BOARD OF OPTOMETRY
BOARD MEETING
JULY 18, 2003

TIME AND PLACE:	The meeting was called to order at 1:30 p.m. on Friday, July 18, 2003 at the Department of Health Professions, 6603 West Broad Street, 5th Floor, Room 3, Richmond, Virginia.
PRESIDING OFFICER:	Thomas R. Cheezum, O.D.
MEMBERS PRESENT:	David H. Hettler, O.D Roxann L. Robinson, O.D. Paula H. Boone, O.D.
MEMBERS NOT PRESENT:	Cathleen Kelly Burk William T. Tiller, O.D.
STAFF PRESENT:	Gail Jaspen, Chief Deputy Director of the Department Howard Casway, Assistant Attorney General, Board Counsel Elizabeth A. Carter, Ph.D., Executive Director for the Board Carol Stamey, Administrative Assistant
OTHERS PRESENT:	Stefan P. Cox, Whitehead Consulting, Richmond, VA Amy Tarker, McSweeney & Crump Bruce Keeney, Virginia Optometric Association
QUORUM:	With four members of the Board present, a quorum was established.
REVIEW AND APPROVAL OF AGENDA:	The order of the agenda was revised: Mr. Banning's presentation under Board Discussion was moved to be heard first and the elections were deferred.
BOARD DISCUSSION:	**Case Review Opinions** Mr. Banning addressed the Board regarding disciplinary case review and the responses needed from board members on their opinion sheets. He explained that staff members are not optometrists, themselves, but that notices involving standard of care issues require a clear explanation of the potential violation. He further stated that the regulations pertaining to standard of care are detailed, when compared with other boards' regulations. Mr. Banning requested that case reviewers provide as much detail as possible regarding the potential violating activity and tie it directly with the corresponding regulatory and/or statutory sites for each

problem. He added that, standard of care and recordkeeping cases involving multiple patients were a particular issue. Mr. Banning requested as much guidance as possible from the case reviewers to be documented on the case opinion sheets.

Board Appointments
Dr. Cheezum reported that William T. Tillar, O.D. of Emporia and Cathleen Kelly Burk, Citizen Member, of Leesburg had been appointed as new board members. Due to the proximity between appointment and board meeting date, neither could be present today.

Election of Officers
The election of Officers was deferred to the October meeting when all members had the opportunity to be present.

PUBLIC COMMENT:

No public comment was presented.

APPROVAL OF MINUTES:

On properly seconded motion by Dr. Robinson, the Board voted unanimously to approve the minutes for the April 25, 2003 meeting.

BOARD DISCUSSION:

Proposed 2004 Legislation

Pursuant to the Board's request at the last meeting, Ms. Yeatts presented the language in "Opt #1." incorporated in the minutes as Attachment 1, to provide for the diagnostic pharmaceutical agents formulary to be placed in regulation and to provide for the inclusion of oral antibiotics in the therapeutic pharmaceutical agents formulary.

A second measure, referred to as "Opt #2," (see Attachment 2) was also considered, which would require new candidates for licensure to become certified. Ms. Yeatts recommended that a new section be added as "C stating effective July 1, 2004 every person who applies for licensure to practice optometry in the Commonwealth of Virginia shall meet the requirements of subsection A to be certified for the treatment of certain diseases of the eye with therapeutic pharmaceutical agents."

Action – On properly seconded motion by Dr. Hettler the Board voted unanimously to accept the draft legislation in "Opt #2" as submitted by Ms. Yeatts with revision to §54.1-3222 to include "on or after July 1, 2004.

Protocol for Issuance of Confidential Consent Agreements (CCA's)
Ms. Jaspen presented a brief overview of the requirements and protocol for CCA's and the brief summary is incorporated into the minutes as Attachment 3. She requested that the Board identify areas of minor misconduct in which CCA's could be utilized.

Action – On properly seconded motion by Dr. Hettler, the Board voted unanimously that the following areas of misconduct could be considered for CCA's:

- CE Violations (first offense);
- Advertising/Professional Designation Titles;
- Incorrect prescription pads;
- Records release and
- Mercantile practice.

Update on Federal Legislation
Dr. Carter presented an overview of federal legislation regarding regulation of non-corrective contact lens and availability of contact lens prescriptions (H.R. 2218 and H.R. 2221). Copies of the legislative bills are incorporated into the minutes as Attachment 4.

Request from Dr. Rinearson
Dr. Rinearson requested clarification regarding whether a website address constitutes a fictitious name.

It was the Board's opinion that a website address is considered an address; however, the site, itself, must contain the optometrist's name.

COMMITTEE REPORTS:

Endorsement Committee
No report.

Newsletter Committee
Newsletters will continue to be distributed through e-mail to save cost. Article topics proposed for publication prior to renewal were: "update on renewals to include the combination of licensure permits," "the ability to renew on-line and update addresses," "use of website addresses/advertising" and "a continuing education requirements reminder."

Professional Designation Committee
No report.

PRESIDENT'S REPORT:

Dr. Smart's (past president) report is incorporated into the minutes as Attachment 5.

EXECUTIVE DIRECTOR'S REPORT:

ARBO Report

Dr. Carter reported that the National Board is revising its national examination and is requesting nominations from the various boards to serve on National Board Exam Review Committee. The basic science section is being revised to be more clinically relevant and a study is being conducted to determine the systemic and ocular clinical conditions encountered in general practice to assist in revising the clinical skills and patient management portions. It is expected that the examination revisions will begin to be implemented in 2005, with final implementation expected in 2006.

A number of member states reported difficulties with contact lens dispensing companies requiring release of prescriptions. Texas had received over 30,000 identical complaints, with fewer than 30 reflecting a valid complaint.

Dr. Carter reported that the California Board had become sunsetted, with an entirely new board membership and executive director being installed this year. As of June, Ohio was facing a similar issue.

Dr. Carter reported that the website for ARBO contained a survey to report patient harm from cosmetic contact lenses that had been obtained with proper prescriptions. Data began being collected earlier this year. The results, thus far, have revealed that a number of patients had been harmed, some with permanent significant sight loss, resulting from ill fit and infection.

ARBO is requesting COPE reviewers and has made training available through their website.

The Mobility Committee is developing a program for credentialing optometrists to provide a certification of the level of competency of the individual for use by states rather than each state having to establish the person's abilities from information from the endorsing state.

Sherry Cooper, with the American Optometric Association, urged the various states to stop using the phrasing "DPA and

TPA". She encouraged the states to begin to use the term "prescriptive authority." This is a phrase that most all health professionals are familiar with, especially pharmacists. She noted that since ophthalmic pharmaceuticals are just that, the DPA and TPA designations are meaningless to those outside of optometric circles.

Dr. Carter reported that the Board's case resolution standards will be published on the Agency's website in November. Optometry's performance for FY 2003 was on par with the agency overall but could be better. Board member review time is good, but because requests for continuances continue to be an issue, Dr. Carter requested guidance regarding the granting of continuances. It was the Board's opinion that requests for continuances must be submitted within thirty (30) days of receipt of a notice and that a firm date for rescheduling must be set prior to granting the continuance.

NEW BUSINESS:

Dr. Hettler requested that the Board review the standards of practice regarding an eye examination in relationship to EN&M Coding.

The issue was tabled till the October meeting.

ADJOURNMENT:

The Board concluded its meeting at 3:25 p.m.

Thomas R. Cheezum, O.D.
Presiding Chair

Elizabeth A. Carter, Ph.D.
Executive Director

Attachment 1

Virginia Board of Optometry

Department of Health Professions
2004 Session of the General Assembly

Draft Legislation

A bill to amend and reenact §§ 2.2-4002, 54.1-3221, and 54.1-3222, relating to administration of diagnostic pharmaceutical agents by DPA-certified optometrists and prescribing of Schedule VI antibiotics by TPA-certified optometrists.

§ 2.2-4002. Exemptions from chapter generally.

A. Although required to comply with § 2.2-4103 of the Virginia Register Act (§ 2.2-4100 et seq.), the following agencies shall be exempted from the provisions of this chapter, except to the extent that they are specifically made subject to §§ 2.2-4024, 2.2-4030 and 2.2-4031:

1. The General Assembly.

2. Courts, any agency of the Supreme Court, and any agency that by the Constitution is expressly granted any of the powers of a court of record.

3. The Department of Game and Inland Fisheries in promulgating regulations regarding the management of wildlife and for all case decisions rendered pursuant to any provisions of Chapters 2 (§ 29.1-200 et seq.), 3 (§ 29.1-300 et seq.), 4 (§ 29.1-400 et seq.), 5 (§ 29.1-500 et seq.), and 7 (§ 29.1-700 et seq.) of Title 29.1.

4. The Virginia Housing Development Authority.

5. Municipal corporations, counties, and all local, regional or multijurisdictional authorities created under this Code, including those with federal authorities.

6. Educational institutions operated by the Commonwealth, provided that, with respect to § 2.2-4031, such educational institutions shall be exempt from the publication requirements only with respect to regulations that pertain to (i) their academic affairs; (ii) the selection, tenure, promotion and disciplining of faculty and employees; (iii) the selection of students; and (iv) rules of conduct and disciplining of students.

7. The Milk Commission in promulgating regulations regarding (i) producers' licenses and bases, (ii) classification and allocation of milk, computation of sales and shrinkage, and (iii) class prices for producers' milk, time and method of payment, butterfat testing and differential.

8. The Virginia Resources Authority.

9. Agencies expressly exempted by any other provision of this Code.

10. The Department of General Services in promulgating standards for the inspection of buildings for asbestos pursuant to § 2.2-1164.

11. The State Council of Higher Education for Virginia, in developing, issuing, and revising guidelines pursuant to § 23-9.6:2.

12. The Commissioner of Agriculture and Consumer Services in adopting regulations pursuant to subsection B of § 3.1-726.

13. The Commissioner of Agriculture and Consumer Services and the Board of Agriculture and Consumer Services in promulgating regulations pursuant to subsections B and C of § 3.1-106.4, subsection B of §§ 3.1-126.12:1, 3.1-271.1, 3.1-530.1, and 3.1-398, subsections B and C of § 3.1-828.4, and subsection A of § 3.1-884.21:1.

14. The Board of Optometry when specifying therapeutic pharmaceutical agents, treatment guidelines, and diseases and abnormal conditions of the human eye and its adnexa for TPA-certification of optometrists or diagnostic pharmaceutical agents administered only by topical application for DPA-certification of optometrists, pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 of Title 54.1.

15. The Virginia War Memorial Foundation.

16. The Virginia Medicaid Prior Authorization Advisory Committee in making recommendations to the Board of Medical Assistance Services regarding prior authorization for prescription drug coverage pursuant to Article 4 (§ 32.1-331.12 et seq.) of Chapter 10 of Title 32.1.

17. The State Board of Education, in developing, issuing, and revising guidelines pursuant to § 22.1-203.2.

18. The Virginia Racing Commission, (i) when acting by and through its duly appointed stewards or in matters related to any specific race meeting or (ii) in promulgating technical rules regulating actual live horse racing at race meetings licensed by the Commission.

19. The Virginia Small Business Financing Authority.

20. The Virginia Economic Development Partnership Authority.

21. The Board of Agriculture and Consumer Services in adopting, amending or repealing regulations pursuant to subsection A (ii) of § 59.1-156.

22. The Insurance Continuing Education Board pursuant to § 38.2-1867.

23. The Board of Health in promulgating the list of diseases that shall be reported to the Department of Health pursuant to § 32.1-35 and in adopting regulations pursuant to subsection C of § 35.1-14 that incorporate the Food and Drug Administration's Food Code pertaining to restaurants or food service.

B. Agency action relating to the following subjects shall be exempted from the provisions of this chapter:

1. Money or damage claims against the Commonwealth or agencies thereof.

2. The award or denial of state contracts, as well as decisions regarding compliance therewith.

3. The location, design, specifications or construction of public buildings or other facilities.

4. Grants of state or federal funds or property.

5. The chartering of corporations.

6. Customary military, naval or police functions.

7. The selection, tenure, dismissal, direction or control of any officer or employee of an agency of the Commonwealth.

8. The conduct of elections or eligibility to vote.

9. Inmates of prisons or other such facilities or parolees therefrom.

10. The custody of persons in, or sought to be placed in, mental, penal or other state institutions as well as the treatment, supervision, or discharge of such persons.

11. Traffic signs, markers or control devices.

12. Instructions for application or renewal of a license, certificate, or registration required by law.

13. Content of, or rules for the conduct of, any examination required by law.

14. The administration of pools authorized by Chapter 47 (§ 2.2-4700 et seq.) of this title.

15. Any rules for the conduct of specific lottery games, so long as such rules are not inconsistent with duly adopted regulations of the State Lottery Board, and provided that such regulations are published and posted.

16. Orders condemning or closing any shellfish, finfish, or crustacea growing area and the shellfish, finfish or crustacea located thereon pursuant to Article 2 (§ 28.2-803 et seq.) of Chapter 8 of Title 28.2.

17. Any operating procedures for review of child deaths developed by the State Child Fatality Review Team pursuant to § 32.1-283.1.

18. The regulations for the implementation of the Health Practitioners' Intervention Program and the activities of the Intervention Program Committee pursuant to Chapter 25.1 (§ 54.1-2515 et seq.) of Title 54.1.

19. The process of reviewing and ranking grant applications submitted to the Commonwealth Neurotrauma Initiative Advisory Board pursuant to Chapter 3.1 (§ 51.5-12.1 et seq.) of Title 51.5.

20. Loans from the Small Business Environmental Compliance Assistance Fund pursuant to Article 4 (§ 10.1-1197.1 et seq.) of Chapter 11.1 of Title 10.1.

21. The Virginia Breeders Fund created pursuant to § 59.1-372.

22. The types of pari-mutuel wagering pools available for live or simulcast horse racing.

23. The administration of medication or other substances foreign to the natural horse.

C. Minor changes to regulations published in the Virginia Administrative Code under the Virginia Register Act, Chapter 41 (§ 2.2-4100 et seq.) of this title, made by the Virginia Code Commission pursuant to § 30-150, shall be exempt from the provisions of this chapter.

§ 54.1-3221. "Diagnostic pharmaceutical agents" defined; utilization; acquisition.

A. Certified optometrists may administer diagnostic pharmaceutical agents only by topical application to the human eye. The Board shall establish in regulation those diagnostic pharmaceutical agents that may be administered by certified optometrists ~~shall be defined as the following drugs in strengths not to exceed those stated~~ to include but not be limited to:

1. Mydriatics and cycloplegics known as tropicamide in a 1.0 percent solution, phenylephrine hydrochloride in a 2.5 percent solution and cyclopentolate hydrochloride in a 1.0 percent solution to be used only on persons three years of age or older;

2. Anesthetic agents known as proparacaine hydrochloride in a 0.5 percent solution, tetracaine in a 0.5 percent solution and benoxinate hydrochloride in a 0.4 percent solution;

3. The miotic known as pilocarpine in a 1.0 percent solution; and

4. Dapiprazole hydrochloride in a 0.5 percent solution.

B. In order to maintain a current and appropriate list of diagnostic pharmaceutical agents that may be administered by DPA-certified optometrists, the Board may, from time to time, amend such regulations under an exemption from the requirements of the Administrative Process Act (§ 2.2-4000 et seq.). Such regulations shall be exempt except to any extent that they may be specifically made subject to §§ 2.2-4024, 2.2-4030, and 2.2-4031; the Board's regulations shall, however, comply with § 2.2-4103 of the Virginia Register Act (§ 2.2-4100 et seq.). The Board shall conduct a public hearing prior to making amendments to the listing of diagnostic pharmaceutical agents. Thirty days prior to conducting such hearing, the Board shall give written notice by mail of the date,

time, and place of the hearing to all currently DPA-certified optometrists and any other persons requesting to be notified of the hearings and publish notice of its intention to amend the list in the Virginia Register of Regulations. Proposed and final amendments to the list shall also be published, pursuant to § 2.2-4031, in the Virginia Register of Regulations. Final amendments shall become effective upon filing with the Registrar of Regulations.

~~B~~ C. Any optometrist who ~~utilizes~~ administers diagnostic pharmaceutical agents without being certified as required by this article shall be subject to the disciplinary sanctions provided in this chapter.

~~C~~ D. Licensed drug suppliers or pharmacists are authorized to supply optometrists with diagnostic pharmaceutical agents upon presentation of evidence of Board certification for administration of such drugs.

§ 54.1-3222. TPA certification; certification for treatment of certain diseases or abnormal conditions with certain therapeutic pharmaceutical agents.

A. The Board shall certify an optometrist to prescribe for and treat certain diseases or abnormal conditions of the human eye and its adnexa with certain therapeutic pharmaceutical agents, if the optometrist files a written application, accompanied by the fee required by the Board and satisfactory proof that the applicant:

1. Is licensed by the Board as an optometrist and certified to administer diagnostic pharmaceutical agents pursuant to Article 4 (§ 54.1-3220 et seq.) of this chapter;

2. Has satisfactorily completed such didactic and clinical training programs for the treatment of diseases and abnormal conditions of the eye and its adnexa as are determined, after consultation with a school or college of optometry and a school of medicine, to be reasonable and necessary by the Board to ensure an appropriate standard of medical care for patients; and

3. Passes such examinations as are determined to be reasonable and necessary by the Board to ensure an appropriate standard of medical care for patients.

B. TPA certification shall enable an optometrist to treat certain diseases and abnormal conditions of the human eye and its adnexa as determined by the Board with certain therapeutic pharmaceutical agents specified by the Board, within the following conditions:

1. Treatment with oral therapeutic pharmaceutical agents shall be limited to antibiotics included on Schedule VI, as defined in § 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.) which are appropriate to treat ocular infection and the analgesics included on Schedules III and VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), which are appropriate to alleviate ocular pain.

2. Prescriptions for oral analgesics to relieve ocular pain shall be limited to dosages for no more than seventy-two hours.

3. Therapeutic pharmaceutical agents shall include topically applied Schedule VI drugs as defined in § 54.1-3455 of the Drug Control Act.

4. Treatment of glaucoma shall require prior consultation with the patient's physician or other appropriate physician, and shall exclude treatment of congenital and infantile glaucoma. Treatment of angle closure glaucoma shall be limited to initiation of immediate emergency care.

5. Treatment through surgery or other invasive modalities shall not be permitted, except for treatment of emergency cases of anaphylactic shock with intramuscular epinephrine, such as that included in a bee sting kit.

6. Entities permitted or licensed by the Board of Pharmacy to distribute or dispense drugs, including, but not limited to, wholesale distributors and pharmacists, shall be authorized to supply TPA-certified optometrists with those therapeutic pharmaceutical agents specified by the Board on the TPA-Formulary.

Attachment 2

OPT#2

Virginia Board of Optometry

Department of Health Professions
2004 Session of the General Assembly

Draft Legislation

A bill to amend and reenact §54.1-3222, relating to requirements for optometrists to be certified in therapeutic pharmaceutical agents.

§ 54.1-3222. TPA certification; certification for treatment of certain diseases or abnormal conditions with certain therapeutic pharmaceutical agents.

A. The Board shall certify an optometrist to prescribe for and treat certain diseases or abnormal conditions of the human eye and its adnexa with certain therapeutic pharmaceutical agents, if the optometrist files a written application, accompanied by the fee required by the Board and satisfactory proof that the applicant:

1. Is licensed by the Board as an optometrist and certified to administer diagnostic pharmaceutical agents pursuant to Article 4 (§ 54.1-3220 et seq.) of this chapter;

2. Has satisfactorily completed such didactic and clinical training programs for the treatment of diseases and abnormal conditions of the eye and its adnexa as are determined, after consultation with a school or college of optometry and a school of medicine, to be reasonable and necessary by the Board to ensure an appropriate standard of medical care for patients; and

3. Passes such examinations as are determined to be reasonable and necessary by the Board to ensure an appropriate standard of medical care for patients.

B. TPA certification shall enable an optometrist to treat certain diseases and abnormal conditions of the human eye and its adnexa as determined by the Board with certain therapeutic pharmaceutical agents specified by the Board, within the following conditions:

1. Treatment with oral therapeutic pharmaceutical agents shall be limited to antibiotics included on Schedule VI, as defined in § 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.) which are appropriate to treat ocular infection and the analgesics included on Schedules III and VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), which are appropriate to alleviate ocular pain.

2. Prescriptions for oral analgesics to relieve ocular pain shall be limited to dosages for no more than seventy-two hours.

3. Therapeutic pharmaceutical agents shall include topically applied Schedule VI drugs as defined in § 54.1-3455 of the Drug Control Act.

4. Treatment of glaucoma shall require prior consultation with the patient's physician or other appropriate physician, and shall exclude treatment of congenital and infantile glaucoma. Treatment of angle closure glaucoma shall be limited to initiation of immediate emergency care.

5. Treatment through surgery or other invasive modalities shall not be permitted, except for treatment of emergency cases of anaphylactic shock with intramuscular epinephrine, such as that included in a bee sting kit.

6. Entities permitted or licensed by the Board of Pharmacy to distribute or dispense drugs, including, but not limited to, wholesale distributors and pharmacists, shall be authorized to supply TPA-certified optometrists with those therapeutic pharmaceutical agents specified by the Board on the TPA-Formulary.

C. Effective July 1, 2004, every person who applies for licensure to practice optometry in this state shall meet the requirements of subsection A to be certified for the treatment of certain diseases and abnormal conditions of the human eye with therapeutic pharmaceutical agents. Optometrists licensed prior to July 1, 2004 who are not TPA-certified may continue to practice optometry but may not prescribe or use therapeutic pharmaceutical agents unless they satisfy the requirements of this section.

Attachment 3

CONFIDENTIAL CONSENT AGREEMENTS

Va. Code § 54.1-2400(14)

House Bill No. 1441 (2003)

§ 54.1-2400. General powers and duties of health regulatory boards.

The general powers and duties of health regulatory boards shall be:

* * *

14. To request and accept from a certified, registered or licensed practitioner, in lieu of disciplinary action, a confidential consent agreement. A confidential consent agreement shall be subject to the confidentiality provisions of § 54.1-2400.2 and shall not be disclosed by a practitioner. A confidential consent agreement shall include findings of fact and may include an admission or a finding of a violation. A confidential consent agreement shall not be considered either a notice or order of any health regulatory board, but it may be considered by a board in future disciplinary proceedings. A confidential consent agreement shall be entered into only in cases involving minor misconduct where there is little or no injury to a patient or the public and little likelihood of repetition by the practitioner. A board shall not enter into a confidential consent agreement if there is probable cause to believe the practitioner has (i) demonstrated gross negligence or intentional misconduct in the care of patients or (ii) conducted his practice in such a manner as to be a danger to the health and welfare of his patients or the public. A certified, registered or licensed practitioner who has entered into two confidential consent agreements involving a standard of care violation, within the 10-year period immediately preceding a board's receipt of the most recent report or complaint being considered, shall receive public discipline for any subsequent violation within the 10-year period unless the board finds there are sufficient facts and circumstances to rebut the presumption that the disciplinary action be made public. **(Effective July 1, 2003)**

Requirements of a CCA:

1. A board may offer a CCA to a Respondent or accept a Respondent's offer to enter into a CCA.

2. A CCA is to be "in lieu of disciplinary action." It is modeled on a private disciplinary procedure utilized by the Virginia State Bar, referred to as an "Agreed Disposition" of a complaint. The Bar's procedure is to make known, privately, to a Respondent the "Charge of Misconduct" against him/her for a period of 21 days. During that period, in appropriate cases,

the Respondent may negotiate for a private discipline. If a private disposition is not agreed to, the Charge of Misconduct is made public on the 22nd day. It may be useful to develop a similar protocol for CCAs.

3. A CCA shall be treated as confidential. It shall not be disclosed, even by the respondent practitioner. Since a CCA is to be "in lieu of disciplinary action," it presumably should not be used to take adverse action against an individual's license (*i.e.*, it should not revoke, suspend, restrict, place on probation, censure, reprimand, require a license surrender, *etc.*). As such, CCAs do not appear to be matters that must be reported to the National Practitioner Data Bank.

4. A CCA shall include findings of fact and may include an admission or a finding of violation.

5. A CCA is not a notice or an order. If the agreement embodied in a CCA is breached or if it is otherwise relevant, it may be considered by a board in a future disciplinary proceeding.

6. A CCA shall only be used to dispose of matters involving:
   - minor misconduct;
   - little or no injury to a patient or the public; and
   - little likelihood of repetition by the practitioner.

7. A CCA shall not be used to dispose of a matter if the practitioner has:
   - demonstrated gross negligence or intentional misconduct in the care of patients; or
   - conducted his practice in such a manner as to be a danger to the health and welfare of his patients or the public.

8. A practitioner who has entered into two CCAs involving standard of care violations within a 10-year period preceding the board's receipt of a most recent complaint, shall not be able to avail himself of a CCA to dispose of subsequent cases within the 10-year period, and shall receive public discipline, unless the board finds sufficient facts and circumstances to rebut the presumption that disciplinary action should be public.

Attachment 4

NEW SEARCH | HOME | HELP

H.R.2218
Title: To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of noncorrective contact lens as medical devices, and for other purposes.
Sponsor: Rep Boozman, John [AR-3] (introduced 5/22/2003) **Cosponsors:** 14
Latest Major Action: 6/2/2003 Referred to House subcommittee. Status: Referred to the Subcommittee on Health.

Jump to: Titles, Status, Committees, Related Bill Details, Amendments, Cosponsors, Summary

TITLE(S): *(italics indicate a title for a portion of a bill)*

- OFFICIAL TITLE AS INTRODUCED:
  To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of noncorrective contact lens as medical devices, and for other purposes.

STATUS: *(color indicates Senate actions)*

5/22/2003:
Referred to the House Committee on Energy and Commerce.
6/2/2003:
Referred to the Subcommittee on Health.

COMMITTEE(S):

Committee/Subcommittee:	Activity:
House Energy and Commerce	Referral
Subcommittee on Health	Referral

RELATED BILL DETAILS:

NONE

AMENDMENT(S):

NONE

COSPONSORS(14), ALPHABETICAL [followed by Cosponsors withdrawn]: (Sort: by date)

Rep Bilirakis, Michael - 5/22/2003 [FL-9]	Rep Brown, Sherrod - 7/8/2003 [OH-13]
Rep Burgess, Michael C. - 5/22/2003 [TX-26]	Rep Burr, Richard - 7/9/2003 [NC-5]
Rep DeLauro, Rosa L. - 7/8/2003 [CT-3]	Rep Fletcher, Ernie - 5/22/2003 [KY-6]
Rep Green, Gene - 7/8/2003 [TX-29]	Rep Moran, Jerry - 7/15/2003 [KS-1]
Rep Napolitano, Grace F. - 7/8/2003 [CA-38]	Rep Norwood, Charlie - 5/22/2003 [GA-9]
Rep Snyder, Vic - 5/22/2003 [AR-2]	Rep Towns, Edolphus - 7/8/2003 [NY-10]

Rep Waxman, Henry A. - 5/22/2003 [CA-30] Rep Weldon, Dave - 5/22/2003 [FL-15]

SUMMARY AS OF:
5/22/2003--Introduced.

mends the Federal Food, Drug, and Cosmetic Act to classify corrective and noncorrective contact lenses and milar articles as medical devices under the Act.

Bill 2 of 50

GPO's PDF version of this bill	References to this bill in the Congressional Record	Link to the Bill Summary & Status file.	*Printer Friendly Display* - 2,416 bytes.[Help]

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of noncorrective contact lens as medical devices, and for other purposes. (Introduced in House)

HR 2218 IH

108th CONGRESS

1st Session

H. R. 2218

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of noncorrective contact lens as medical devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

May 22, 2003

Mr. BOOZMAN (for himself, Mr. WAXMAN, Mr. NORWOOD, Mr. SNYDER, Mr. FLETCHER, Mr. WELDON of Florida, Mr. BURGESS, and Mr. BILIRAKIS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of noncorrective contact lens as medical devices, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. FINDINGS.

The Congress finds as follows:

(1) Both corrective and noncorrective contact lenses have significant effects on the eye and pose serious potential health risks if improperly manufactured or used without the supervision of a qualified eyecare practitioner.

(2) Noncorrective lenses sold outside the protections of medical device regulation have caused eye injuries in children.

(3) Both corrective and noncorrective lenses have been approved as medical devices by the Food and Drug Administration (`FDA').

(4) FDA has until recently publicly claimed jurisdiction over both corrective and noncorrective contact lenses as medical devices.

SEC. 2. REGULATION OF CERTAIN ARTICLES AS MEDICAL DEVICES.

Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following subsection:

`Regulation of Contact Lens as Devices

`(n)(1) Both corrective and noncorrective contact lenses and similar articles shall be considered devices under section 201(h).

`(2) With respect to an article that is not described in paragraph (1), such paragraph may not be construed as having any legal effect on any determination by the Secretary of whether the article is a food, a drug, a device, or a cosmetic.'.

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H.R.2221
Title: To provide for availability of contact lens prescriptions to patients, and for other purposes.
Sponsor: Rep Burr, Richard [NC-5] (introduced 5/22/2003) **Cosponsors:** 5
Latest **Major Action:** 6/2/2003 Referred to House subcommittee. Status: Referred to the Subcommittee on Commerce, Trade and Consumer Protection.

Jump to: Titles, Status, Committees, Related Bill Details, Amendments, Cosponsors, Summary

TITLE(S): (*italics indicate a title for a portion of a bill*)

- SHORT TITLE(S) AS INTRODUCED:
  Fairness to Contact Lens Consumers Act

- OFFICIAL TITLE AS INTRODUCED:
  To provide for availability of contact lens prescriptions to patients, and for other purposes.

STATUS: (*color indicates Senate actions*)

5/22/2003:
Referred to the House Committee on Energy and Commerce.
6/2/2003:
Referred to the Subcommittee on Commerce, Trade and Consumer Protection.

COMMITTEE(S):

Committee/Subcommittee:	Activity:
House Energy and Commerce	Referral
Subcommittee on Commerce, Trade and Consumer Protection	Referral

RELATED BILL DETAILS:

NONE

AMENDMENT(S):

NONE

COSPONSORS(5), ALPHABETICAL [followed by Cosponsors withdrawn]: (Sort: by date)

Rep Conyers, John, Jr. - 6/16/2003 [MI-14] Rep Gibbons, Jim - 6/16/2003 [NV-2]
Rep Matheson, Jim - 5/22/2003 [UT-2] Rep Sensenbrenner, F. James, Jr. - 5/22/2003 [WI-5]
Rep Tauzin, W. J. (Billy) - 5/22/2003 [LA-3]

SUMMARY AS OF:
5/22/2003--Introduced.

Fairness to Contact Lens Consumers Act - Requires a "prescriber" (a person permitted under State law to issue prescriptions for contact lenses) to provide to the patient a copy of the patient's contact lens prescription free of charge.

Declares that a contact lens prescription shall expire: (1) on the date specified by the law of the State involved, if that date is one year or more after the issue date of the prescription; or (2) not less than one year after the issue date of the prescription, if such State law specifies no date or a date that is less than one year after the date of the prescription. Permits an exception in either instance for a patient's ocular health.

Prohibits advertising that lenses for which a prescription is required may be obtained without a prescription. Prohibits a prescriber from issuing certain waivers.

States that any violation of this Act shall be treated as a violation of the Federal Trade Commission Act regarding unfair or deceptive acts or practices.

Fairness to Contact Lens Consumers Act (Introduced in House)

HR 2221 IH

108th CONGRESS
1st Session
H. R. 2221

To provide for availability of contact lens prescriptions to patients, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

May 22, 2003

Mr. BURR (for himself, Mr. TAUZIN, Mr. SENSENBRENNER, and Mr. MATHESON) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To provide for availability of contact lens prescriptions to patients, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the `Fairness to Contact Lens Consumers Act'.

SEC. 2. AVAILABILITY OF CONTACT LENS PRESCRIPTIONS TO PATIENTS.

(a) IN GENERAL- Upon completion of a contact lens fitting, a prescriber--

(1) whether or not requested by the patient, shall provide to the patient a copy of the contact lens prescription; and

(2) shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription by electronic or other means.

(b) LIMITATIONS- A prescriber may not--

(1) require purchase of contact lenses from the prescriber or from another person as a condition of providing a copy of a prescription or verification of a prescription under subsection (a);

(2) require payment in addition to the examination fee as a condition of providing a copy of a prescription or verification of a prescription under subsection (a); or

(3) require the patient to sign a waiver or release as a condition of verifying or releasing a prescription.

SEC. 3. EXPIRATION OF CONTACT LENS PRESCRIPTIONS.

A contact lens prescription shall expire--

(1) on the date specified by the law of the State involved, if that date is one year or more after the issue date of the prescription;

(2) not less than one year after the issue date of the prescription if such State law specifies no date or a date that is less than one year after the issue date of the prescription; or

(3) notwithstanding paragraphs (1) and (2), on the date specified by the prescriber, if that date is based on the medical judgment of the prescriber with respect to the ocular health of the patient.

SEC. 4. CONTENT OF ADVERTISEMENTS AND OTHER REPRESENTATIONS.

Any person that engages in the manufacture, processing, assembly, sale, offering for sale, or distribution of contact lenses may not represent, by advertisement, sales presentation, or otherwise, that contact lenses may be obtained without a prescription.

SEC. 5. PROHIBITION OF CERTAIN WAIVERS.

A prescriber may not 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 prescriber for the accuracy of the eye examination.

SEC. 6. VIOLATIONS.

Any violation of this Act shall be treated as a violation of a rule under section 18 of the Federal Trade Commission Act (15 U.S.C. 57a) regarding unfair or deceptive acts or practices.

SEC. 7. STUDY AND REPORT.

(a) STUDY- The Federal Trade Commission shall undertake a study to examine the strength of competition in the sale of prescription contact lenses. The study shall include an examination of the following issues:

(1) The States that have laws that require active or passive verification for the sale of contact lenses.

(2) With respect to the States that require active verification, the practices of prescribers in complying with State law, the effect of noncompliance, and the harm to competition and consumers that results from noncompliance.

(3) With respect to the States that require active verification, the level of enforcement and any problems relating to enforcement.

(4) The impact on competition of verification standards adopted by retail sellers of prescription contact lenses.

(5) With respect to States that require passive verification or have no applicable verification laws, the possible effect of such laws or lack thereof on the ocular health of patients. In addition, the effect of such laws or lack thereof on compliance by sellers in confirming valid contact lens prescriptions, including expiration dates. The Commission shall consult the Food and Drug Administration on this particular issue.

(6) The incidence, if any, of contact lens prescriptions that specify brand name or custom labeled contact lenses, the reasons for the incidence, and the effect on consumers and competition.

(7) Any other issue that has an impact on competition in the sale of prescription contact lenses.

(b) REPORT- Not later than 9 months after the date of the enactment of this Act, the Chairman of the Federal Trade Commission shall submit to the Congress a report of the study required by subsection (a).

SEC. 8. DEFINITIONS.

As used in this Act:

(1) CONTACT LENS FITTING- The term `contact lens fitting' means the process that begins after the initial eye examination and ends when the prescriber is satisfied that a successful fit has been achieved or, in the case of a renewal prescription, ends when the prescriber determines that no change in prescription is required, and such term may include--

(A) an examination to determine lens specifications;

(B) except in the case of a renewal of a prescription, an initial evaluation of the fit of the lens on the eye; and

(C) medically necessary followup examinations.

(2) PRESCRIBER- The term `prescriber' means, with respect to contact lens prescriptions, an ophthalmologist, optometrist, or other person permitted under State law to issue prescriptions for contact lenses in compliance with any applicable requirements established by the Food and Drug Administration.
(3) CONTACT LENS PRESCRIPTION- The term `contact lens prescription' means a prescription, issued in accordance with State and Federal law, that contains the specifications necessary for a patient to obtain contact lenses and may include such items as the following:
(A) The name of the patient.
(B) The date of the examination.
(C) The issue date and the expiration date of the prescription.
(D) A clear notation contact lenses are suitable for the patient.
(E) The parameters and instructions that are necessary for manufacture and duplication of the lenses.
(F) The name, postal address, telephone number, and facsimile telephone number of the prescriber.
(G) The expiration date of the prescription.

SEC. 9. EFFECTIVE DATE.

This Act shall take effect 60 days after the date of the enactment of this Act.

Attachment 5

Stamey, Carol S.

Submitted by Dr. Smart

From: Cox SMTP east
nt: Tuesday, June 24, 2003 8:37 PM
: Stamey, Carol S.

REPORT FROM ARBO 2003

1. National Board: a) item writers for the board are needed. You will receive a manual and it may lead to serving on committees that select the actual test. b) The new test will be more clinically related in all phases.
c) while the initial numbers of those who pass may look bad in actual fact by the time they graduate the pass rate is 91% in '02. Only o.5% did not pass any of the parts by graduation. d) The reason it takes so long to get the results is that a number of committees have to review the results on the questions in order to decide if they are valid etc. If it is determined there is a problem with a particular question it is removed. In a questionable case the decision is tilted towards the student. 2. New test: a) will be condition based and will test entry level skills in general optometry. b) it will be a lengthy process due to the development and testing that will need to be done. c.) It is doubtful that a computer based test will be able to be developed due to cost and availability of testing sites. It is hard to get enough sites at one time to give the test and doing it on various days involves multiple tests. d)The new test will be based on conditions encountered in general practice. e) if you would like to be a collection point for the basic data for the test contact Mort Soroka and the SUNY Center for Vision Care Policy. There is a form you will submit on what you run into on a typical day in the office. 3. ARBO action plan. a) continue the ARBO/NBEO relationship b) develop a database that will serve the entire industry , possibly a unique OD ID # so can track where a doctor is, maybe by end of 2003 c) enhance industry relationships to improve financial support etc d)license mobility e)continuing compentency f)expand COPE internationally g) fer fee for service recertification/licensure to the member boards.
AOSA : there are about 5800 students and about 5300 of them are AOSA mbers. Many are involved and the challenge is to keep them involved in organized optometry after they graduate. 5. COPE : a)approved initially in 1993. b) this year 1874 courses approved for 500 events. b) since the start there have been 10,000 courses provided at more than 3000 events. c) this is the first year that there has been a positive cash flow for COPE. prior to this ARBO made up the deficit. d) the web site is being updated faster. e) if a COPE course is not given properly you are asked to notify the COPE office of the date/course# etc and approval will be reviewed. f)Course reviewers are needed. Vistacon has agreed to provide funding for training for reviewers. 6. CELMO: a) resolution approved to proceed with the project. Copy attached. b)At present I have been asked to continue on the committee. The committee met after ARBO and is moving forward to address some of the concerns voiced during the meeting as well to gather additional information as to requirements for endorsement in various states. 7. Vistacon: 1800 Contacts has to validate Rx but has 8 Business hours for you to respond. If you do not then it is passive verification. If the Doctor puts ax expiration date on the Rx that goes into the "chart" for the patient and will kick out the Rx if it is past the date. Patient will be notified
to contact the doctor for care. Vistacon has testors validating that this is happening and they say it is working. Some doctors report seeing patients they have not seen in years. The down side is that this is only for Vistacon products. 8. As my Dr Harrill often said before me " if you have not at least spent a weekend observing a clinical care test site or better yet as a tester you should do it at least once" They always need doctors to do the testing and it is interesting as well as educational.