BOARD OF OPTOMETRY
BOARD MEETING
JULY 13, 2001

TIME AND PLACE: The meeting was called to order at 3:30 p.m. on Friday, July 13, 2001 at the Department of Health Professions, 6606 West Broad Street, 5th Floor, Room 3, Richmond, Virginia.

PRESIDING OFFICER: John L. Howlette, O.D.

MEMBERS PRESENT: Samuel C. Smart, O.D.
Thomas R. Cheezum, O.D.
Jeff Smith, Citizen Member
Roxann L. Robinson, O.D.
Gary St. Clair, O.D.

STAFF PRESENT: Howard M. Casway, Assistant Attorney General, Board Counsel
Elaine Yeatts, Policy Analyst
Elizabeth A. Carter, Ph.D., Executive Director
Carol Stamey, Administrative Assistant

OTHERS PRESENT: Betty Graumlich, McSweeney, Burtch & Crump

QUORUM: With six members of the Board present, a quorum was established.

PUBLIC COMMENT: Laura Burke, O.D. addressed the Board regarding her application for reinstatement of her license.

REVIEW AND APPROVAL OF AGENDA: No additions or revisions were made to the agenda.

APPROVAL OF MINUTES: On properly seconded motion by Dr. Smart, the Board voted unanimously to approve the minutes of the November 1, 2000 meeting.

Ms. Yeatts informed the Board of the proposed legislation schedule deadlines.

The Board reconsidered its request for a legislative proposal for an additional board member and asked that it be rescinded.

BOARD DISCUSSION:

Adoption of 18 VAC 105-10-et seq, Public Participation Guidelines

On properly seconded motion by Dr. Smart, the Board voted unanimously to adopt the Public Participation Guidelines, §18 VAC-10-et seq, as final regulations (see Attachment 1).

Professional Designation, §18 VAC-105-20.50.B.1

This regulation states that an optometrist must practice in the registered professional designation. Questions have been posed to the board office concerning what amount of time constitutes acceptable "practice in" the location. This has been a particular issue in cases of professional designations with multiple locations.

The Board agreed that public input needs to be received on the issue and that a guidance document or clarifying amendments to the regulations should result.

Letter from Opticians Association of Virginia, Prescription Release

The Board reviewed a letter from Josef Silverman requesting the Board's position on prescription release. This letter is incorporated into the minutes as Attachment 2.

On properly seconded motion by Dr. Smart, the Board voted unanimously that it was the Board's opinion that the patients are entitled to a copy of their prescription when the examination is deemed complete and all fees are paid. Further, since the prescription is part of the patient's record, it is not releasable to a third party without the patient's signed consent.

Dr. Carter was requested to forward a letter regarding the Board's position in the matter.

Continuing Education (CE) Sponsor/Provider

The Board discussed the issue of the appropriateness of classifying CE sponsors as "specialty organizations." The discussion centered on the lack of clear definition of "specialty organizations" in optometry currently. As

such, the Board's current policy remains. CE that is provided by a sponsor that is not in the approved regulation listing in regulations or is not approved by COPE with consideration of Virginia's requirements must be reviewed on a course-by-course basis.

COMMITTEE REPORTS:

Newsletter Committee

The annual newsletter was completed in June, 2001 and reached licensees and Public Participation Guidelines members in early July.

Legislative/Regulatory Review Committee

The Committee requested that a legislative proposal be prepared which would require competency in the use of therapeutic pharmaceutical agents for all new licensees.

PRESIDENT'S REPORT:

Dr. Howlette reflected upon his youth and pride in the optometry profession. In closing he encouraged the Board members to be different, to stand up for what is right and true, and to be inspired by a higher authority than their own.

EXECUTIVE DIRECTOR'S REPORT:

Dr. Carter referred the Board to the statistics on open cases. She reported that the closed case statistics would be forwarded to them after the meeting.

Dr. Carter informed the Board of Dr. Robinson's and her attendance at the ARBO Meeting on June 24-26, 2001 in Boston. Dr. Robinson, represented Virginia as its voting Delegate at the meeting.

Dr. Robinson reported to the Board on the update of the NBEO examinations. She noted that effective 2005, the examinations would be restructured to include a more clinical approach in the Basic Science section.

Dr. Robinson also reported that the issue of Delegation of Authority was a topic of panel discussion.

Dr. Carter reported that Phillip Keefer, President of Vistakon gave a presentation regarding the antitrust case against Johnson & Johnson. A copy of her notes regarding the subject matter of the presentation has

been incorporated into the minutes as Attachment 3.

Dr. Carter also reported that Louisiana and some other southern states were beginning to report the illegal sale or distribution of colored contact lenses to the DEA. The DEA was pursuing the cases as criminal offenses under the federal Drug Control Act as related to the improper distribution of medical devices.

Dr. Carter reported on Ohio's dilemma regarding inactive licensure and Maryland's quality assistance peer review. She further reported that Maryland had taken a proactive approach to improved record keeping by forming the Peer Assistance Committee. The Committee audits 10 percent of the licensee's records and utilizes the audit to educate the licensees on improvements.

Dr. Carter informed the Board that at its next meeting she would demonstrate the websites for COPE and ARBO if the Board would like.

Further, Dr. Carter reported that there were now three levels of paraoptometrics recognized by the American Optometric Association, all seeking recognition as professions. In ascending order they are : 1. Certified Paraoptometric (CPO), 2. Certified Paraoptometric Assistant (CPOA) & 3. Certified Paraoptometric Technician (CPOT).

As a note of concern, Dr. Carter informed the Board that there was a tremendous drop in the number of optometric students. Over the past two years there has been a 35% drop in applicants to schools of optometry. The rationale given was that scientifically oriented undergraduates who may have historically selected to go to optometric graduate programs are now finding lucrative jobs in technology businesses.

Dr. Carter also reported that a number of opticians in Alberta, Canada were gathering legislative momentum which would allow them to perform refractions.

NEW BUSINESS:

Dr. St. Clair stated that the disciplinary sanctions listed in the optometry newsletter revealed that the Board may be inconsistent in the sanctions that it imposes for

similar allegations. Dr. Carter informed the Board that the Board of Health Professions was conducting a study into developing sanction reference tables for individual board's uses. Reports on the progress on the study will be provided when they are available.

ADJOURNMENT: The meeting concluded at 6:00 p.m.

Thomas R. Cheezum, O.D., Vice-President

Elizabeth A. Carter, Ph.D., Executive Director

Attachment 1

PROPOSED REGULATIONS OF THE VIRGINIA BOARD OF OPTOMETRY

18 VAC 105-10-10 et seq.

PUBLIC PARTICIPATION GUIDELINES

Part I.
Statement of Purpose.

18 VAC 105-10-10. Purpose.

The purpose of this chapter is to provide guidelines for the involvement of the public in the development and promulgation of regulations of the Board of Optometry. The guidelines do not apply to regulations exempted or excluded from the provisions of the Administrative Process Act (§ 9-6.14:4.1.1 of the Code of Virginia). These rules seek to expand participation by providing for electronic exchange with the public and thereby increasing participation, reducing costs, and improving the speed of communication.

18 VAC 105-10-20. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise:

"*Administrative Process Act*" means Chapter 1.1:1 (§ 9-6.14:1 et seq.) of Title 9 of the Code of Virginia.

"*Board*" means the Board of Optometry.

"*Notification lists*" means lists used by the board to notify persons pursuant to these rules. Such lists may include electronic mailing lists maintained through a state website or regular mailing lists maintained by the board.

"*Person*" means an individual, a corporation, a partnership, an association, a governmental body, a municipal corporation, or any other legal entity.

Part II.
~~Mailing List~~ Notification Lists.

18 VAC 105-10-30. Composition of ~~the mailing list~~ lists.

A. The board shall maintain ~~a list~~ lists of persons ~~or entities~~ who have requested to be notified of the formation and promulgation of regulations.

B. Any person ~~or entity~~ may request to be placed on ~~the mailing~~ a notification list by indicating so electronically or in writing to the board. The board may add to ~~the~~ a list any person ~~or entity~~ it believes will serve the purpose of enhancing participation in the regulatory process.

C. The board may maintain additional ~~mailing~~ lists for persons ~~or entities~~ who have requested to be informed of specific regulatory issues, proposals, or actions.

D. The board shall periodically request those persons on the ~~mailing list~~ notification lists to indicate their desire to either continue to receive documents by regular mail, be notified electronically or be deleted from the ~~list~~ lists. Persons who elect to be included on an electronic mailing list may also request that all notices and mailings be sent in hard copy. When either regular or electronic mail is returned as undeliverable or there has been no response to the request from the board, ~~individuals or organizations~~ such persons shall be deleted from the list.

18 VAC 105-10-40. Documents to be sent to persons ~~or entities~~ on the ~~mailing list~~ lists.

Persons ~~or entities~~ on the ~~mailing list~~ notification lists, as described in 18 VAC 105-20-30, shall be mailed or have electronically transmitted the following documents related to the promulgation of regulations:

1. A ~~Notice of Intended Regulatory Action~~ notice of intended regulatory action.

2. A ~~Notice of Comment Period~~ notice of the comment period on a proposed regulation and instructions as to how to obtain a copy of the regulation and any supporting documents, either electronically or from the board office.

3. A ~~copy of any final regulation adopted by the board~~ notification of the adoption of a final regulation and instructions as to how to obtain a copy of the regulation and any supporting documents, either electronically or from the board office.

4. A notice soliciting comment on a final regulation when the regulatory process has been extended.

Part III.
Public Participation Procedures.

18 VAC 105-10-60. Notice of Intended Regulatory Action.

A. The ~~Notice of Intended Regulatory Action~~ notice of intended regulatory action (NOIRA) shall state the purpose of the action and a brief statement of the need or problem the proposed action will address.

B. The NOIRA shall indicate whether the board intends to hold a public hearing on the proposed regulation after it is published. If the board does not intend to hold a public hearing, it shall state the reason in the NOIRA.

C. ~~The NOIRA shall state that a public hearing will be scheduled, if, during the 30-day comment period, the board receives requests for a hearing from at least 25 persons.~~ If prior to the close of the 30-day comment period on the NOIRA, the board receives a request for a public hearing on the proposed regulation from at least 25 persons, such a hearing shall be scheduled.

18 VAC 105-10-70. Notice of Comment Period.

A. The ~~Notice of Comment Period~~ notice of comment period (NOCP) shall indicate that copies of the proposed regulation are available electronically or from the board and may be requested in writing from the contact person specified in the NOCP.

B. The NOCP shall indicate that copies of the statement of substance, issues, basis, purpose, and estimated impact of the proposed regulation may also be requested in writing.

C. The NOCP shall make provision for ~~either oral or written submittals~~ comments ~~on~~ pertaining to the proposed regulation ~~or on the impact on regulated entities and the public and on the cost of compliance with the proposed regulation~~ by regular mail, internet, facsimile or electronic means. With the exception of comment received at a scheduled public hearing, oral comment may not be accepted.

18 VAC 105-10-80. Notice of Meeting.

A. At any meeting of the board or advisory committee, at which the formation or adoption of regulation is anticipated, the subject shall be described in ~~the Notice of Meeting~~ a notice of meeting, which has been posted electronically on the Internet and transmitted to the Registrar for inclusion in The Virginia Register.

B. If the board anticipates action on a regulation for which an exemption to the Administrative Process Act is claimed under § 9-6.14:4.1. of the Code of Virginia, the ~~Notice of Meeting~~ notice of meeting shall indicate that a copy of the proposed regulation is available on a state website or upon request to the board at least two days prior to the meeting and that a copy of the regulation shall be made available to the public attending such meeting.

18 VAC 105-10-100. ~~Biennial~~ Periodic review of regulations.

A. ~~At least once each biennium~~ Unless otherwise directed by Executive Order, the board shall conduct an informational proceeding at least every two years to receive comment on all existing regulations as to their effectiveness, efficiency, necessity, clarity, and cost of compliance.

B. Such proceeding may be conducted separately or in conjunction with other informational proceedings or hearings.

C. Notice of the proceeding shall be transmitted to the Registrar for inclusion in The Virginia Register and shall be sent to the mailing list identified in 18 VAC 105-10-30.

Attachment 2
7-11-01

Opticians Association of Virginia
Josef Silvermap
125 Executive Dr.
Danville VA 24541

Board of Optometry:

There is concern among some of our members regarding prescription release. According to Release rule all Prescriptions for eyeglasses must be given to the patent. Some of our members are running into problems with this. When they call for a prescription, Dr. tells Optician the patient must come in and sign a prescription release. Some Drs. make Optician fax release and others insist patient comes into Dr. office.
Would you please clarify Board of Optometry position on this.

Thank you,

Josef Silverman
Pres. Opticians Association of Virginia

Attachment 3

Elizabeth Carter's Notes taken Tuesday, June 26, 2001 on

CONTACT LENS PRESCRIPTION RELEASE: THE VISTAKON SETTLEMENT – WHAT IT REALLY MEANS

Presented by Mr. Phillip R. Keefer, President, Vistakon Americas

He discussed two lawsuits:

1. the Antitrust case begun in June 1994 against Vistakon, Bausch & Lomb, Ciba-Geigy, and the American Optometric Association
2. 1-Day Acuvue lens case (warning not to wear over a day should have been on the label – is still being settled – likely $860 M).

The first case is more important for Boards' consideration. It involved a class-action suit against the above parties taken by 32 Attorneys General charging conspiracy to limit distribution of CLs. In 1997, Ciba-Geigy settled for $5M who must now sell to mail order firms unconditionally for 5 years. In February 2001, Bausch & Lomb settled for $17.5M and some other terms I did not get as they whizzed by. In March 2001, the American Optometric Association settled (terms not specified).

Vistakon continued its battle until there was publicity about 1-Day Acuvue and both sides thought there was a strong possibility for mistrial. The settlement for Vistakon won't be final until September – but it is anticipated that it will indicate

- that Vistakon was not found guilty of any of the charges
- An Eye Care Professional must be involved in the purchase of Acuvue for patients who have/need such lenses.
- Vistakon does not have to sell to anyone who
  - Sells without a valid Rx
  - Breaks state/federal law
  - Sells diagnostic lenses
- There were $25 M in attorney fees
- $30 M in consumer offers ($50 rebates on 4 boxes of Acuvues, $25 rebate on eye exams (hum?), and $25 rebate on future purchases of the lenses.
- For those consumers who no longer wear Acuvues, they will be awarded $50 in Johnson & Johnson products.

The consumer provisions apply to anyone in Acuvues from 1988 to the present. They will be notified through direct mail about the settlement and informed to use the following telephone number to obtain further information: (888) 437-1294. There is also a website: www.acuvuerebates.com

What Vistakon gets out of this is that the Federal Judge in Florida, Schlessinger, will be ordering that the 32 AG's MUST enforce their own state laws related to the sale/dispensing of contact lenses – but only in the case of Acuvue lenses. Mr. Keefer indicated that this means that it is no longer a matter of discretion on the part of the AG's.

He stated that while the settlement will cover the 32 states involved in the antitrust case, other states could join in, if they wanted to.

He indicated that each state Board will be sent a letter that Vistakon will be sending anyone with evidence of illegal dispensing of Acuvues to them for complaint investigation and adjudication.

There were questions from the audience about how Vistakon tracks the distribution of its own product. Mr. Keefer indicated that from manufacture they track initial and secondary distribution only. Anything beyond that they do not know about. Concern was raised by some of the states in the southwest that lenses were coming in from Mexico. He agreed that they would not necessarily know about such lenses.