods covering the initial fittings, and 1979-81, the periods covered by the Yellow Pages used in classification, I cannot conclude the classification process was unreliable. Inasmuch as the classification was based on trade name usage, branch offices, commercial locations and corporate employment, not merely on whether optometrists advertised, I do not find the classification of optometrists for CLS to be arbitrary. See Finding 113.

I. The rulemaking record provides substantial support for the conclusion that commercial practice restrictions limit the availability of vision care services to consumers. The testimony of individual witnesses, (See Findings 35,40,46,49,52,58,59,67, 68,152,154), the conclusions reached by the staff based on the BE and CL studies, (See Finding 151), which I find supported by the record, and the inferences that can be drawn from the record as a whole indicating wider availability of vision care in jurisdictions which do not impose all forms of commercial practice restrictions, support this conclusion. The record adequately demonstrates that fewer bans or restrictions of the type under consideration in this proceeding can be equated to greater consumer access to vision care. The economic arguments found in

the record, even where unsupported by separate empirical evidence, lend weight to that which can be adduced from other evidentiary submissions. The quality of care arguments which have been urged in connection with this issue, i.e., that vision care services are functionally unavailable to consumers due to alleged differences in the quality of vision care offered by commercial and noncommercial practitioners, is not persuasive in this context. See Finding 156. Undoubtedly several factors, other than commercial practice restrictions, bear upon the question of availability of vision care services in individual states. Matters relating to population density, income, the number of available optometrists and similar matters may indeed be relevant. In particular states, and especially in the geographically large and sparsely populated states, these factors may take on substantial significance when examined in that limited context. However, in reaching the conclusion set forth above, it is not necessary to apportion weight to competing factors which may or may not contribute to unavailability of vision services in individual jurisdictions. The fact of unavailability is satisfactorily demonstrated by the record and I can discern no requirement that this overall conclusion be qualified by ascertaining the extent to which commercial practice restrictions are a separate factor in each of the individual states.

III. LEGAL CONSIDERATIONS

A. Jurisdiction of the Commission.

Section 18(a)(1)(B) of the FTC Act, 15 U.S.C. 57a(a)(1)(B),

authorizes the Commission to prescribe rules which define with specificity acts or practices which are unfair, including requirements prescribed for the purpose of preventing such unfair acts.

In the previous rulemaking involving this industry (Advertising of Ophthalmic Goods and Services, 16 CFR 456) the Commission discussed at length the meaning of the term "unfair" which was set forth in the Statement of Basis and Purpose published in conjunction with the promulgation of that Trade Regulation Rule. 43 Fed. Reg. 23992, note 3 at 24000. In so doing, the Commission set forth a two-part test to determine what practices should be deemed unfair:

> (1) Whether the acts or practices result in substantial injury to consumers. In making this determination both the economic and social benefits and losses flowing from the challenged conduct must be assessed.
>
> (2) Whether the challenged conduct offends public policy.

43 Fed. Reg. at 24001.

In subsequent litigation involving the earlier rule, the U.S. Circuit Court for the District of Columbia upheld the prescription release requirement contained in the rule, but remanded the advertising portions of the rule for further consideration by the Commission. American Optometric Association v. FTC, 626 F.2d 896 (D.C. Cir. 1980). In so doing, the Court observed that as to the prescription release provision, it could not say the Commission erred, but made no further comment. 626 F.2d 896, 915.

The staff, in making its recommendations to proceed with

rulemaking in the instant matter, applies the two-part test for unfairness to evidentiary materials intended for the rulemaking record, advising the Commission that both the "consumer injury" and "public policy" segments of the test can be demonstrated on the record. Based upon the staff recommendations, the Commission issued the notice of proposed rulemaking stating it has reason to believe that enforcement of any state laws, rules, or regulations which impose the restraints contemplated in §456.4 of the proposal on forms of commercial optometric practice may be unfair acts or practices within the meaning of Section 5(a)(1) of the FTC Act, 15 U.S.C. 45.

The Commission's fundamental authority to assert jurisdiction in this rulemaking over unfair acts or practices under the provisions of Sections 18(a)(1)(B) and 5(a)(1) of the FTC Act was not contested on this rulemaking record. Although the jurisdiction of the Commission was not called into question, the record contains substantial comment and argument concerning the extent of the Commission's authority to adopt the remedies proposed in the rulemaking concerning alleged unfair acts or practices. In view of the specific grant of authority in the aforementioned sections of the FTC Act and the action of the court in the American Optometric Association case in affirming the earlier action of the Commission relating to prescription release, it appears settled that the Commission has jurisdiction to proceed with the present rulemaking.

B. Authority of the Commission to Preempt State Laws.

According to information provided in the 1980 Staff Report,

only two jurisdictions, the State of Nebraska and the District of Columbia, impose no commercial practice restrictions on optometrists. R-B-2-1 at 28. While the reach of the restrictions in various states is unclear from the staff presentation, due to the characterization of some statutes as being ambiguous, it is nonetheless clear that the effect of any affirmative action by the Commission in this rulemaking to adopt the proposal set forth in §456.4 will affect a substantial majority of the states. It should be noted that there is some record evidence to indicate that certain of the states have taken action to amend or otherwise modify various state laws and/or regulations to an unspecified extent since the information on state laws was collected for the 1980 report. The record contains no evidence, however, to indicate that there has been a wholesale change in the status of state imposed restrictions since 1980.

The Supreme Court has, on at least two occasions in recent years, had the opportunity to scrutinize forms of commercial practice restrictions enacted by state legislatures and challenged under provisions of the Fourteenth Amendment. In the earlier case, Williamson v. Lee Optical Co., 348 U.S. 482 (1955), the court affirmed, among other things, the authority of the Oklahoma legislature to enact a statute making illegal the act of any retail merchandiser to rent space, sublease departments or otherwise permit any person "purporting to do eye examination or visual care" to occupy space in a retail store. In so doing, the court stated:

> It seems to us that this regulation . . . is an attempt to free the profession, to as great an extent as possible, from all taints of commercialism. . . Moreover, it may be deemed important to effective regulation that the eye doctor be restricted to geographical locations that reduce the temptations of commercialism. Geographical location may be an important consideration in a legislative program which aims to raise the treatment of the human eye to a strictly professional level. We cannot say that the regulation has no rational relation to that objective and therefore is beyond constitutional bounds.

348 U.S. 482, 491.

In the more recent case, Friedman v. Rogers, 440 U.S. 1 (1979), the court considered a trade name ban imposed by the Texas legislature. In reviewing the legislative history which led to the adoption of the ban the court advised:

> The concerns of the Texas Legislature about the deceptive and misleading uses of optometrical trade names were not speculative or hypothetical, but were based on experience in Texas with which the legislature was familiar when in 1969 it enacted §5.13(d). The forerunner of §5.13(d) was adopted as part of a "Professional Responsibility Rule" by the Texas State Board of Examiners in Optometry in 1959.

440 U.S. 1, 13.

After determining that the trade name ban did not stifle commercial speech and was therefore outside the decisions in Virginia Pharmacy and Bates, the court concluded:

> It is clear that the State's interest in protecting the public from the deceptive and misleading use of optometrical trade names is substantial and well demonstrated. We are convinced that §5.13(d) is a constitutionally permissible state regulation in furtherance of this interest.

440 U.S. 1, 15.

It appears from the foregoing there can be no argument as to the general authority of state legislatures to utilize the police powers of the state to place certain types of restrictions, in the nature of those under consideration in this rulemaking, on

the practice of commercial optometry.

Relatively recent cases involving rulemaking matters emanating from the Commission have addressed the question of the Commission's authority to preempt state laws and regulations. In Katharine Gibbs School (Inc.) et al. v. FTC, 612 F.2d 658 (2d Cir. 1979), the court gave special consideration to the authority of the Commission to assert preemptive authority over state laws. The court noted it has long since been firmly established that state statutes and regulations may be superseded by validly enacted regulations of federal agencies such as the FTC, citing to Free v. Bland and subsequent cases. 612 F.2d 658, 667. The court emphasized, however, that before preemption shall be deemed to have occurred, there must be either a clear manifestation of such congressional intent or a conflicting inconsistency between state and federal regulations. This is particularly true, the court stated, where the field of regulation is one that has been traditionally occupied by the states. 612 F.2d 658, 667.

Turning to rulemaking by the FTC, the court stated that in enacting the Magnuson-Moss Act, Congress did not intend that the Commission's regulations should "occupy the field" so as to preclude any state regulation whatever. The Magnuson-Moss Act, the court observed, contains no preemption provisions. Such indications of congressional intent as may be gleaned from the legislative history of the 1975 enactment and the predecessor bills considered by Congress show that the Commission's regulations were to have no more preemptive effect than that which flows inevitably from a repugnancy between the Commission's

valid enactments and state regulations. 612 F.2d 658, 667.

The opinion of the court in American Optometric Association expressed cautionary language concerning the Commission's preemption efforts in the previous rulemaking affecting Ophthalmic Practices. The court noted:

> . . .the Commission's proposed pre-emption of state law is almost as thorough as human ingenuity could make it. Consequently, the Commission has at least approached the outer boundaries of its authority and may have infringed on that deference to the states' exercise of their police powers dictated by the principles of federalism.

626 F.2d 897, 910.

The court listed a series of issues which were raised by the earlier rule, including whether Congress authorized the Commission to preempt state laws. If so, did the scope of the Commission's delegated power permit it to preempt state laws to the extent of preempting the whole field of ophthalmic advertising? Does the "state action" doctrine of Parker v. Brown, 317 U.S. 341 (1943) forbid the agency to issue this rule? 626 F.2d 897, 910.

Parties both supporting and opposing this rulemaking have given special attention to the issue of whether the "state action" doctrine of Parker v. Brown forbids the Commission from issuing a rule in this proceeding. In Parker v. Brown the court refused to allow the Sherman Act to upset a state regulatory scheme limiting the production and marketing of agricultural products in California. One commentator has observed that "[d]espite considerable confusion over the scope and meaning of what has become known as the Parker doctrine, the case is inevitably linked to a resolution of the preemption issue. This

is because Parker is one of the few judicial attempts to reconcile the twin policies of antitrust and federalism. Even Goldfarb, which seemingly strengthens current antitrust policies, does not fail to acknowledge the continued viability of the Parker doctrine."[1]

A review of the legislative history of Magnuson-Moss amendments to the FTC Act discloses that in 1970 the Senate Committee on Commerce recommended expansion of the Commission's commerce jurisdiction with a grant of substantive rulemaking powers.[2] In recommending expansion of the Commission's jurisdiction from matters "in" to those "affecting" interstate commerce, the Senate Committee cautioned that the expansion was not meant to create federal occupation of the consumer protection field.[3] At least one commentator is of the view that this effort to assure that any expanded commerce jurisdiction, by its mere existence, would not exclude states and localities from the field of consumer protection regulation permeates all successive legislative history. It seems simply to clarify the issue for "affecting" commerce jurisdiction in the way that case law had clarified the issue for the original grant of "in" commerce

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[1] Preemption of State Law By the Federal Trade Commission, Paul R. Verkuil, 1976 Duke L.J. 225 at 227.

[2] See Id. 235-243 for discussion of the legislative history of the Magnuson-Moss Amendment to FTCA and an evaluation of Congressional intent.

[3] S. Rep. No. 91-1124, 91st Cong., 2d Sess. (1970).

jurisdiction. The FTC Act, by itself, does not exclude or "replace" state antitrust and consumer protection efforts.[4]

Subsequent legislation arising in the Senate addressed the question of preemption in the context of a proposed grant of rulemaking authority. While none of these proposals were finally enacted and the House of Representatives remained essentially silent on the subject of preemption, the legislative history makes clear that the Senate, at least, considered that preemptive authority was a necessary consequence of any grant of rulemaking authority to the Commission.[5]

Ultimately, Senate Bill 356, the Magnuson-Moss Warranty-FTC Improvement Act, was enacted by the Congress and became law on January 4, 1975 (Public Law 93-637). Section 102 of Magnuson-Moss (15 U.S.C. 2302) specifically authorizes the Commission to prescribe rules for disclosure, among other things, of the terms and conditions of a consumer product warranty and the manner and form of clearly and conspicuously disclosing the terms of a written warranty. Rules relating to these matters were subsequently promulgated by the Commission.[6]

It is argued that, while Parker cautioned that "an unexpressed purpose to nullify a state's control over its officers and agents is not lightly attributed to Congress,"

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[4] Preemption and the Federal Trade Commission, Remarks of Bruce M. Chadwick, Dec. 12, 1977. R-G-4 at 11-12.

[5] Note 1, supra, at 236-240. See also Chadwick, note 4, supra, at 12-16.

[6] 16 C.F.R. 701, 702.

Congress debated the preemption issue in connection with the Magnuson-Moss legislation and, in effect, "expressed" a purpose when it went forward with the legislation that contemplated warranty rulemaking which would affect state laws and regulations. Unlike the situation in Parker with the Sherman Act, the preemption issue here is one that Congress had before it. In reality, preemption became a natural consequence of the Magnuson-Moss amendments, unless Congress clearly rebutted the implication. Under these circumstances preemptive authority is not "lightly attributed" to Congress.[7]

Other factors which appear to support preemptive authority in Magnuson-Moss rulemaking include the fact that such activity involves the exercise of the Commission's authority over unfair acts and practices and not its authority over unfair competition or antitrust jurisdiction. Much of the concern with Sherman Act preemption expressed in Parker had to do with the potential of antitrust actions to restructure the states' economic organization. It is observed by one commentator that judicial decisions and regulatory self-restraint will control the Commission's authority over unfair acts and practices. In the instant proceeding, the Commission proposes to preempt only total bans on certain kinds of commercial practices and such fact can be regarded as an exercise in regulatory self-restraint.[8] Moreover, unlike adjudication, the procedural framework of

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7 Dean Paul Verkuil, Tulane Law School, Tr. 402.

8 Id., at 402, 413.

rulemaking gives affected states a greater opportunity to shape the ultimate rule. The forum for shaping the rule resembles that of a legislative hearing rather than a courtroom and if vital states' interests are affected, states can organize to make them known to the Commission.[9] The last factor supporting preemptive authority is the judicial review provisions pertaining to Magnuson-Moss rulemaking which contemplate a substantial evidence review. This has been characterized as a more stringent standard of review than that normally associated with notice and comment rulemaking and undoubtedly a more demanding standard than that involved in review of legislation itself.[10]

Opponents to this rulemaking argue that neither the statutory language nor the legislative history of Magnuson-Moss reasonably indicates that Congress intended FTC to exercise its rulemaking power to preempt valid state laws and that the opinion of the court in the AOA case casts serious doubt on the Commission's authority to preempt. The opponents of preemption point to the language of the Director of the Bureau of Consumer Protection, in an April 13, 1984 Memorandum to the Commission, indicating the view of that official in recommending this rulemaking that the legislative history of Magnuson-Moss suggests Congress assumed that trade regulation rules would preempt inconsistent state laws. It is argued that the view the legislative history "suggests" that Congress "assumed" preemption falls far short of reflecting the requisite degree of clarity

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9 Id., at 404.
10 Id.

necessary for a court to give credence to the Commission's contention that Congress intended preemption authority.[11]

As briefly discussed above, however, the legislative history preceding the adoption of Magnuson-Moss is of sufficient clarity to lead to the conclusion that preemption authority was, indeed, intended to be included within the Commission's rulemaking authority and utilized under appropriate circumstances. Moreover, while the preemption issue was not decided in the AOA case, nothing within the body of that opinion can be reasonably adduced which leads solely to the conclusion that the Commission lacks preemptive authority in any rulemaking proceeding. The language of the opinion is directed solely at the precise rule under consideration, in the first instance, and in the broader context, pointed the way to a conclusion that preemptive authority may reside with the Commission depending upon the resolution of a series of issues which the Court set forth in the opinion.

The question of whether it is the intention of the Commission to "occupy the field" in regulating the forms of permissible commercial practice arises from the opinions in both the Katharine Gibbs and AOA cases. The Notice of Proposed Rulemaking, 50 Fed. Reg. 598 (NPR), §456.4, contains a specific expression of Commission intent which advises that a rule is not intended to interfere with a state's ability to enforce any law, rule or regulation which: (1) is designed to control specific

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11 AOA, R-H-81 at 5-9; Appendices A and B.

harmful practices, such as improper interference in the professional judgment of optometrists or sellers or compensation schemes use to pay employed optometrists or sellers which encourage over-prescription; (2) interfere with a state's ability to enforce any law, rule, or regulation requiring that ophthalmic goods and services or eye examinations provided at each office be supplied by a person qualified to do so or regulating the services provided at each office; (3) interfere with the state's ability to enforce general zoning laws or any law, rule, or regulation which prohibits the location of optometric or optical practice in areas which would create a public health or safety hazard; and (4) enforce any law, rule, or regulation which requires that the identity of an optometrist or seller be disclosed to a patient at the time an eye examination is performed or ophthalmic goods or services dispensed, or from enforcing laws reasonably necessary to prevent the deceptive use of trade names in advertising.

The proposal has been challenged as being so sweeping and vague as to be arbitrary and capricious, however, and it is alleged that despite the statement of intent expressed by the Commission in §456.5, the effect is self-contradictory and fails to define with specificity the acts or practices which are unfair. AOA, R-H-81 at 11. It is urged that whereas the language of the NPR claims any final rule would only prevent State "total bans" of restrictions on "commercial practice," as in §456.4(a)(1) relating to other business relationships between optometrists and non-professional corporations or unlicensed

persons, for instance, the effect of the proposal would be to oust state jurisdiction to regulate any professional optometric activity other than solely among optometrists. R-H-81 at 12. It is suggested such a result, if effected through promulgation, flies in the face of the specific court language in the AOA case indicating "the Commission's proposed pre-emption of state law is . . .as thorough as human ingenuity could make it." 626 F.2d 896, 910. Moreover, it is further argued that in light of the fact a number of states have determined that fee splitting, use of runners, cappers and steerers, corporate employment, or the conditioning of income to an optometrist upon the sale of eyeglasses are harmful practices, it is less than forthright for the Commission to claim that it is proposing anything less than the complete nullification of a wide variety of reasonable state efforts to protect consumers in the area of optometric services. R-H-81 at 12-13. The language in the NPR is selfcontradictory as to effectively mask the actual scope of coverage of the proposed rule, AOA contends. For example, the NPR advises that the proposed rule would allow states, among other things, to choose to prohibit commission payments as a form of compensation for optometrists, while at the same time preventing business relationships between optometrists and persons other than optometrists. Such commission payments, it is argued, are a form of business relationship, and the two provisions are therefore contradictory. R-H-81 at 13-14.

The proposal to remove trade name restrictions, while at the same time stating the intent to permit states to enforce laws

that are reasonably necessary to prevent the deceptive use of trade names, is further cited as an instance of inconsistency. In view of the Supreme Court's conclusion in Friedman v. Rogers, upholding the Texas trade name banning statute as a means of regulating the deceptive use of trade names, it is argued the alleged irrationality of the proposed rule cannot be rectified with the qualification that states can enforce laws to prevent the deceptive use of trade names. R-H-81 at 15-17.

It is clear from the express language of the NPR that it is not the intention of the Commission to occupy the field as part of preemption efforts undertaken in this rulemaking. However, this record contains no evidence to indicate whether the actual effect of the undertaking in this proceeding may not, in fact, be other than that which was specifically intended by the Commission. This record contains adequate testimony indicating that the preemptive effects of this proposal will not likely interfere with the authority of the states to, for example, establish and regulate educational and licensing requirements of optometrists, prescribe minimum examination requirements and minimum equipment requirements, or establish minimum professional standards. The record is devoid of information, however, to indicate what specific actions the states may undertake to make substitutions for statutory or regulatory provisions intended to be preempted by the rulemaking proposal. The failure of the various state governments to more widely participate in this proceeding than has been the case and, in particular, to comment on the effects of the Commission's undertaking imposes

substantial limitations on any consideration of this matter. It is unclear whether the comments and observations of AOA have indeed identified a material defect in the rulemaking proposal or if the perceived problem is actually one of draftsmanship. It is a matter, nonetheless, which requires close scrutiny and consideration as this rulemaking goes forward.

Comments by some of the state attorneys general, as well as state boards of optometry, indicate clear opposition on the part of those enforcement and regulatory authorities to adoption of the rulemaking proposal. Some of these officials offered the opinion that neither the language of Magnuson-Moss nor its legislative history reflect a clear intent to allow federal preemption of valid state health care laws. See Hon. Steve Clark of Arkansas, Tr. 3012; Hon. Lacy Thornburg of North Carolina, R-E-34 at 3. The principle of federalism discussed in the Parker and Bates cases prohibits the preempting of state law absent clear authority from Congress. See Hon. Jim Smith of Florida, R-E-32 at 2. Where clear Congressional intent is lacking, the principle of federalism must be applied to recognize that states may validly regulate their own healing arts professions. Smith, Tr. 3012. Others characterized preemption as an abuse of federal authority, arguing that matters involving ophthalmic practice are better left to local control based upon statewide needs more readily identified by the state itself. Strulowitz, New Jersey Board of Optometrists. Tr. 18.

One witness, Hon. Sam Vinson, Assistant Minority Leader, Illinois House of Representatives, argued against preemption from

a policy and state legislative viewpoint. While detailing recent activities of the Illinois legislature, this witness offered the view that state legislatures are currently involved in a process that has actually placed them ahead of the FTC and federal government in making the practice of medicine, of health care in all its diverse groupings, a more competitive enterprise. The witness advised that if the FTC chooses to command on a limited basis and preempt state law in the health care field in narrow areas such as that proposed, one of the results will be to muddy the water and make it more difficult for state legislatures to move toward a more competitive structure in health care delivery generally. In Mr. Vinson's view, if the Commission goes ahead with the rulemaking proposal, one of the results may be to substantially inhibit the introduction of competition and the benefits of competition in the general health care field. Tr. 2150-52. The effect of preemption, he believes, is going to be paralysis among groups in the medical community and legislatures in the overall direction of moving health care toward a competitive structure. Vinson, Tr. 2153.

C. Alternative to rulemaking.

Limited comment and arguments were received on the record as to alternatives to rulemaking which the Commission should consider. Of these, the alternative of a model state law was most often cited. United States Senator George Mitchell stated that considerable deference should be given to state legislatures in regulating their professional communities. Ideally, he would prefer to see the Commission promulgate a model state law rather

than new federal regulations in this area. R-E-44 at 1. The Attorney General's office of the State of Washington observed that while the model law approach would not have the force of a trade regulation rule, consideration of such a law is warranted. In so recommending, it was noted that similar efforts have been successful in various policy areas, such as the Uniform Commercial Code. Wesley Howard, Assistant Attorney General, R-E-5 at 10-11. Representative Hal Stratton, Chairman of the Judiciary Committee, New Mexico House of Representatives, testified that he serves on the National Commission on Uniform State Laws, and that such laws have been good for the country. He argued that model laws are an excellent tool to use at the local level and preserve local control of regulation. Tr. 1750. Rep. Stratton recommended that at the conclusion of this rulemaking the Commission issue a public report and a recommended model state law with the adoption left to the discretion of each state. HX-J-43 at 4. A similar recommendation, issuance of a public report and model law, was made by the Optometric Council of New York, together with a recommendation for issuance of guidelines for voluntary change which embody the Commission's findings and objectives. Alexander Singer, Executive Director, R-H-48 at 2. The representative for the North Dakota Board of Optometry recommended that the Commission provide its findings to all the states so that the states could use them as an aid in their own rulemaking process to meet the needs of the unique circumstances within each state. Louise Zuern, Tr. 1562.

While the alternative of no further action was repeatedly

mentioned in comment and testimony of opponents of the rulemaking, little support appears on the record for the alternative of proceeding in this area with complaints issued on a case-by-case basis.

IV. RECOMMENDED DECISION

1. The provisions of the rulemaking proposal seeking modification of §456.1, Definitions, and §456.2, Separation of Examination and Dispensing, directed at clarification and minor modification of the existing prescription release rule are either unopposed in their entirety or fully supported, but with further revisions to proposed language suggested for purposes of clarification as indicated in Part II.A. of this report.

2. While the rulemaking record contains no serious dispute of the Commission's authority to preempt state laws under appropriate circumstances, this record is insufficient to provide the basis for the preemption action proposed by §456.4 of the rulemaking proposal. As discussed in Part II.B. herein, the record is insufficient to reach a conclusion as to whether commercial practice bans or restrictions have positive effects on the quality of vision care provided to the citizens of the various states. It is therefore not possible, based on the totality of the record, to assess whether consumer injury in the form of higher prices or limited availability for vision care services which result from such bans or restrictions are, in some manner, counterbalanced by quality of care considerations. The conclusions reached in the BE and CL studies on quality of care are not supported on the record to the extent that ultimate

conclusions on the quality issue can be made with any substantial degree of assurance. Inasmuch as the accuracy, reliability and comprehensiveness of the BE and CL studies have been successfully called into question, and since these two evidentiary submissions are the primary evidence supporting the proposed action set forth in §456.4, the record must be adjudged insufficient to support the proposal to preempt state bans on commercial optometric practice. Aside from the results of the BE and CL studies themselves and the testimony given in support of these studies, no other separate, independent body of evidence has been placed into the record, either by the staff or other interested or affected parties to the rulemaking, which offers an adequate or substantial basis for recommending promulgation of §456.4.

3. The Commission has been urged to abandon the §456.4 proposal and, as an alternative, to undertake the development of a model law for consideration by the legislatures of the various states. Because there has been no broad participation by those authorities in the states in position to address questions concerning the desirability or suitability of a model law proposal, the question of whether a model law is a practical alternative to rulemaking cannot be established on this record.

James P. Greenan
Presiding Officer

May 1, 1986

APPENDIX I

RULEMAKING NOTICE AND AMENDMENT

Notice of Proposed Rulemaking, January 4, 1985.

Notice of Postponement of Scheduled Public Hearings and Extension of Time Within Which to File Prepared Statements of Testimony by Witnesses and Exhibits, June 7, 1985.

(The following has been reprinted from the
Federal Register of January 4, 1985 - 50 FR 598)

FEDERAL TRADE COMMISSION

16 CFR Part 456

Ophthalmic Practice Rules; Proposed Trade Regulation Rule

AGENCY: Federal Trade Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would remove total bans imposed by state law and certain forms of commercial ophthalmic practice. The proposed rule is intended to prevent consumer injury arising from public restraints on the permissible forms of ophthalmic practice that appear to increase consumer prices for ophthalmic goods and services, but which do not appear to protect the public health or safety. The proposed rule also contains minor modifications intended to clarify the prescription release requirement of 16 CFR Part 456 (the Advertising of Ophthalmic Goods and Services Trade Regulation Rule, referred to in this notice as the "Eyeglasses Rule").

This notice sets out the rulemaking procedures to be followed, the text of the proposed rule (set forth as a modification of the Eyeglasses Rule), reference to the legal authority under which the rule is proposed, a statement of the Commission's reasons for proposing this rule, a list of specific questions and issues upon which the Commission Particularly desires written and oral comment, an invitation for written comments, and instructions for prospective witnesses and other interested persons who desire to present oral statements or otherwise participate in this proceeding.

DATES: Written comments must be submitted on or before April 5, 1985.

Notification of interest in questioning witnesses must be submitted on or before March 8, 1985.

Prepared statements of witnesses and exhibits, if any, must be sumitted on or before April 26, 1985 for witnesses at the Washington, D.C., hearings and May 31, 1985 for witnesses at the San Francisco, California, hearings.

Public hearings commence at 9:30 a.m. on May 20, 1985 in Washington, D.C., and at 9:30 a.m. on June 17, 1985 in San Francisco, California.

ADDRESSES: Written comments notifications of interest, prepared statements of witnesses and exhibits should be submitted in five copies to James P. Greenan, Presiding Officer, Federal Trade Commision, Washington, D.C., 20580, 202-523-3564. The Public hearings will be held in Room 332 Federal Trade Commision Building, 6th Street and Pennsylvania Avenue NW., Washington D.C., and in Room 12470, San Francisco Regional Office of the Federal Trade Commission, 450 Golden Gate Avenue, San Francisco, California.

FOR FURTHER INFORMATION CONTACT: Gary Hailey, Matthew Daynard, or Renee Kinscheck Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580, 202-523-3452, 202-523-3427, or 202-523-3377.

SUPPLEMENTARY INFORMATION: The proposed rule would remove four major restraints imposed by state law on premissible forms of commercial practice: (1) Restrictions on employer-employee or other business relationships between optometrists or opticians and non-professional corporations or unlicensed persons; (2) limitations on the number of branch offices an optometrist or optician may operate: (3) restictions on the practice of optometry on the premises of merchantile establishments (such as department stores); and (4) bans on the practice of optometry under a trade name.

The proposed rule would only prevent state or local governments from enforcing total bans on these forms of commercial ophthalmic practice; it would not interfere with the states' ability to regulate specific harmful practices as long as commercial practice itself is not directly or indirectly prohibited.

"Commercial practice" in the retail optical market is generally understood to refer to large-scale, high-volume providers. "Non-commercial practice," on the other hand, describes small firms or independent "solo" practitioners.

Legal impediments to the practice of optometry and opticianry in commercial settings restrain the growth and development of retail optical firms that offer optometric services and also restrain other high-volume, "commercial" businesses, which, through managerial efficiencies and economies of scale, are often able to charge lower prices for ophthalmic goods and services than small "noncommercial" practitioners. These restrictions also prevent commercial firms, as well as opticians and non-dispensing optometrists, from competing effectively with dispensing optometrists and ophthalmologists who offer both examination and dispensing services. Individual practitioners are also precluded from establishing practices in mercantle locations such as shopping centers or department stores, where the potential for high-volume business exists.

Proponents of commercial practice restraints justify them as necessary to protect the public health, safety and welfare. The Commission has reason to believe, however, that these practice restrictions unnecessarily increase the price and reduce the accessibility of vision care without having any significant positive impact on the quality of vision care. This tentative belief is based primarily on empirical research conducted by the Commission's Bureaus of Economics and Consumer Protection and othe published studies. Comment on the methodology and validity of those studies is specifically requested.

The proposed rule would also modify slightly the prescription release requirement of the Eyeglasses Rule, 16 CFR Part 456. The proposed changes are intended to eliminate areas of confusion which existed concerning the scope of the Eyeglasses Rule. The proposed rule modifications would involve no preemption of state law.

Copies of the staff report (entitled "State Restrictions on Vision Care Providers: The Effects on Consumers," July 1980), the Bureau of Economics report (entitled "Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry," September 1980), the contact lens report (entitled "A Comparative Analysis of Cosmetic Contact Lens Fitting by Ophthalmologists, Optometrists and Opticians," December 1983), the Bureau of Consumer Protection's study of the duplication of eyeglass lenses without a prescription (entitled "A Comparison of a Random Sample of Eyeglasses," July 1979), and the study of the impact of the prescription release requirement (entitled "FTC Eyeglasses Study: An Evaluation of the Precription Release Requirement," 1981) may be obtained in person or by mail from: Public Reference Room (Room 130), Federal Trade Commission, 6th Street and Pennsylvania Avenue NW., Washington, DC 20580.

Section A. Statement of the Commission's Reasons for the Proposed Rule

On January 20, 1976, the Commission directed the staff on the Bureau of Consumer Protection to initiate an investigation to determine whether restrictions on forms of commercial ophthalmic practice and limitations on the scope of practice of opticianry were unfair acts or practices within the meaning of section 5(a)(1) of the Federal Trade Commission Act. The decision to commence this investigation was based on consideration of evidence received

during the Commission's earlier ophthalmic advertising rulemaking proceeding. That investigation examined the adequacy of information available to consumers of vision care. It focused on how state and private advertising restrictions affect the cost, availability, and quality of vision care.[1] Evidence presented in that proceeding indicated that advertising restictions were but one part of a larger system of public and private restraints on ophthalmic practice which may limit competition, increase prices, and limit the availability of vision care.

The Commission staff addressed various types of public and private restraints in the course of this second investigation. With repect to restrictions on forms of commercial practice by ophthalmic providers, the staff examined four restraints imposed by state law: (1) Restrictions on employer-employee or other business relationships between optometrists or opticians and lay individuals and non-professional corporations; (2) limitations on the number of branch offices an optometrist or optician may operate; (3) restrictions on the practice of optometry and opticianry in commercial locations or on the premises of mercantile establishments; and (4) bans on the use of trade names by optometrists. Two categories of limitations on the scope of practice of opticianry were also studied by the staff: (1) Restrictions preventing opticians from fitting contact lenses; and (2) restrictions prohibiting opticians from duplicating existing eyeglasses lenses in order to produce new pairs of eyeglasses.

Staff assessed the impact on the price, quality, and availability of vision care of these restrictions. The ultimate issue addressed was whether higher prices and diminished access to vision care result from these restrictions and, if so, whether such consumer injury is counterbalanced by positive effects on quality of care. Staff received comments from private citizens, members of the professions involved and their professional associations, and government officials during the investigation. Staff also researched current state laws, private associations' regulations, and industry practices. To obtain data on the impact of these restrictions on the price, availability and quality of vision care, staff performed several research studies: (1) A study by the FTC's Bureau of Economics measured the price and quality effects of commercial practice restrictions; (2) a shopper survey of optical establishments measured the accuracy of the duplication process; and (3) a study administered by Bureau of Consumer Protection staff measured the comparative ability of ophthalmologists, optometrists, and opticians to fit contact lenses. Professional groups including the American Academy of Ophthalmology, the Contact Lens Association of Ophthalmologists, the American Optometric Association, the Contact Lens Society of America, the Opticians Association of America, and the National Association of Optometrists and Opticians assisted in the design and administration of the contact lens fitting study and the American Optometric Association reviewed and analyzed the BE commercial practices study data. Studies performed by others were also reviewed.

The staff has set forth the results of its initial investigation in a publicly available report entitled "State Restrictions on Vision Care Providers: The Effect on Consumers" (July 1980). The Commission's decision to commence this rulemaking proceeding is based on consideration of the staff report and the public comments received in response to the Advance Notice of Proposed Rulemaking ("ANPR").[2] The ANPR, which was published in the Federal Register on December 2, 1980, requested comment on the issues presented by this investigation and on what action, if any, the Commission should take. Specifically, the public was invited to comment on the evidence and findings contained in the staff report, and on various alternatives to rulemaking. During the 60-day comment period, 247 comments were received from consumers, industry members and government officials. After consideration of the evidence contained in the staff report, the ANPR comments, and the recommendations of the staff, the Commission has determined that rulemaking is the most appropriate way to explore further the issues raised by this investigation.

With respect to the proposed rule provisions concerning commercial practice restrictions, the staff report presents evidence that state laws which restrict the ability of optometrists to practice in commecial settings raise consumer prices but do not maintain or enhance the quality of vision care. Results obtained from the 1980 Bureau of Economics study ("BE Study") indicate that: (1) Prices of eyeglasses and eye examinations are significantly lower in cities where commercial practice is not restricted and in cities where advertising is not restricted; (2) commercial optometrists charge lower prices than non-commercial optometrists; (3) non-commercial providers who operate in markets where commercial practice is permitted charge less than their counterparts in cities where commercial practice is proscribed; and (4) there is no difference in overall quality of care between cities where commercial practice is permitted and cities where commercial practice is restricted. To assess quality, the study evaluated the accuracy of the prescriptions written by the sampled optometrists, the accuracy and workmanship of the eyeglasses dispensed by the examining optometrist, the thoroughness of the eye examination, and the extent of unnecessary prescribing of eyeglasses. Comment regarding the methodology and analysis of the BE study is requested below.

The 1983 Bureau of Consumer Protection and Bureau of Economics study of contact lens wearers concluded that: (1) The quality of cosmetic contact lens fitting provided by opticians and commercial optometrists was not lower than that provided by ophthalmologists and non-commercial optometrists, and (2) commercial optometrists charged significantly less for contact lenses than did any other group. To assess the quality of contact lens fitting, the study evaluated the relative presence or absence of several potentially pathological corneal conditions related to contact lens wear. Comment regarding the methodology and analysis of the contact lens study is requested below.

The staff recommendation that the Commission engage in rulemaking proceedings regarding commercial practice restrictions is based primarily on the results of these studies, which contradict the claim that the entry of commercial firms into the market lowers the overall level of quality of vision care. At the same time, the results show

[1] The Commission found public and private bans on nondeceptive advertising by vision care providers and those providers' failure to release spectacle prescriptions to be unfair acts or practices in violation of section 5 of the FTC Act. The resulting Eyeglasses Rule (16 CFR Part 456) eliminated those bans on nondeceptive advertising and required vision care providers to furnish copies of prescriptions to consumers after eye examinations. Subsequently, the U.S. Court of Appeals for the District of Columbia in American Optometric Association v. FTC, 626 F.2d 896 (D.C. Cir. 1980), upheld the prescription release requirement but remanded the advertising portions of the Eyeglasses Rule for further consideration in light of the Supreme Court decision in Bates v. State Bar of Arizona, 433 U.S. 350 (1977), which found the right of lawyers to advertise to be protected free speech under the First Amendment to the Constitution.

[2] 45 FR 79,823 (1980).

that average prices are significantly higher where commercial practice is restricted. Therefore, the Commission has reason to believe that these restrictions may be unfair acts or practices within the meaning of Section 5 of the FTC Act.

The proposed trade regulation rule would also modify the definition of the term "prescription" in the current Eyeglasses Rule to eliminate all references to contact lenses. Confusion has arisen as to whether eye doctors are required by the rule to state that patients whom they had examined were suitable candidates for contact lenses by writing "OK for contacts" or similar language on the prescription. This modification is consistent with staff's recommendation that the Commission not employ rulemaking to address the question of who should be permitted to fit contact lenses. Finally, the Commission has proposed several nonsubstantive changes to clarify the rule.

The staff report presented evidence that consumers are not always given eyeglasses prescriptions or contact lens specifications following the purchase of eyeglasses or contact lenses. If this were true, the report concluded, consumers' ability to obtain duplicate or replacement spectacle or contact lenses from the dispensers or fitters of their choice would be limited. This would be particularly true in states that prohibit duplication of spectacle lenses or contact lens fitting by opticians.

However, the staff report did not recommend rulemaking to eliminate those state restraints on duplication of lenses or contact lens fitting by opticians. The Commission concurs with this recommendation and, therefore, has not proposed rulemaking in this area. The staff report recommended that, instead of proposing to remove these state restraints, the Commission extend the prescription release requirement of the Eyeglasses Rule to require a consumer's eyeglasses dispenser or contact lens fitter to provide upon request a copy of that consumer's current eyeglasses prescription after the dispensing process is complete, or a copy of the complete contact lens specifications after the initial fitting process is complete. However, the proposed trade regulation rule does not contain provisions extending the prescription release requirement of the Eyeglasses Rule. The recommendations in the staff report regarding extension were based on complaints that consumers were sometimes denied access to their eyeglasses prescriptions and contact lens specifications. However, those complaints were few in number, and the Commission has no reason to believe that a significant number of dispensers are currently refusing to provide consumers with their prescriptions or specifications. Nevertheless, comment is requested on these issues.

The Commission has carefully and deliberately considered the staff report and recommended trade regulation rule and the comments received in response to the Advance Notice of Proposed Rulemaking. Based on the evidence presented to date, the Commission believes that the initiation of a rulemaking proceeding would be in the public interest.

The public is advised that the Commission has not adopted any findings or conclusions of the staff. All findings in this proceeding shall be based solely on the rulemaking record. Accordingly, the Commission invites comment on the advisability and manner of implementation of the proposed rule.

The Commission's Rules of Practice shall govern the conduct of the rulemaking proceeding, except that, to the extent that this notice differs from the Rules of Practice, the provisions of this notice shall govern. This alternative form of proceeding is adopted in accordance with § 1.20 of those rules (16 CFR 1.20).

Section B. Section-by-Section Analysis

The following discussion is intended to highlight the major provisions of the proposed rule, and to explain briefly their anticipated effect. Sections of the Eyeglasses Rule that would remain unchanged and which were explained in the Statement of Basis of Purpose of the Eyeglasses Rule[3] will not be described here.

Section 456.1 defines relevant terms and contains new definitions as well as technical modifications to terms in the Eyeglasses Rule.

The term "patient" has been substituted for the term "buyer" in paragraph (a) to conform more closely to industry usage.

The specific terms "ophthalmologist" and "optometrist" in paragraphs (e) and (f) have been substituted for the general word "refractionist" in § 456.1(h) of the original rule to define those categories of providers—Doctors of Medicine, Osteopathy and Optometry—who are qualified under state law to perform eye examinations. This change was made for two reasons. First, the use of the term "refractionist" in the original rule has caused confusion because it is not generally used by consumers or the industry. Second, certain provisions of the proposed rule permitting commercial practice do not apply to ophthalmologists. The term "refractionist" has been deleted so that this distinction is clear.

The term "prescription" is defined in paragraph (h) as those specifications necessary to obtain spectacle lenses. Thus, the prescription that is released to the patient need only contain the data on the refractive status of the patient's eyes, and any information, such as the date or signature of the examining optometrist or ophthalmologist, that state law requires in a legally fillable eyeglass prescription. In addition, all references to contact lenses have been deleted from the definition in order to end the confusion generated by the original definition concerning the obligation of optometrists and ophthalmologists to place the phrase "OK for contact lenses" (or similar words) on prescriptions. No such obligation would exist under the proposed definition. Another purpose of this change is to clarify the fact that the prescription release requirement (§ 456.2) does not affect state laws regulating who is legally permitted to fit contact lenses. This proposed change would not affect the current requirement that optometrists and ophthalmologists give spectacle prescriptions to all patients whose eyes they examine, including those patients who wear or intend to purchase contact lenses.

A "trade name ban" is defined in paragraph (j) to cover any state law or regulation that prohibits optometrists from practicing or holding themselves out to the public under trade or corporate names. The discussion of § 456.4(a)(4) below explains the scope of the proposed rule with respect to eliminating trade name bans on how the states may regulate the use of trade names.

Sections 456.2 through 455.6 of the Eyeglasses Rule have been deleted in accordance with the court's decision in *American Optometric Association* v. *FTC*, 626 F.2d 897 (D.C. Cir. 1980), which remanded those portions of the rule to the Commission for further consideration.

New § 456.2 contains minor modifications to the release of prescription requirement of the Eyeglasses Rule (originally § 456.7) which was upheld by the court in *American Optometric Association* v. *FTC*, and which remains in effect. The rule requires that eye doctors give spectacle prescriptions to consumers

[3] 43 FR 23,992 (1978).

immediately after performing eye examinations. Comment is requested below as to whether the prescription release requirement should be modified in a variety of ways.[4]

Section 456.4(a) would prohibit state or local governments from enforcing certain existing bans on commercial ophthalmic practice. By removing prohibitions on these forms of practice, the rule would permit optometrists and opticians to engage in commercial ophthalmic practice if they desire to do so; it would not mandate that any practitioner engage in any specific mode of practice. At the same time, the rule would not interfere with a state's ability to control specific harmful practices as long as the commercial practices allowed by this section are not directly or indirectly prohibited. Section 456.5, paragraphs (b) through (e), serve primarily to explain the limited scope of § 456.4(a) by providing examples of how the states might regulate commercial practice, if necessary, short of prohibiting it altogether. For this reason, the provisions of § 456.5(b)–(e) are discussed here with the corresponding operative provisions of § 456.4(a).[5]

Paragraph (a)(1) would prevent state and local governments from prohibiting employer-employee or other business relationships between optometrists or opticians and persons other than ophthalmologists or optometrists. Specifically, this section would remove a variety of state-imposed restrictions that prevent optometrists and opticians from working for or associating with non-professional corporations or lay individuals.

The rule would allow the states to take action, however, to protect the health and safety of their citizens to the extent it may be threatened by specific practices. As indicated in § 456.5(b), for example, a state may decide to prevent unlicensed persons from improperly interfering in the professional judgments of optometrists and opticians. Or a state could choose to prohibit commission payments as a form of compensation for optometrists or opticians. The proposed rule would only prohibit regulations or restrictions that effectively ban employer-employee or other business relationships between optometrists or opticians and others.

Paragraph (a)(2) would prohibit state or local restrictions on the number of offices that an optometrist, optician or any other person may operate. This provision would permit any person, including any corporation, who provides eye examinations or ophthalmic goods and services to own or operate any number of offices. Thus, a state under this section could not require that an office be open only when the optometrist who owns it is in personal attendance.

The proposed rule would not, however, prevent states from regulating how services are provided at each office. For example, as explained in § 456.5(c), states could require that ophthalmic goods or eye examinations provided at each office be supplied by a person qualified under state law to do so. The proposed rule would only prohibit regulations that restrict the ownership of any particular number of offices by optometrists, opticians, or other persons.

Paragraph (a)(3) would remove state and local restrictions that prohibit optometrists from locating an office in a pharmacy, department store, shopping center, retail optical dispensary, or other mercantile location. This provision would permit optometrists to establish offices in high-traffic areas, such as drug stores and shopping centers, or near retail opticians. Optometrists would also be able to lease office space from non-professional corporations or lay individuals.

As explained in § 456.5(d), however, the proposed rule would not interfere with a state's ability to enforce general zoning laws. In addition, states would retain the discretion to regulate leasing arrangements between optometrists and corporations or lay persons in order to prevent specific harmful practices. The proposed rule would remove only those regulations that prohibit optometrists from practicing in mercantile locations.

Paragraph (a)(4) would prohibit all state or local bans that prevent optomerists from practicing or holding themselves out to the public under a trade name. This provision would permit an optometrist to adopt an assumed or corporate name, or any name other than the one appearing on the petitioner's license, subject of course to the laws and regulations governing deception or infringement that apply to trade name practice by all persons.

Section 456.5(e) explains that the proposed rule would not, however, prevent states from enforcing laws that are reasonably necessary to prevent the deceptove use of trade names. If states desire to ensure full professional identification, for example, they could require that the identity of the optometrist be disclosed to the patient at the time the eye exmination is performed or opthalmic goods and services are dispensed. The proposed rule only would prevent a state from enforcing restrictions that prohibit the practice of optometry under a trade name.

Section 456.4(b) restates the last paragraph of § 456.3 of the original Eyeglasses Rule. It simply exempts every state or local governmental entity or officer from financial liability for violations of the proposed rule.

Section 456.5(f) would make it clear that the Commission intends that the proposed rule could be used as a defense in legal or administrative proceedings, or affirmatively for declarative, injunctive, or other relief.

Section C. Invitation To Comment

All interested persons are hereby notified that they may submit data, views, or arguments on any issue of fact, law or policy which may have bearing upon the proposed rule. Such comments may be either in writing or orally. Written comments will be accepted until April 5, 1985 and should be addressed to James P. Green, Presiding Officer, Federal Trade Commission, Washington, D.C. 20580, 202–523–3564. To assure prompt consideration, comments should be identified as "Ophthalmic Practice Rulemaking Comment." Please furnish five copies of all comments. (Instructions for persons wishing to present their views orally are found in Sections E and F of this notice).

While the Commission welcomes comments on any issues which you feel may have bearing upon the proposed rule, questions on which the Commission particularly desire comments are listed in Section E below. All comments and testimony should be referenced specifically to either the Commission's questions or the section of the proposed rule being discussed. Comments should include reasons and data for the position. Comments opposing the proposed rule or specific provisions should, if possible, suggest a specific alternative. Proposals for alternative regulations should include reasons and data that indicate why the alternatives would better serve the purposes of the proposed rule. Comments should include a full discussion of all the relevant facts and be based directly or firsthand knowledge, personal experience or

[4] The staff had recommended that the rule be modified to require the release of a prescription only when a patient requests one. The Commission has decided to propose no change in this rule provision at this time, but rather to request comment on the issue.

[5] The Commission does not intend to imply that the types of regulation cited in § 456.5(b)–(e) are desirable, but cites them merely as examples of state regulation that would not be eliminated if the proposed rule were adopted.

general understanding of the particular issues addressed by the proposed rule.

Section D. Questions and Issues

In the Advance Notice of Proposed Rulemaking, the Commission invited public comment regarding which hearing format should be used if the Commission decided to initiate a rulemaking proceeding; however, none of the comments we received dealt with this issue. The Commission has decided to employ a modified version of the rulemaking procedures specified in § 1.13 of the Commission's Rules of Practice, proceeding with a single Notice of Proposed Rulemaking and the "no designated issues" format. Set forth below is a list of sepcific questions and issues upon which the Commission particularly desires comment and testimony. The list of questions is not intended to be a list of "disputed issues of material fact that are necessary to resolve," and any right to cross-examine will be determined with reference to the criteria set forth in the Commission's Rules of Practice.

Interested persons are urged to consider carefully the following questions. The Commission retains its authority to promulgate a final rule which differs from the proposed rule in ways suggested by these questions and based upon the rulemaking record.

1. The 1980 BE study selected survey subjects who had myopia, which is a relatively routine visual problem. Is there any evidence to indicate that the quality results would have differed if the study had included patients with less common vision problems?

2. Persons with eye pathology were excluded from the sample in the BE study. The study did, however, attempt to measure whether the tests necessary to detect pathology and assess vision problems were performed. Is the use of "process" tests, rather than outcome tests, inappropriate methodology? Are there reasons to believe that the procedures and tests performed to detect eye disease were not performed adequately by those optometrists surveyed?

3. The BE study was designed to measure the effects of commercial practice independent of advertising and, in fact, found that commercial practice had an independent downward impact on price even where advertising was permitted. The BE study data, however, were collected before the advent of advertising in some states. Some people have asserted that the study's price findings concerning the impact of advertising restrictions are unreliable because the data were collected before the full impact of the *Bates* case was felt. Are there reasons why the study's findings that commercial practice has an indepndent effect on price should not be relied on?

4. In its study of commercial practice, the FTC's Bureau of Economics used a multivariate statistical technique to make certain adjustments to the raw price data to account for cost of living differences between cities, differences among survey subjects in prescriptive needs, differences among cities in the supply of optometrists, and differences among cities in the demand for optometric services. The Bureau of Economics states that failure to account for the effects of these variables could lead to inappropriate conclusions about the impact of commercial practice restrictions on price. In a study of this nature, is it appropriate to analyze differences between average adjusted prices rather than average unadjusted prices? Would any other adjustment technique have been more appropriate thant he technique used by the Bureau of Economics?

5. The 1983 contact lens wearer study analyzed only cosmetic contact lens wearers. Is there any evidence to indicate that the quality results would have differed if the study's subjects had included wearers who were aphakic or who suffered from unusual medical or visual problems?

6. The contact lens wearer study analyzed current contact lens wearers rather than former wearers. Is there any reason to believe that the distribution of former contact lens wearers (or, "unsuccessful wearers") among the different fitter groups is significantly different than that of current wearers (or "successful wearers")?

7. What are the costs and benefits of trade name bans? How do trade name bans affect the ability of optometrists to engage in commercial practice? Are these bans necessary to prevent deception? Would it be possible for commercial ophthalmic practice to develop if employment, branching and location restrictions were eliminated, but not trade name bans?

8. What is the effect of laws that require that trade name advertising disclose the names of all optometrists practicing under the trade name? Are such disclosure requirements necessary to prevent deception or other harm to consumers?

9. The proposed rule would remove restrictions on commercial optometric practice imposed by state law or regulation. Do private associations also restrain commercial practice through restrictive membership requirements or other means? If state-imposed restrictions were removed, would association-imposed restrictions have a significant impact on the nature and extent of commercial practice? If so, should the proposed rule be amended to remove association-imposed restrictions?

10. Should the prescription release requirement contained in the Eyeglasses Rule be modified to require that spectacle lens prescriptions be given to patients only in those instances where patients requested them? If so, for how long a period of time should ophthalmologists and optometrists be required to respond to that request? Does the current requirement that a prescription be tendered in every instance result in confusion in some consumers' minds as to whether they should in every instance fill that prescription? What costs does the current requirement impose on ophthalmologists and optometrists who are required to tender a prescription that every patient may not want? Are consumers generally aware of their right to seek and obtain their prescriptions? If so, are consumers generally aware of how they may use their prescriptions?

11. Should the prescription release requirement be modified to require ophthalmologists and optometrists to offer to provide spectacle lens prescriptions to patients? If so, what are the relative merits of requiring that the examiner make that offer (a) orally, (b) by posting a written notice in his or her office, or (c) in some other manner? Should the offer be required to include some explanation of why the offer is being made, or how the offered prescription can be used by the consumer? To what extent, if any, would a requirement to offer to provide prescription reduce the costs of the current requirement?

2. Should the prescription release requirement be repealed altogether? Is this requirement, even when modified to require release only upon request, unnecessary? What are the costs and benefits of the prescription release requirement?

13. Should optometrists and ophthalmologists be required to release duplicate copies of prescriptions to consumers who lose or misplace their original prescriptions? If so, should they be allowed to charge for the duplicate copies?

14. The staff had received few complaints from consumers who wished to obtain replacement or duplicate pairs of eyeglasses from someone other than their original dispenser but were refused access to their current spectacle lens prescriptions. Do a significant number of eyeglass dispensers refuse to return

fillable prescriptions to consumers? Can consumers reasonably avoid such problems? What are the costs and benefits of (a) a rule provision requiring that eyeglass dispensers return fillable prescriptions to consumers, (b) efforts to increase consumer awareness of the need to determine whether a particular dispenser will provide a copy of the prescription before deciding where to purchase eyeglasses, or (c) other actions?

15. The staff has received few complaints from consumers who wanted to buy replacement contact lenses from someone other than their original fitter but were refused access to their lens specifications. Are a significant number of contact lens wearers refused access to their lens specifications? Can consumers reasonably avoid such problems? What are the costs and benefits of (a) a rule provision requiring release of specifications, (b) efforts to increase consumer awareness of the need to determine whether a particular examiner will provide specifications before deciding where to purchase lenses, or (c) other actions?

16. The contact lens study found that the prices charged for replacement contact lenses vary widely. Is that price dispersion explained by differences in lens or service quality, or is it evidence of a lack of competition? If the latter, what is the cause of this lack of competition?

Section E. Public Hearings

Two sets of public hearings will be held on this proposed trade regulation rule. The first will commence on May 20, 1985 at 9:30 a.m. in Room 332, 6th Street and Pennsylvania Avenue, NW, Washington, DC. The second will commence on June 17, 1985, at 9:30 a.m. in Room 12470, 450 Golden Gate Avenue, San Francisco, CA. Tentatively scheduled are 10 days of public hearings at each site.

Persons desiring to present their views orally at the hearings should advise James P. Greenan, Presiding Officer, Federal Trade Commission, Washington, D.C. 20580, 202–523–3564, as soon as possible.

The Presiding Officer appointed for this proceeding shall have all powers prescribed in 16 CFR 1.13(c), subject to any limitations described in this notice.

Section F. Instruction to Witnesses

1. *Advance notice.* If you wish to testify at the hearings, please notify the Presiding Officer immediately by letter or telephone of your desire to appear and file with him or her your complete, word-for-word statement no later than April 26, 1985 for witnesses at the Washington, D.C. hearings and May 31, 1985 for witnesses at the San Francisco, California hearings. (You may testify at only one of the hearings.) This advanced notice is required so that other interested persons can determine the need to ask you questions and have an opportunity to prepare. Any cross-examination that is permitted may cover any of your written testimony, which will be entered into the record exactly as submitted. Consequently, it will not be necessary for you to repeat this statement at the hearing. You may simply appear to answer questions with regard to your written statement or you may deliver a short summary of the most important aspects of the statement within time limits to be set by the Presiding Officer. As a general rule, your oral summary should not exceed twenty minutes.

Prospective witnesses are advised that they may be subject to questioning by designated representatives of interested parties and by members of the Commission's staff. Prospective witnesses are also advised that they may be questioned about any data they have that supports or was used as a basis for general statements made in their testimony. Such questioning will be conducted subject to the descretion and control of the Presiding Officer and within such time limitations as he may impose. In the alternative, the Presiding Officer may conduct such examination himself or he may determine that full and true disclosure as to any issue or question may be achieved through rebuttal submissions or the presentation of additional oral or written statements. In all such instances, the Presiding Officer shall be governed by the need for a full and true disclosure of the facts and shall permit or conduct such examination with due regard for relevance to the factual issues raised by the proposed rule and the testimony delivered by each witness.

2. *Use of Exhibits.* Use of exhibits during oral testimony is encouraged, especially when they are to be used to help clarify technical or complex matters. If you plan to offer documents as exhibits, file them as soon as possible during the period for submission of written comments so they can be studied by other interested persons. If those documents are unavailable to you during this period you must file them as soon as possible thereafter and not later than the deadline for filing your prepared statement. Mark each of the documents with your name, and number them in sequence, (*e.g.*, Jones Exhibit 1). Please also number all pages of each exhibit. The Presiding Officer has the power to refuse to accept for the rulemaking record any hearing exhibits that you have not furnished by the deadline.

3. *Expert Witnesses.* If you are going to testify as an expert witness, you must attach to your statement a *curriculum vitae*, biographical sketch, resume or summary of your professional background and a bibliography of your publications. It would be helpful if you would also include documentation for the opinions and conclusions you express by footnotes to your statements or in separate exhibits. If your testimony is based upon or chiefly concerned with one or two major research studies, copies should be furnished. The remaining citations to other works can be accomplished by using footnotes in your statement referring to those works.

4. *Results of surveys and other research studies.* If in your testimony you will present the results of a survey or other research study, as distinguished from simple references to previously published studies conducted by others, you must also present as an exhibit or exhibits all of the following information that is available to you:

(a) A complete report of the survey or other research study and the information and documents listed in (b) through (e) below if they are not included in that report.

(b) A description of the sampling procedures and selection process, including the number of persons contacted, the number of interviews completed, and the number of persons who refused to participate in the survey.

(c) Copies of all completed questionnaires or interview reports used in conducting the survey or study if respondents were permitted to answer questions in their own words rather than required to select an answer from one or more answers printed on the questionnaire or suggested by the interviewer.

(d) A description of the methodology used in conducting the survey or other research study including the selection of and instructions to interviewers, introductory remarks by interviewers to respondents, and a sample questionnaire or other data collection instrument.

(e) A description of the statistical procedures used to analyze the data and all data tables which underlie the results reported.

Other interested persons may wish to examine the questionnaires, data collection forms and any other underlying data not offered as exhibits and which serve as a basis for your testimony. This information, along with computer tapes that were used to

conduct analyses, should be made available (with appropriate explanatory data) upon request of the Presiding Officer. The Presiding Officer will then be in a position to permit their use by other interested persons or their counsel.

5. *Identification, number of copies, and inspection.* To assure prompt consideration, all materials filed by prospective witnesses pursuant to the instructions contained in paragraphs 1–4 above should be identified as "Ophthalmic Practice Rulemaking Statement" ("and Exhibits," if appropriate), submitted in five copies when feasible and not burdensome, and should include the name, title, address, and telephone number of the prospective witness.

6. *Reasons for requirement.* The foregoing requirements are necessary to permit us to schedule the time for your appearances and that of other witnesses in an orderly manner. Other interested parties must have your expected testimony and supporting documents available for study before the hearing so they can decide whether to question you or file rebuttals. If you do not comply with all of the requirements, the Presiding Officer has the power to refuse to let you testify.

7. *General procedures.* These hearings will be informal and courtroom rules of evidence will not apply. You will not be placed under oath unless the Presiding Officer so requires. You also are not required to respond to any question outside the area of your written statement. However, if such questions are permitted, you may respond if you feel you are prepared and have something to contribute. The Presiding Officer will assure that all questioning is conducted in a fair and reasonable manner and will allocate time according to the number of parties participating, the legitimate needs of each group for full and true disclosure, and the number and nature of the factual issues discussed. The Presiding Officer further has the right to limit the number of witnesses to by heard if the orderly conduct of the hearing so requires.

The deadlines established by this notice will not be extended and hearing dates will not be postponed unless hardship can be demonstrated.

Section G. Notification of Interest

If you wish to avail yourself of the opportunity to question witnesses you must notify the Presiding Officer by March 8, 1985 of your position with respect to the proposed rulemaking proceeding. Your notification must be in sufficent detail to enable the Presiding Officer to identify groups with the same or similar interests respecting the general questions and issues provided in Section E of this notice. The Presiding Officer may require the submission of additional information if your notification is inadequate. If you fail to file an adequate notification in sufficient detail, you may be denied the opportunity to cross-examine witnesses.

Before the hearings commence, the Presiding Officer will identify groups with the same or similar interests in the proceeding. These groups will be required to select a single representative for the purpose of conducting direct or cross-examination. If they are unable to agree, the Presiding Officer may select a representative for each group. The Presiding Officer will notify all interested persons of the identity of the group representatives at the earliest practicable time.

Group representatives will be given an opportunity to question each witness on any issue relevant to the proceeding and within the scope of the testimony. The Presiding Officer may disallow any questioning that is not appropriate for full and true disclosure as to relevant issues. The Presiding Officer may impose fair and reasonable time limitations on the questioning. Given that questioning by group representatives and the staff will satisfy the statutory requirements with respect to disputed issues, no such issues will be designated by the Presiding Officer.

Section H. Post-Hearing Procedures

The Presiding Officer will establish the time that you will be afforded after the close of the hearings to file rebuttal submissions, which must be based only upon identified, properly cited matters already in the record. The Presiding Officer will reject all submissions which are essentially additional written comments rather than rebuttal. The rebuttal period will include the time consumed in securing a complete transcript.

Within a reasonable time after the close of the rebuttal period, the staff shall release its recommendations to the Commission as required by the Commission's Rules of Practice. The Presiding Officer's report shall be released not later than 30 days thereafter and shall include a recommended decision based upon his or her findings and conclusions as to all relevant and material evidence. Post-record comments, as described in § 1.13(h) of the Rules of Practice, shall be submitted not later than 60 days after the publication of the Presiding Officer's report.

Section I. Rulemaking Record

In view of the substantial rulemaking records that have been established in prior trade regulation rulemaking proceedings (and the consequent difficulty in reviewing such records), the Commission urges all interested persons to consider the relevance of any material before submitting it for the rulemaking record. While the Commission encourages comments on its proposed rule, the submission of material that is not generally probative of the issues posed by the proposed rule merely overburdens the rulemaking record and decreases its usefulness, both to those reviewing the record and to interested persons using it during the course of the proceeding. The Commission's rulemaking staff has received similar instruction.

Material that the staff has obtained during the course of its investigation prior to the initiation of the rulemaking proceeding but that is not placed in the rulemaking record will be made available to the public to the extent that it is considered to be nonexempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552.

The rulemaking record, as defined in 16 CFR 1.18(a), will be made available for examination in Room 130, Public Reference Room, Federal Trade Commission, 6th Street and Pennsylvania Avenue NW, Washington, D.C.

Section J. Preliminary Regulatory Analysis

I. Need for, and Objectives of, the Proposed Rule

The Federal Trade Commission (FTC) is examining restrictions on the delivery of eye care services and products in an effort to ensure maximum consumer access to these goods and services at the lowest possible price, without any compromise in the quality of vision care. This preliminary regulatory analysis is included in the Notice of Proposed Rulemaking in order to facilitate its availability to the public.

The proposed rule would remove state-imposed restrictions that bar certain forms of commercial ophthalmic practice and would clarify the current prescription release provisions of 16 CFR Part 456, the Advertising of Ophthalmic Goods and Services Trade Regulation Rule, which is referred to in this analysis as the "Eyeglasses Rule." Detailed information regarding the investigation, findings, and reasoning that support the proposed rule is contained in preceding sections of this Notice and is incorporated by reference

into this analysis, and in the FTC Staff Report entitled "State Restrictions on Vision Care Providers: The Effects on Consumers" (July 1980).

The Federal Trade Commission has identified several such restrictions that it has reason to believe limit competition in the delivery of eye care goods and services and cause substantial consumer injury. These restrictions appear to decrease consumer access to vision care services, increase the cost of these services, and impede the growth of "non-traditional" eye care practices, but fail to provide offsetting improvements in quality of care. The restrictions in question prohibit: (1) Business relationships between optometrists or opticians and lay individuals or firms; (2) the operation or ownership of branch offices by vision care providers; (3) the location of optometrists' offices in pharmacies, department stores, shopping centers, retail optical dispensaries, or other mercantile settings; and (4) the use of trade names by optometrists. The proposed rule would prohibit enforcement of the restrictions enumerated above but would not interfere with a state's ability to enforce specific restrictions aimed at control of harmful practices.

The proposed rule would also clarify the Eyeglasses Rule's current prescription release requirement by modifying the definition of prescription.

II. Legal Authority

The Commission has reason to believe that the public restrictions discussed above may be unfair acts or practices within the meaning of sections 5 and 18 of the Federal Trade Commission Act, 15 U.S.C. 45 and 57(a) because such restrictions may cause substantial injury to consumers that is not outweighed by any countervailing benefits and that consumers cannot reasonably avoid.

III. Alternatives Considered by the Commission

The Commission notes that alternatives under consideration are procedural, not substantive. Unlike some regulatory initiatives where alternative substantive approaches to attain the same ends may exist, in this instance the Commission's intent is to permit certain forms of ophthalmic practice to exist in the marketplace, in the face of state laws explicitly banning them. Thus, the alternatives to the promulgation of a rule focus solely on other approaches for attaining the relaxation of those state restrictions. In the discussion that follows we detail the costs and benefits associated with the attainment of the goal of permitting commercial ophthalmic practice. Assuming the broadest application of successful outcomes, the same costs and benefits would result irrespective of the process used to achieve those ends. We discuss all costs and benefits for the rulemaking option only. To the extent that the use of alternative procedural options may impose different costs and benefits in pursuing the substantive goals, we discuss those in each section.

1. Model State Law

Rather than promulgating a trade regulation rule, the Commission could issue a public report with a model state law or guidelines for voluntary change which embody the Commission's findings and objectives. Adoption of these guidelines in whole or in part would be at the discretion of each state. (See Advance Notice of Proposed Rulemaking, 45 FR 79828–79829 (1980), for a detailed discussion of possible subjects to include in such a model state law.)

2. Cases

One alternative to rulemaking is for the Commission to issue formal complaints on a case-by-case basis against a particular state, private association or ophthalmic practitioner alleged to have engaged in unfair acts or practices.

3. No Further Action by the FTC

The Commission could take no further action and close the investigation. The staff report and economic studies which serve as the primary evidentiary bases for the Commission's decision to proceed with rulemaking could instead be made available to state regulatory bodies in the hope that they would take corrective action in this area.

IV. Cost-Benefit Analysis

The entities that will be affected by the proposed rule are state and local agencies involved in regulation of vision care providers; optometrists, ophthalmologists, opticians, and other persons engaged in the provision of eye care; and consumers of vision care goods and services. The following cost-benefits analyses of the proposed rule and each alternative refer to particular affected entities whenever possible.

In 1982, approximately 22,000 optometrists, 12,000 ophthalmologists, and 26,000 opticians were engaged in active practice. The majority of optometrists are self-employed or practice with the other optometrists as members of a professional corporation. Approximately 10% of optometrists are employed by large optical chains, department stores, or opticians. Consumers annually spend approximately $6 billion on ophthalmic goods and services. Chain optical stores currently hold 15% of the retail eyeware market.

1. Proposed Rule

Costs, Adverse Effects: No direct compliance costs would be imposed on any affected sector by the proposed rule's removal of state restrictions on commercial forms of practice.

a. *Costs to Affected Government Entities*: The proposed rule would remove state statutes and state board regulations which ban commerical forms of practice. Indirect costs might arise should state or local regulatory agencies decide to enact new regulations to control potentially harmful practices. In addition to the cost involved in enacting such regulations, the regulatory agencies might incur some additional enforcement costs.

B. *Costs to Industry Members:* No direct costs would be imposed on optometrists, ophthalmologists, or opticians by the removal of state bans on commercial forms of practice. The rule would only permit, not require, providers to operate branch offices, maintain offices in mercantile locations, use trade names and be employed by lay corporations and individuals.

The only "costs" borne by industry members would be the indirect effects of doing business in a market where greater consumer choice creates more competition. The indirect effect of the rule on various industry members cannot be determined with any degree of precision. A range of consequences can be expected to flow from this restructuring of the market, depending at least in part of how individual providers respond to the changing market conditions.

In markets where commercial practice is now prohibited, it can be anticipated that commercial firms will enter. The market share that firms will capture in those states cannot be predicted. However, in states that currently permit commercial practice, it appeas to co-exist with traditional solo practice.

Data from studies of the ophthalmic market indicate that this market is price elastic: that is, as prices of eye examinations and eyeglasses decline, there is a proportionately greater increase in consumption. Thus, the staff anticipate an increase in total expenditures for vision care products and services. However, the market will be a more competitive one. Some less efficient providers will undoubtely lose business.

c. *Costs to Vision Care Consumers:* No direct economic cost would be

imposed on consumers of vision care by the removal of bans on commercial forms of practice. To the contrary, two FTC studies indicate that average prices for eye examinations, eyeglasses, and contact lenses are lower in markets where commercial practice is permitted, and that no adverse impact on the quality of vision care services should result from the removal of restrictions on forms of practice.

Benefits: a. *Benefits to Affected Government Entities:* State and local regulatory agencies would incur lower compliance and enforcement costs if bans on commercial forms of practice were removed. However, these lower costs might be offset to some extent if states or agencies enact new regulations to control potentially harmful practices.

b. *Benefits to Industry Members:* Present vision care practitioners would be able to own and operate more than a limited number of offices, locate in mercantile settings, use a trade name for their practice, and enter into employment, leasing, or other business arrangements with lay individuals and firms, notwithstanding current state law to the contrary. Corporations or other business entities presently selling ophthalmic goods would be able to hire, lease space to, or associate with optometrists in order to offer one-stop shopping to consumers.

c. *Benefits to Vision Care Consumers:* By removing state restrictions on commercial practice, consumers of vision care should be able to purchase vision care goods and services at lower prices without any compromise in quality of care. FTC studies indicate that: (1) Prices are significantly lower in cities where commercial practice and advertising are not restricted; (2) commercial optometrists charge lower prices than non-commercial optometrists; (3) non-commercial providers who operate in markets where commercial practice is permitted charge less than their counterparts in cities where commercial practice is prohibited; and (4) overall quality of care is no lower in commercial than in non-commercial markets. Consumers may be able to obtain these lower prices that result from increased competition from two groups: non-commercial practitioners who lower their prices in response to increased competition and commercial practitioners who offer vision care at low prices by taking advantage of economies of scale. Due to the lifting of restrictions on commercial forms of practice, it can be anticipated that some consumers will purchase vision care on a more frequent basis.

In addition, consumers would be able to obtain one-stop service (eye examination plus eyeglasses or contact lenses) from optometrists who are located near or lease space from a retail optical dispensary in response to the lifting of location restrictions, or from retail optical firms which offer the services of an optometrist to perform eye examinations.

2. No Rule—Model State Law

Costs, Adverse Effects: a. *Costs to Affected Government Entities:* A model state law would impose no costs directly because it is an option to be adopted by state government entities at their discretion.

b. *Costs to Industry Members:* Assuming that all states adopted a model law, costs to industry members should be the same as if a rule were adopted. However, if some states do not enact the model state law while others enact only certain provisions or different versions altogether, the end result would be a lack of uniformity in the state laws concerning commercial practices. This might burden practitioners or firms who wish to maintain interstate operations.

c. *Costs to Vision Care Consumers:* As stated above, no direct economic costs would be imposed on consumers by removal of bans on commercial forms of practice. In addition, on the basis of the results of the FTC studies, no adverse impact on the quality of vision care is expected to result if a state adopts a model state law permitting commercial forms of practice.

Benefits: a. *Benefits to Affected Government Entities:* A model state law would provide states with valuable information, but would not remove state laws. Individuals states or state boards could modify the model law to meet particular circumstances.

b. *Benefits to Industry Members:* If a state adopts a model state law which permits the commercial forms of practice contained in the proposed rule, benefits to industry members in that state would be similar to those resulting from promulgation of a trade regulation rule. This result assumes that commercial practice would not be burdened indirectly by restrictive state enforcement policies or regulations.

c. *Benefits to Vision Care Consumers:* If a state adopts a model state law permitting commercial forms of ophthalmic practice, benefits to consumers in that state would be the same as those resulting from promulgation of the trade regulation rule.

3. Cases Against Private Associations and/or State Government Entities

Costs, Adverse Effects: a. *Costs to Affected Parties:* The issuance of a complaint by the Commission against a private association or against a state regulatory body alleging Section 5 unfairness concerning commercial practice restrictions would result in adjudication costs for that entity. If the Commission issued a final order, a party against whom the complaints were issued would have a comply with the terms of that order. Compliance costs would parallel those of a trade regulation rule.

b. *Costs to Industry Members:* If the Commission pursued the option of a case-by-case adjudication, those cases would necessarily be against states and private associations that have imposed commercial practice bans. Costs to industry members in the event of successful litigation by the Commission would be the same as if a rule were adopted. The only significant difference in procedural costs would be that rulemaking entitles affected industry groups to participate. In adjudication against a specific state governmental entity, affected industry members would have to seek intervenor or *amicus curiae* status.

c. *Costs to Vision Care Consumers:* Assuming the broadest application of a final order, successful litigation would result in the same substantive costs and benefits as rulemaking. However, consumers would not have a right to participate in litigation as they would in rulemaking proceedings.

Benefits: a. *Benefits to Affected Parties:* Private associations or state and local regulatory agencies would incur lower compliance and enforcement costs if bans on commercial forms of practice were removed. However, these lower costs might be offset to some extent if such entities enact new ethical codes or regulations to control potentially harmful practices.

b. *Benefits to Industry Members:* A case against a particular state would produce benefits to industry members in that state similar to those that would result from promulgation of a trade regulation rule.

A case against an association in a state that prohibited commercial practice would result in little if any benefit to industry members. A case against an association in a state that permits commercial practice would enable industry members who wished to engage in commercial practice to enjoy the benefits of association membership.

c. *Benefits to Vision Care Consumers:* Any case that resulted in the removal of barriers to commercial practice in a particular state would produce benefits to consumers in that state similar to those that would result from promulgation of a trade regulation rule.

4. No Further Action by the FTC

Costs, Adverse Effects: a. *Costs to Affected Government Entities:* None. Should the FTC take no further action regarding state-imposed commercial restrictions, these state restrictions will remain operative. FTC materials could be provided to state and local regulatory entities should they wish to consider modification of existing state laws or regulations.

b. *Costs to Industry Members:* Present conditions of practice will probably continue to exist if the FTC terminates its activity regarding commercial restraints. Ophthalmic practitioners who would adopt forms of commercial practice if permitted to do so by state law would be adversely affected by FTC inactivity.

c. *Costs to Vision Care Consumers:* Consumer injury, which the Commission has reason to believe results from restraints on commercial forms of practice, will continue if the Commission terminates its activity in this area. Consumers residing in markets where restrictions exist will be adversely affected since the *status quo* of these markets presently limits competition. As a result, consumers in markets where restrictions exist may continue to face artifically high costs due to limited competition in the eye care goods and services markets.

Benefits: a. *Benefits to Affected Government Entities:* State law and regulation will not be preempted by federal regulation if the FTC takes no further action. State and local governments will not be obliged to reevaluate existing laws or enact any new laws.

b. *Benefits to Industry Members:* Non-commercial practitioners may continue to operate without encountering increased competion.

c. *Benefits to Vision Care Consumers:* None. Consumers would not benefit by termination of Commission activity in this area. The potential benefits associated with commercial practice would be foreclosed if the Commission took no further action and no action at the state level were forthcoming

V. Explanation of why the Commission has Initiated a Rulemaking Proceeding

The Commission has considered all remedial options discussed in Part 1 of this Regulatory Analysis. Of all the alternatives considered, the Commission believes that rulemaking is the most efficient and orderly way to explore further the complex issues involved in this investigation. Although the Commission has decided to initiate a rulemaking proceeding, it should be noted that the commercial practice portion of the proposed rule is essentially deregulatory in nature. By barring enforcement of state restrictions on commercial forms of practice, the proposed rule would reduce barriers to competition and remove direct government interference with practitioners' decisionmaking. The evidence to date indicates that these restrictions result in substantial consumer injury by causing prices to be unnecessarily high and by limiting access to care. At the same time, these restraints do not offer any countervailing benefit in terms of higher quality vision care. In addition, this injury is not one consumers can reasonably avoid because it results from government-imposed restrictions. Therefore, the Commission has reason to believe that such restrictions may be unfair to consumers. The proposed modification of the prescription release requirement would simply clarify the nature and extent of that requirement.

The Commission has carefully considered the option of preparing a model state law. The model state statute could include provisions permitting the forms of practice contained in the proposed rule. The preparation of such a statute, however, would be only a recommendation by the Commission and would depend on voluntary action by the states themselves to accomplish the desired changes. While the preparation of a model state law might provide an impetus for state action, it is unlikely that most or all 50 states would enact the model state law. Despite the 1980 publication of the Bureau of Economics study, which found that commercial practice restrictions cause higher prices but do not maintain or enhance quality of care, there has been little movement at the state level to change the applicable laws. Moreover, a significant change in the current state regulatory scheme is not likely to occur in the time that it could be accomplished by the Commission through promulgation of a trade regulation rule. Finally, some states might only enact certain portions of the model statute or might enact different versions altogether.

Another remedial option is for the Commission to issue complaints against individual states or private associations concerning commercial practice restrictions. The Commission has considered this alternative and has determined that this is not the most appropriate way to proceed for several reasons. First, an action against a private association would still leave state laws intact. Second, a final order against a state or private association might not have application to others; hence, much of the consumer injury believed to exist might not be alleviated. Given the number of states which restrict commercial practice, the Commission has determined that the issuance of individual complaints would not be an efficient use of Commission resources. Only a remedy with nationwide application will eliminate the widespread consumer injury.

For these reasons, the Commission has determined that initiation of a rulemaking proceeding is the most appropriate way to proceed and is the most efficient use of Commission resources. Through rulemaking, the Commission can present a thorough analysis of the issues raised by this investigation. Rulemaking also permits direct participation by all interested parties. If the Commission ultimately determines that state commercial practice restraints are unfair under Section 5, a trade regulation rule is the only remedy that would alleviate the consumer injury nationwide.

Section K. Initial Regulatory Flexibility Analysis

The following discussion is included with the Commission's Preliminary Regulatory Analysis for the proposed rule pursuant to the requirements of the Regulatory Flexibility Act, Pub. L. 96-354. The Act requires an analysis of the anticipated impact of the proposed rule on small business.[6] The analysis must contain a description of: (1) The reasons why action is being considered; (2) the objectives of and legal basis for the proposed rule; (3) the class and number of small entities affected; (4) the projected reporting, recordkeeping and other compliance requirements of the proposed rule; (5) any existing relevant federal rules which may duplicate, overlap or conflict with the proposed rule; [7] and (6) any significant alternatives to the proposed rule which accomplish its objectives and, at the same time, minimize its impact on small entities.[8] The preliminary regulatory analysis preceding this section discussed items, 1, 2 and 6 above in detail and therefore will not be repeated

[6] 5 U.S.C. 603(a) (1983).
[7] 5 U.S.C. 603(b) (1)-(5) (1983).
[8] 5 U.S.C. 603(c) (1983).

here.[9] Thus, this analysis will discuss items 3–5 above.

I. Entities to Which the Rule Applies

The proposed rule will directly affect all ophthalmologists and optometrists who perform eye examinations and all optometrists, opticians and others who desire to engage in commerical ophthalmic practice. In 1982, there were approximately 12,000 ophthalmologists, 22,000 optometrists, and 26,000 opticians in active practice in the United States. Most ophthalmologists and optometrists are self-employed. The majority of opticians are self-employed or employed in "independent" retail optical establishments. An increasing number of vision care providers, however, appear to be adopting alternate modes of practice, including partnerships, group practice, and, in the case of optometrists and opticians, employment by or leasing arrangements with commercial optical establishments (such as department stores or large retail optical chains).

Ophthalmologists, optometrists and opticians all provide eye care service to consumers. Ophthalmologists and optometrists examine the eyes and prescribe and dispense eyeglasses and contact lenses. Opticians dispense eyeglasses, and, in some states, they fit and dispense contact lenses.

Most ophthalmologists are doctors of medicine, but some are doctors of osteopathy. They specialize in the diagnosis and treatment of eye diseases and abnormal conditions, including refractive errors. As physicians, they are authorized to perform surgery or to prescribe drugs, lenses or other treatment to remedy these conditions.

Doctors of optometry examine the eye and related structures to determine the presence of vision problems, eye diseases or other abnormalities. They prescribe and adapt corrective lenses or other optical aids and may use visual training aids when indicated to preserve or restore maximum visual acuity. Generally, optometrists do not prescribe drugs, definitively diagnose or treat eye diseases, or perform surgery. In a few states, however, they may be able to treat eye diseases in certain circumstances.

Dispensing opticians (or ophthalmic dispensers) make, fit, supply and adjust eyeglasses according to prescriptions written by ophthalmologists or optometrists. In many states they are also authorized to duplicate spectacle lenses without a prescription, and, in some states, they may fit contact lenses on their own authority or under the direction or supervision of an ophthalmologists or optometrist. By custom, practice and tradition, opticians in many states also dispense contact lenses pursuant to an eye doctor's written specifications or under certain other conditions.

II. Compliance Requirements

The Commission believes that reporting, recordkeeping or other compliance requirements of the proposed rule should not have a disproportionate impact on small entities as compared to large firms. The proposed rule, in fact, would impose no such mandatory requirements on any entities for compliance purposes. Rather, the primary impact of the proposed rule on small entities would stem from the increased competition in the vision care industry which can be anticipated as a result of the rule's deregulatory effects.

The economic impact on individual small entities from increased competition in the vision care industry, although difficult to determine, could be substantial. However, the proposed rule provisions removing certain public restraints on commercial ophthalmic practice would permit small entities (*i.e.*, optometrists and opticians) to engage in alternate modes of practice, including commercial practice, or to expand, should they desire to do so.

The proposed rule provisions removing certain commercial practice restraints could adversely affect some small entities while benefitting others. This result would stem from the increased competition anticipated as a result of removing bans on commercial ophthalmic practice. In states that currently restrict commercial practice, for example, the market share of small entities providing vision care might tend to decline as large commercial practices enter the market. However, other small entities that wish to engage in commercial practice are not permitted to do so under current state laws.

We are aware of no existing federal rules that duplicate, overlap or conflict with the proposed rule.

Section E. Proposed Trade Regulation Rule

Notice is hereby given that the Federal Trade Commission, pursuant to the Federal Trade Commission Act, as amended, 15 U.S.C. 41 *et seq.*, the provisions of part 1, subpart B of the Commission's Procedures and Rules of Practice, 16 CFR 1.7 *et seq.*, and the Administrative Procedure Act, 5 U.S.C. 553 *et seq.*, has initiated a proceeding for the promulgation of a trade regulation rule concerning ophthalmic practice.

Accordingly, the Commission proposes the following Trade Regulation Rule in the form of a revision of 16 CFR Part 456. Set forth below is the full text of the proposed rule, which has been integrated into the existing Eyeglasses Rule. In the text which immediately follows, new rule provisions are highlighted by arrows and deleted provisions are bracketed.[10] The text of the proposed rule then appears without the deleted portions for easier reading.

PART 456—[ADVERTISING OF OPHTHALMIC GOODS AND SERVICES] ►OPHTHALMIC PRACTICE RULES◄

§ 456.1 Definitions.

(a) A [*"buyer"*] ►"patient"◄ is any person who has had an eye examination.

[(b) The "dissemination of information" is the use of newspapers, telephone directories, window displays, signs, television, radio, or any other medium to communicate to the public any information, including information concerning the cost and availablity of a product or service.]

[(c)] ►(b)◄ An "*eye examination*" is the process of determining the refractive condition of a person's eyes or the presence of any visual anomaly by the use of objective or subjective tests.

[(d)] ►(c)◄ "*Ophthalmic goods*" consist of eyeglasses, or any component of eyeglasses, and contact lenses.

[(e)] ►(d)◄ "*Ophthalmic services*" are the measuring, fitting, and adjusting of ophthalmic goods to the face subsequent to an eye examination.

►(e) An "*ophthalmologist*" is any Doctor of Medicine or Osteopathy who perfoms eye examinations.◄

►(f) An "*optometrist*" is any Doctor of Optometry.◄

[(f)] ►(g)◄ A "*person*" means any party over which the Federal Trade Commission has jurisdiction. This includes individuals, partnerships, corporations, [and] professional associations►, and other entities.◄

[(g)] ►(h)◄ A "*prescription*" is the written specifications for [ophthalmic] ►spectacle◄ lenses which are derived from an eye examination►, including◄ [The prescription shall contain all of the information necessary to permit the buyer to obtain the necessary ophthalmic goods from the seller of his choice. In the case of a prescription for contact lenses, the refractionist must

[9] 5 U.S.C. 605(a) explicitly permits such incorporation.

[10] Some of the deleted portions correspond to those provisions of the original Rule which were remanded by virtue of the decision in American Optometric Association v. Federal Trade Commission, 626 F.2d 887 (D.C. Cir. 1980).

include in the prescription only those measurements and directions which would be included in a prescription for spectacle lenses.]

[All prescriptions shall include] all of the information specified by state law, if any, ►necessary to obtain spectacle lenses.◄

[(h) A "*refractionist*" is any Doctor of Medicine Osteopathy, or Optometry or any other person authorized by state law to perform eye examinations.]

(i) A "*seller*" is any person, or his ►or her◄ employee or agent, who sells or provides ophthalmic goods and services directly to the public.

►(j) A "*trade name ban*" is any state law, rule or regulation which prohibits optometrists from practicing or holding themselves out to the public under the name of the person by whom they are employed or a name other than the name shown on their license or certificate of registration.◄

[§ 456.2 Private Conduct].

[(a) It is an unfair act or practice for sellers to fail to disseminate information concerning ophthalmic goods and services notwithstanding state or local law to the contrary. *Provided*, Violation of this subpart by any seller acting alone shall not be deemed to be a violation of section 5(a)(1) of the Federal Trade Commission Act.]

[To prevent this unfair act or practice, any seller may engage in the dissemination of information concerning ophthalmic goods and services subject to the limitations expressed in § 456.5 below.]

[(b) It is an unfair act or practice for refractionists to fail to disseminate information concerning eye examinations notwithstanding state or local law to the contrary. *Provided*, Violation of this subpart by any refractionist acting alone shall not be deemed to be a violation of section 5(a)(1) of the Federal Trade Commission Act.]

[To prevent this unfair act or practice, any refractionist may engage in the dissemination of information concerning eye examinations. Nothing in this subpart shall excuse a refractionist from compliance with any state or local law which permits the dissemination of information concerning eye examinations, including information on the cost and availability of those examinations but require that specified affirmative disclosures also be included.]

[§ 456.3 Public Restraints].

[It is an unfair act or practice under Section 5 of the Federal Trade Commission Act for any state or local government entity or any subdivision thereof, state instrumentality, or state or local governmental official to enforce any:]

[(a) prohibition, limitation or burden on the dissemination of information concerning ophthalmic goods and services by any seller or group of sellers, or]

[(b) prohibition, limitation or burden on the dissemination of information concerning eye examinations by any refractionist. *Provided:* Nothing in subpart (b) shall be construed to prohibit the enforcement of a state or local law which permits the dissemination of information concerning eye examinations, including information on the cost and availability of those examinations, but requires that specified affirmative disclosures also be included.]

[Violation of subparts (a) and (b) shall not be deemed for purposes of section 5(m)(1)(A) or section 19 of the Federal Trade Commission Act to be a violation of section 5(a)(1) of the Act.]

[§ 456.4 Conformance to State Law].

[It is an unfair act or practice under section 5 of the Federal Trade Commission Act:]

[(a) for any seller to reduce, limit or burden the dissemination of information concerning ophthalmic goods and services in order to comply with any law, rule, regulation or code of conduct of any nonfederal legislative, executive, regulatory or licensing entity or any other entity or person, which would have the effect of prohibiting, limiting, or burdening the dissemination of this information, or]

[(b) for any refractionist to reduce, limit, or burden the dissemination of information concerning eye examinations in order to comply with any law, rule, regulation or code of conduct of any nonfederal legislative, executive, regulatory or licensing entity or any other entity or person, which would have the effect of prohibiting, limiting, or burdening the dissemination of this information. *Provided:* To the extent that a state or local law, rule, or regulation permits the dissemination of information concerning eye examinations, including information on the cost and availability of those examinations, compliance with that law or regulation shall not be construed to reduce, limit or burden the dissemination of information concerning eye examinations.]

[§ 456.5 Permissible State Limitations].

[(a) To the extent that a state or local law, rule, or regulation requires that any or all of the following items be included within any dissemination of information concerning opthalmic goods and services, such a law, rule, or regulation shall not be considered to prohibit, limit, or burden the dissemination of information.]

[(1) whether an advertised price includes single vision and/or multifocal lenses;]

[(2) whether an advertised price for contact lenses refers to soft and/or hard contact lenses;]

[(3) whether an advertised price for ophthalmic goods includes an eye examination;]

[(4) whether an advertised price for ophthalmic goods includes all dispensing fees, and]

[(5) whether an advertised price for eyeglasses includes both frames and lenses.]

[(b) Where a state or local law, rule, or regulation applies to all retail advertisements of consumer goods and services (including a law, rule, or regulation which requires the affirmative disclosure of information or imposes reasonable time, place and manner restrictions), such a law or regulation shall not be considered to prohibit, limit, or burden the dissemination of information.]

[(c) If, upon application of an appropriate state or local governmental agency, the Commission determines that any additional requirement of any such state or local governmental agency deemed by that agency to be necessary to prevent deception or unfairness is reasonable and does not unduly burden the dissemination of information, then that requirement shall be permitted to the extent specified by the Commission.]

[§ 456.6 Private Restraints.]

[(a) It is an unfair act or practice for any person, other than a state or a political subdivision or agency thereof, to prohibit, limit or burden:]

[(1) the dissemination of information concerning opthalmic goods and services by any seller;]

[(2) the dissemination of information concerning eye examinations by any refractionist. *Provided:* Nothing in this subpart shall be construed to prohibit any person from imposing reasonable affirmative disclosure requirements on the dissemination of information concerning eye examinations.]

[(b) Any organization or association which is not composed primarily of sellers and/or refractionists, which adopts or enforces self-regulatory guidelines for the dissemination of information which apply to all retail advertisements of consumer goods and

services, shall not be deemed to be in violation of this subpart.]

[(c) The conditioning of membership in a professional or trade association of sellers or refractionists on a requirement that members or prospective members of that association not engage in the dissemination of information concerning opthalmic goods and services and eye examinations or a requirement that opthalmic goods and services be advertised only in a prescribed manner shall be deemed to prohibit, limit or burden the dissemination of that information.]

§ 456.[7] ▶2◀ Separation of Examination and Dispensing.

[In connection with the performance of eye examinations] ▶I◀t is an unfair act or practice for [a refractionists] ▶an opthalmologist or optometrist◀ to:

(a) Fail to give to the [buyer] ▶patient◀ [a] ▶one◀ copy of the [buyer's] ▶patient's spectacle lens◀ precription immediately after the eye examination is completed. *Provided*: [A refractionist] ▶An opthalmologist or optometrist◀ may refuse to give the [buyer] ▶patient◀ a copy of the [buyer's] ▶patient's◀ prescription until the [buyer] ▶patient◀ has paid for the eye examination, but only if that [refractionist] ▶ophthalmologist or optometrists◀ would have required immediate payment from that [buyer] ▶patient◀ had the examination revealed that no ophthalmic goods were required;

(b) Condition the availability of an eye examination to any person on a requirement that [that person] ▶the patient◀ agree to purchase any opthalmic goods from the [refractionist] ▶opthalmologist or optometrist◀;

(c) Charge the [buyer] ▶patent◀ any fee in addition to the [refractionist's] ▶ophthalmologist's or optometrist's◀ examination fee as a condition to releasing the prescription to the [buyer] ▶patient◀. *Provided*: [A refractionist] ▶An opthalmologist or optometrist◀ may charge an additional fee for verifying ophthalmic goods dispensed by another seller when the additional fee is imposed at the time the verification is performed; or

(d) Place on the prescription, or require the [buyer] ▶patient◀ to sign, or deliver to the [buyer] ▶patient◀ a form or notice waiving or disclaiming the liability or responsibility of the [refractionist] ▶ophthalmologist or optomertrist◀ for the accuracy of the eye examination or the accuracy of the ophthalmic goods and services dispensed by another seller.

§ 456.[8] ▶3◀ Federal or State Employees.

[Nothing in this part shall be construed to prohibit any federal, state or local government entity from adopting and enforcing standards or requirements concerning the dissemination of information and release of prescriptions by sellers or refractionists employed by those governmental entities.]

▶The requirements of § 456.2 of this rule do not apply to ophthalmologists, optometrists or sellers in the employ of any federal, state or local governmental entity.◀

▶§ 456.4 State Bans on Commercial Practice.

(a) It is an unfair act or practice for any state or local governmental entity to enforce any law, rule or regulation which directly or indirectly:

(1) Prohibits employer-employee or other business relationships between optometrists or sellers and persons other than ophthalmologists or optometrists;

(2) Limits the number of offices which an optometrist or seller may own or operate;

(3) Prohibits an optometrist from practicing in a pharmacy, department store, shopping center, retail optical dispensary or other mercantile location;

(4) Imposes a trade name ban.

(b) If any state or local governmental entity or officer violates any of the provisions of § 456.4(a) (1)–(4), that person will not be subject to any liability under Sections 5(m)(1)(A) or 19 of the Federal Trade Commission Act.

§ 456.[9] ▶5◀ Declaration of Commission Intent.

[(a) It is the purpose of this part to allow retail sellers of ophthalmic goods and services to disseminate information concerning those goods and services in a fair and nondeceptive manner to prospective purchasers. This part is intended to eliminate certain restraints, burdens, and controls imposed by state and local governmental action as well as by private action on the dissemination of information, including advertising, concerning ophthalmic goods and services.]

[It is the intent of the Commission that this part shall preempt all state and local laws, rules, or regulations that are repugnant to this part, and that would in any way prevent or burden the dissemination of information by retail sellers of ophthalmic goods and services to prospective purchasers, except to the extent specifically permitted by this part. All state or local laws, rules, or regulations which burden the dissemination of information by requiring affirmative disclosure specifically addressed to ophthalmic goods and services are preempted, except for those specifically permitted by this part. State and local laws, rules, or regulations which apply to advertising of all consumer goods and services, including those that require affirmative disclosure of information, are not preempted.]

[(b) It is the Commission's intent that state laws which do not permit refractionists to disseminate information concerning eye examinations, including information concerning the cost and availability of those examinations, be preempted. State and local laws, rules or regulations which require affirmative disclosure of information in all disseminations of information concerning eye examinations are not preempted.]

[(c) The Commission intends this part to be as self-enforcing as possible. To that end, it is the Commission's intent that this part may be used, among other ways, as a defense to any proceeding of any kind which may be brought against any retail seller of ophthalmic goods and services or refractionist who advertises in a nondeceptive and fair manner.]

[(d) It is not the Commission's intent to compel any seller or refractionist to disseminate information by virtue of this part. On the contrary, the provisions of this part are intended solely for the protection of those sellers and refractionists who want to disseminate information but have been restrained or prevented from advertising due to the prohibitions and restrictions of state and local laws and regulations, or by private action.]

[(e)] (a) In prohibiting the use of waivers and disclaimers of liability in § [456.7(d)] 456.2(d), it is not the Commission's intent to impose liability on [a refractionist] an opthalmologist or optometrist for the ophthalmic goods and services dispensed by another seller pursuant to that [refractionists's] ophthalmologist's or optometrist's prescription.

▶(b) It is the purpose of this rule to allow optometrists or sellers of ophthalmic goods and services to work for or enter into other business relationships (such as partnerships or franchise agreements) with non-professional corporations or unlicensed persons. The rule is not intended to interfere with a state's ability to enforce any law, rule, or regulation designed to control specific harmful practices, such as improper interference in the professional judgment of optometrists or sellers or compensation schemes used to pay employed optometrists or sellers

which encourage over-prescription so long as the law, rule, or regulation does not directly or indirectly prohibit optometrists or sellers from working for or entering into other business relationships with nonprofessional corporations or unlicensed persons.◄

►(c) It is the purpose of this rule to allow optometrists, sellers, or any other person to own or operate any number of offices. The rule is not intended to interfere with a state's ability to enforce any law, rule, or regulation requiring that opthalmic goods, services or eye examinations provided at each office be supplied by a person qualified under state law to do so or regulating the services provided at each office, as long as states do not directly or indirectly limit the number of offices which an optometrist or seller can own or operate.◄

►(d) It is the purpose of this rule to allow optometrists to practice in a pharmacy, department store, shopping center, retail optical dispensary or other mercantile location. The rule is not intended to interfere with the state's ability to enforce general zoning laws or any law, rule, or regulation which prohibits the location of optometric or optical practice in areas which would create a public health or safety hazard.◄

►(e) It is the purpose of this rule to allow optometrists to practice or hold themselves out to the public under trade names. The rule is not intended to prevent states from enforcing any law, rule, or regulation which requires that the identity of an optometrist be disclosed to a patient at the time an eye examination is performed or ophthalmic goods or services are dispensed. This rule also is not intended to prohibit states from enforcing any state law, rule, or regulation that is reasonably necessary to prevent the deceptive use of trade names in advertising.◄

►(f) The Commission intends the rule to be as self-enforcing as possible. To that end, it is the Commission's intent that this rule may be used, among other ways, as a defense to any proceeding of any kind which may be brought against any seller or optometrist for practicing under a trade name, working for or associating with a non-professional corporation or unlicensed person, operating branch offices or practicing in a mercantile location.◄

[(f)] ►(g)◄ The rule, each subpart, and the Declaration of Commission Intent and their application are separate and severable.

* * * * *

Part 456—Ophthalmic Practice Rules

§ 456.1 Definitions

(a) A "*patient*" is any person who has had an eye examination.

(b) An "*eye examination*" is the process of determining the refractive condition of a person's eyes or the presence of any visual anomaly by the use of objective or subjective tests.

(c) "*Ophthalmic goods*" consist of eyeglasses, or any component of eyeglasses, and contact lenses.

(d) "*Ophthalmic services*" are the measuring, fitting, and adjusting of ophthalmic goods to the face subsequent to an eye examination.

(e) An "*ophthalmologist*" is any Doctor of Medicine or Osteopathy who performs eye examinations.

(f) An "*optometrist*" is any Doctor of Optometry.

(g) A "*person*" means any party over which the Federal Trade Commission has jurisdiction. This includes individuals, partnerships, corporations, professional associations, or other entities.

(h) A "*prescription*" is the written specifications for spectacle lenses which are derived from an eye examination, including all of the information specified by state law, if any, necessary to obtain spectacle lenses.

(i) A "*seller*" is a person, or his employee or agent, who sells or provides ophthalmic goods and services directly to the public.

(j) A "*trade name ban*" is any state law, rule or regulation which prohibits optometrists from practicing or holding themselves out to the public under the name of the person by whom they are employed or a name other than the name shown on their license or certificate of registration.

§ 456.2 Separation of Examination and Dispensing

It is an unfair act or practice for an ophthalmologist or optometrist to:

(a) Fail to give to the patient one copy of the patient's spectacle lens prescription immediately after the eye examination is completed. Provided: An ophthalmologist or optometrist may refuse to give the patient a copy of the patient's prescription until the patient has paid for the eye examination, but only if that ophthalmologist or optometrist would have required immediate payment from that patient had the examination revealed that no ophthalmic goods were required;

(b) Condition the availability of an eye examination to any person on a requirement that the patient agree to purchase any ophthalmic goods from the ophthalmologist or optometrist;

(c) Charge the patient any fee in addition to the ophthalmologist's or optometrist's examination fee as a condition to releasing the prescription to the patient. *Provided:* An ophthalmologist or optometrist may charge an additional fee for verifying ophthalmic goods dispensed by another seller when the additional fee is imposed at the time the verification is performed; or

(d) Place on the prescription, or require the patient to sign, or deliver to the patient a form or notice waiving or disclaiming the liability or responsibility of the ophthalmologist or optometrist for the accuracy of the eye examination or the accuracy of the ophthalmic goods and services dispensed by another seller.

§ 456.3 Federal or State Employees

The requirements of Section 456.2 of this rule do not apply to ophthalmologists, optometrists or sellers in the employ of any federal, state or local governmental entity.

§ 456.4 State Bans on Commercial Practices.

(a) It is an unfair act or practice for any state or local governmental entity to enforce any law, rule or regulation which

(1) Prohibits employer-employee or other business relationships between optometrists or sellers and persons other than ophthalmologists or optometrists;

(2) Limits the number of offices which an optometrist or seller may own or operate;

(3) Prohibits optometrist from practicing in a pharmacy, department store, shipping center, retail optical dispensary or other mercantile location

(4) Imposes a trade name ban.

(b) If any state or local governmental entity or officer violates any of the provisions of § 456.4(a) (1)–(4), that person will not be subject to civil penalty, redress, or any other monetary liability under sections 5(m)(1)(A) or 19 of the Federal Trade Commission Act.

§ 456.5 Declaration of Commission Intent

(a) In prohibiting the use of waivers and disclaimers of liability in § 456.2(d), it is not the Commission's intent to impose liability on an ophthalmologist or optometrist for the ophthalmic goods and services dispensed by another seller pursuant to the ophthalmologist's or optometrist's prescription.

(b) It is the purpose of the rule to allow optometrists or sellers of ophthalmic goods and services to work for or enter into other business relationships (such as partnerships or

franchise agreements) with non-professional corporations or unlicensed persons. The rule is not intended to interfere with a state's ability to enforce any law, rule, or regulation designed to control specific harmful practices, such as improper interference in the professional judgment of optometrists or sellers or compensation schemes used to pay employed optometrists or sellers which encourage over-prescription, so long as the law, rule, or regulation does not directly or indirectly prohibit optometrists or sellers from working for or entering into other business relationships with non-professional corporations or unlicensed persons.

(c) It is the purpose of this rule to allow optometrists, sellers, or any other person to own or operate any number of offices. The rule is not intended to interefere with a state's ability to enforce any law, rule, or regulation requiring that ophthalmic goods, services or eye examinations provided at each office be supplied by a person qualified to do so or regulating the services provided at each office, as long as states do not directly or indirectly limit the number of offices which an optometrist, seller or any other person may own or operate.

(d) It is the purpose of this rule to allow optometrists to practice in a pharmacy, department store, shopping center, retail optical dispensary or other mercantile location. The rule is not intended to interfere with the state's ability to enforce general zoning laws or any law, rule, or regulation which prohibits the location of optometric or optical practice in areas which would create a public health or safety hazard.

(e) It is the purpose of this rule to allow optometrists to practice or hold themselves out to the public under trade names. The rule is not intended to prevent states from enforcing any law, rule, or regulation which requires that the identity of an optometrist or seller be disclosed to a patient at the time an eye examination is performed or ophthalmic goods or services are dispensed. This rule also is not intended to prohibit states from enforcing any state law, rule, or regulation that is reasonably necessary to prevent the deceptive use of trade names in advertising.

(f) The Commission intends the rule to be as self-enforcing as possible. To that end, it is the Commission's intent that this rule may be used, among other ways, as a defense to any proceeding of any kind which may be brought against any seller or optometrist for practicing under a trade name, working for or associating with a non-professional corporation or unlicensed person, operating branch offices or practicing in a mercantile location.

(g) The rule, each subpart, and the Declaration of Commission Intent and their application are separate and severable.

By direction of the Commission, Commissioner Azcuenaga abstaining.

Emily H. Rock,

Secretary.

[FR Doc. 85-1 Filed 1-3-85; 8:45 am]

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(The following has been reprinted from the Federal Register of June 7, 1985 - 50 FR 23996)

16 CFR Part 456

Ophthalmic Practice Rules; Proposed Trade Regulation Rule

AGENCY: Federal Trade Commission.

ACTION: Notice of Postponement of Scheduled Public Hearings and Extension of Time Within Which to File Prepared Statements of Testimony by Witnesses and Exhibits.

SUMMARY: The Federal Trade Commission has postponed public hearings in the Ophthalmic Practice Rules Trade Regulation Rule Proceeding, scheduled for San Francisco, California, until July 1, 1985. The time for filing statements of testimony by witnesses and exhibits has been extended to June 7, 1985.

DATE: Public Hearings will commence in Room 12470, San Francisco Regional Office of the Federal Trade Commission at 9:30 a.m., July 1, 1985.

Prepared statements of testimony by witnesses and exhibits must be submitted on or before June 7, 1985.

ADDRESSES: Prepared statements of testimony by witnesses and exhibits should be sent to Presiding Officer James P. Greenan, Federal Trade Commission, 6th Street and Pennsylvania Avenue, NW., Washington, D.C. 20580.

FOR FURTHER INFORMATION CONTACT: John Mooney, Renee Kinscheck or Jack L. Young, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580, 202-523-4697, 202-523-3377 or 202-523-3596.

SUPPLEMENTARY INFORMATION: By Federal Register Notice of January 4, 1985 (50 FR 598) the Commission published the proposed rule, announced scheduled hearing dates and set dates for filing statements of testimony by witnesses and exhibits in the Ophthalmic Practice Trade Regulation Rule Proceeding (Public Record 215-63). In addition to scheduled hearings in Washington, D.C., hearings were also scheduled to commence in San Francisco, California, on June 17, 1985. In conjunction with the San Francisco hearings, prepared statements of testimony by witnesses and exhibits were to be filed on or before May 31, 1985.

In granting the motion of one of the participants in the rulemaking for modification of the procedural schedule, the Presiding Officer has postponed the commencement date for hearings in San Francisco, California, until July 1, 1985. In so doing, the Presiding Officer also extended the time within which to file prepared statements of testimony by witnesses and exhibits to June 7, 1985.

Issued: May 21, 1985.

James P. Greenan,

Presiding Officer.

[FR Doc. 85-13712 Filed 6-6-85; 8:45 am]

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APPENDIX II

ORGANIZATION AND LOCATION OF
DOCUMENTS IN RULEMAKING RECORD

ORGANIZATION OF RULEMAKING RECORD

215-63-AA. Guide to Rulemaking Record.

A. Public notices, petitions, and motions, etc. not specifically referred to in other categories.

B. Initial Staff Report (July, 1980) and relevant material gathered in staff investigation; staff studies; and memorandum from Director, Bureau of Consumer Protection, to Commission, dated April 13, 1984.

C. Advance Notice of Proposed Rulemaking (ANPR) and comments in response to the advance notice.

D. Comments from consumers, consumer organizations and representatives of other non-industry groups.

E. Comments from representatives of federal, state and local governmental entities.

F. Comments from members of the scientific and academic communities not associated with providers of ophthalmic goods or services.

G. Staff submissions.

H. Comments from providers or sellers of ophthalmic goods or services and from ophthalmic organizations.

I. Miscellaneous comments.

J. Transcripts of informal hearings and hearing exhibits.

K. Rebuttal submissions.

L. Final Staff Report to the Commission; Presiding Officer's Report containing recommended decision.

M. Comments on Reports of the Staff and Presiding Officer.

N. Comments and/or other submissions made in connection with oral presentations to the Commission.

O. Statement of Basis and Purpose, Final Rule, and other Commission actions or proceedings.

P. Court documents.

R. In Camera Record.

APPENDIX II

LOCATION OF DOCUMENTS
IN RULEMAKING RECORD

215-63-AA Guide to Rulemaking Record.

215-63-A Public notices, petitions, motions, etc. not specifically referred to in other categories.

Binder Nos.	Document Nos.	Page Nos.
A-1	NPR draft	1-75
	Letters	76-79
	A-1-A49	80-505
A-2	A-50-A-72	506-693

215-63-B Initial Staff Report (July, 1980) and relevant materials gathered in staff investigation; staff studies; and memorandum from Director, Bureau of Consumer Protection, to Commission, dated April 13, 1984.

B-1	B-1-B-2-23	1-811
B-2	B-2-24-B-2-37	812-1510
B-3	B-2-38-B-2-51-31	1511-2160
B-4	B-2-51-32-B-5-10	2161-2810
B-5	B-5-11-B-12-41	2811-3286

215-63-C Advance Notice of Proposed Rulemaking (ANPR) and comments in response to the advance notice.

C-1	C-1-C-90	1-486
C-2	C-91-C-248	487-875

215-63-D Comments from consumers, consumer organizations and representatives of other non-industry groups.

D-1	D-1-D-12	1-23

215-63-E Comments from representatives of federal, state and local governmental entities.

E-1	E-1-E-69	1-510

215-63-F	Comments from members of the scientific and academic communities not associated with providers or sellers of ophthalmic goods or services.		
	F-1	F-1-F-3	1-10
215-63-G	Staff submissions.		
	G-1	G-1-G-12	1-486
	G-2	G-13-G-21	486a-1020
215-63-H	Comments from providers or sellers of ophthalmic goods and services and from ophthalmic organizations.		
	H-1	H-1-H-78a	1-455
	H-2	H-78a-H-98	456-1018
	H-3	H-99-H-159	1019-1161
215-63-I	Miscellaneous comments - Not used.		
215-63-J	Transcripts of informal hearings and hearing exhibits. (Witness statements)		
	J-1	J-1-J-7a	1-613
	J-2	J-7b-J-23d	614-1201
	J-3	J-23e-J-35b	1202-1676
	J-4	J-36a-J-41k	1677-1928
	J-5	J-411-J-65	1929-2323
	J-6	J-66a (Vol. I&II)	2324-2856
	J-7	J-66a (Vol. III)-J-67c	2857-3502
	J-8	J-68-J-81	3503-4096
215-63-J-71	Transcripts of informal hearing and hearing exhibits. (Official transcripts).		
	J-71-1	May 20-23	1-653
	J-71-2	May 24-July 1	654-1205
	J-71-3	July 2, 3 & 5	1206-1898
	J-71-4	July 8-10	1899-2474
	J-71-5	July 11 & 12	2475-2857
215-63-K	Rebuttal submissions.		
	K-1	K-1-K-12	1-422
	K-2	K-13-K-25	423-925
	K-3	K-26-K-28	926-1125

215-63-L Final Staff Report to the Commission; Presiding Officer's Report containing Recommended Decision

215-63-M Comments on Reports of Staff and Presiding Officer.

215-63-N Comments and/or other submissions made in connection with oral presentations to the Commission.

215-63-O Statement of Basis and Purpose, Final Rule, and other Commission actions or proceedings.

215-63-P Court Documents.

215-63-R In Camera Record.

APPENDIX III

TABLE OF ABBREVIATIONS

ANPR	Advanced Notice of Proposed Rulemaking
AARP	American Association of Retired Persons
AOA	American Optometric Association
BCP	Bureau of Consumer Protection
BE	Bureau of Economics
CADO	California Association of Dispensing Opticians
COLA	California Optical Laboratories Association
COA	California Optometric Association
CU	Consumers Union
CLS	Contact Lens Study (Also CL Study)
FTC	Federal Trade Commission
HMO	Health Maintenance Organizations
IFA	International Franchise Association
NAOO	National Association of Optometrists and Opticians
NPR	Notice of Proposed Rulemaking
OAA	Opticians Association of America
RRNA	Robert R. Nathan Associates, Inc.
SMSAs	Standard Metropolitan Statistical Areas