

**BOARD OF OPTOMETRY
TPA FORMULARY ADVISORY COMMITTEE MEETING
AUGUST 9, 2004
RICHMOND, VA**

TIME AND PLACE: The meeting was called to order at 9:05 a.m. on Monday, August 9, 2004 at the Department of Health Professions, 6603 West Broad Street, 5th Floor, Room 3, Richmond, Virginia.

PRESIDING CHAIR: William T. Tillar, O.D.

MEMBERS PRESENT: Thomas Cheezum, O.D. (replacing Dr. Green)
Craig Hensle, M.D.
Susan Keene, O.D.
Ralph Small, R.Ph.
Samuel C. Smart, O.D.
E. Winston Trice, M.D.

STAFF PRESENT: Emily Wingfield, Assistant Attorney General, Board Counsel
Elaine Yeatts, Senior Regulatory Analyst
Elizabeth A. Carter, Ph.D.
Carol Stamey, Administrative Assistant

OTHERS PRESENT: Bruce Keeney, Virginia Optometric Association (VOA)
Cal Whitehead, VA Society of Ophthalmology
Pat Jackson, VOA
Tom O'Brien, Esquire, VOA

QUORUM: With all members of the Committee present, a quorum was established.

PUBLIC COMMENT: Tom O'Brien stated that the VOA supported the passage of HB 856, and his comments are incorporated into the minutes as Attachment 1.

Bruce Keeney, Executive Director and Legislative Counsel for the VOA, stated that all U.S. schools of optometry provide extensive didactic and clinical training in the treatment of ocular disease with pharmaceutical agents. Further, he reported that all optometry schools staff ophthalmologists, Ph.D. pharmacologists, pharmacists, and optometrists who specialize in this area. He stated that, excluding surgical training, the classroom and clinical education received by optometrists is equal to or often times greater than that received by ophthalmologists and is vastly superior to the training received by primary care physicians in the treatment of eye disease. Mr. Keeney stated that in recognition of the

difficulty and complexity of forum reviews, the VOA had conducted its own national research to assist the Committee. Specifically, their research revealed that the reference book, *Ophthalmic Drug Facts*®, written by a team of national experts, was commonly used by ophthalmologists and optometrists. Further, that this reference book is updated annually and thereby tracks new drugs.

Mr. Keeney noted that the issue of providing care to the public was the purpose of the Committee and Board. He stated that there were many optometrists throughout Virginia who were the only primary eye care source in their area. Further, he held that failure to provide the tools necessary for optometrists to provide care to patients could delay care, threaten sight, engender duplication of service, and increase costs.

APPROVAL OF MINUTES:

On properly seconded motion by Dr. Smart, the Committee voted unanimously to approve the minutes of the June 17, 2004 meeting.

CHAIR'S REMARKS:

Dr. Tillar reported that the meeting's purpose was to develop amendments to the formulary portion of the Therapeutic Pharmaceutical Agents Regulations (§18 VAC 105-30-10 *et seq.*) in keeping with the requirements of HB 856 - - Chapter 744 of the Acts of the Assembly for the 2004 Session. The Committee was assembled today to further develop its recommendations concerning the formulary to the Board of Optometry.

COMMITTEE DISCUSSION OF PROPOSED LANGUAGE:

The Committee reviewed the proposed TPA Formulary submitted by the VOA. The document is incorporated into the minutes as Attachment 2.

A question was posed about other states' formularies. Staff presented a handout summarizing the various states' TPA formulary statutes and regulations. There was discussion with regard to the relevancy of the various state regulations regarding TPA, given the differences in statutory bases.

On properly seconded motion, Dr. Cheezum moved that the proposed formulary established at the June 17, 2004 meeting be set aside and to move forward in the agenda. The motion was passed with four in favor (Cheezum, Smart, Keene and Tillar) and three opposed (Hensle, Small, and Trice).

The Committee agreed that Item A should read as follows:

A TPA certified optometrist, acting within the scope of his practice, may procure, administer and prescribe the following pharmaceutical therapeutic agents (or any therapeutically appropriate combination thereof) appropriate to treat diseases and abnormal conditions of the human eye and adnexa within the following categories:

Ms. Wingfield was questioned about drug classifications for the TPA formulary as opposed to individual drugs. Ms. Wingfield responded that the statute was drafted broadly enough to include the use of drug classifications.

On properly seconded motion, Dr. Cheezum moved that the Committee establish the TPA formulary based upon categories rather than specific drugs. The motion passed with four approving (Cheezum, Keene, Smart, and Tillar) and three opposing (Hensle, Small, and Trice).

On properly seconded motion, Dr. Smart moved that the following language be added to the formulary:

A.1. Oral Analgesics:

- a. Schedule III narcotic and non-narcotic oral analgesics preparations;*
- b. Schedule IV narcotic and non-narcotic oral analgesic preparations;*
- and*
- c. Schedule VI oral analgesics within the following categories: steroidal and non-steroidal anti-inflammatory agents; and centrally acting analgesics.*

A.2. Topically administered Schedule VI agents:

- a. Alpha-Adrenergic Blocking Agents;*
- b. Anesthetics (including Esters and Amides);*
- c. Anti-allergies (including Antihistamines and Mast Cell Stabilizers);*
- d. Antifungals*
- e. Anti-glaucoma;*
- f. Anti-Infectives (including Antibiotics and Antivirals);*
- g. Anti-Inflammatories (including Steroidal and Non-steroidal);*
- h. Cyclopegics and Mydriatics;*
- i. Decongestants;*
- j. Hypotensive Agents (including Carbonic Anhydrase Inhibitors and*

Hyperosmotics); and
k. Immunosuppressive Agents.

Dr. Smart accepted a friendly amendment from Dr. Hensle to add the word “ocular” in front of Anti-glaucoma (e) and Hypotensive Agents (j).

Dr. Smart accepted a friendly amendment from Dr. Trice to remove item j. and add the following language to item e. (*including Carbonic Anhydrase Inhibitors and Hyperosmotics*).

Dr. Smart accepted a friendly amendment from Dr. Trice to strike the words *Steroidal and Non-steroidal* from 1 c.

Ms. Wingfield noted the words “the following” in the second line of section A should be dropped due to duplication.

Dr. Small questioned whether "Centrally Acting Analgesics" constitute a category rather than a mechanism.

Ms. Yeatts recommended that the word “preparation” A. 1.a.b. and c. be changed to “agents”.

Dr. Cheezum suggested that 1.a read as follows:
Schedule III, IV, VI narcotic and non-narcotic agents.

Dr. Cheezum called for the question on the motion on the floor and amendments thereto just discussed. The motion passed with four approving (Cheezum, Keene, Smart, and Tillar) and three opposing (Hensle, Small, and Trice).

On properly seconded motion, Dr. Cheezum moved to reconsider Section A.3. to read as follows:

Orally administered Schedule VI agents within the following categories:

- a. Aminocaproic Acids (including Antifibrinolytic Agents);*
- b. Anti-allergy (including antihistamines and Leukotrient Inhibitors);*
- c. Anti-fungal*
- d. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);*
- e. Anti-infectives (including Antibiotics and Antivirals);*
- f. Anti-inflammatory (including steroidal and non-steroidal);*

g. Decongestants

*h. Hypotensive Agents (including Carbonic Anhydrase Inhibitors and Hyperosmotics);
and*

i. Immunosuppressive Agents.

Dr. Cheezum accepted a friendly amendment from Dr. Trice to strike item h.

Dr. Cheezum called for the question on the motion regarding Section 3. The motion passed with four approving (Cheezum, Keene, Smart, and Tillar) and three opposing (Hensle, Small, and Trice).

On properly seconded motion, Dr. Hensle moved that item i. be deleted from Section A.3. The motion passed with four supporting (Hensle, Small, Smart, and Trice), two opposing (Tillar and Keene), and one abstaining (Cheezum).

On properly seconded motion, Dr. Smart moved that the word “appropriate” be removed from item A. The motion carried unanimously.

On properly seconded motion, Dr. Smart moved that item B read as follows:

The following drugs are excluded from the list of pharmaceutical therapeutic agents: Any Schedule I, II or V drugs.

Ms. Yeatts recommended that the language for item B read as follows:

Schedule I, II and V drugs are excluded from the list of therapeutic pharmaceutical agents.

Dr. Smart accepted the revision. Dr. Smart called for the question on the floor, the motion carried unanimously.

On properly seconded motion, Dr. Cheezum moved that item C read as follows:

Over-the-counter topical and oral medications for the treatment of the eye and its adnexa may be procured for administration, administered, prescribed or dispensed.

Dr. Cheezum called for the question and the motion passed with four approving (Cheezum, Keene, Smart, Tillar), and three opposing (Hensle, Small, and Trice).

Dr. Smart moved that item D read as follows:

Any optometrist may prescribe and dispense contact lenses for therapeutic purposes.

Dr. Trice requested that item D be removed.

Dr. Smart withdrew his motion.

Dr. Smart moved that item E read as follows and becomes item D:

A TPA-certified optometrist may inject epinephrine intramuscularly for emergency treatment of anaphylactic shock.

Upon discussion that this was adequately covered in statute, Dr. Smart withdrew this motion.

The Committee's entire proposal is incorporated into the minutes as Attachment 3.

ADJOURNMENT:

Dr. Cheezum moved to adjourn the meeting at 11:20 a.m.

William T. Tillar, O.D., Chairman

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

TPA-FORMULARY COMMITTEE

August 9, 2004

Comments from J. Thomas O'Brien, Jr.

I. Overview

My name is Tom O'Brien. I'm an attorney with Spotts Fain, P.C. here in Richmond.

I am here today representing the Virginia Optometric Association, which represents approximately 85% of the active, practicing optometrists in the Commonwealth.

The Virginia Optometric Association (which I will sometimes refer to as the "VOA") supported the passage of House Bill 856. This Bill made changes to the regulation of the practice of optometry, and now permits a "TPA Certified Optometrist" to prescribe and administer, within his scope of practice, Schedules III through VI controlled substances and devices to treat diseases and abnormal conditions of the human eye and its adnexa.

The Code of Virginia requires the Board of Optometry to adopt a "TPA Formulary." The TPA Formulary is the inclusive list of the therapeutic Pharmaceutical agents that a TPA-certified optometrist may prescribe. To assist the Board in the specification of the TPA Formulary, this Committee is tasked with

recommending to the Board those therapeutic pharmaceutical agents to be included on the TPA-Formulary.

In June, this Committee met and proposed a Formulary that was questioned by Ms. Emily Wingfield of the Attorney General's Office as being flawed, in part due to references to the current edition of "Drug Facts and Comparisons". A minority recommendation was also proposed by some members of the TPA Formulary Committee.

The Board at its June 30 meeting asked that the TPA Formulary Committee reconvene to prepare a new recommendation for the Formulary.

At the request of the VOA, I contacted Ms. Wingfield and we talked about her concern that the TPA Formulary Committee's original recommendation was legally questionable. I then worked, with the VOA and its Executive Director, Bruce Keeney, to prepare a draft TPA-Formulary that met the technical requirements of the Virginia Code. In preparing these regulations, we sought the input of various optometrists who are members of VOA, as well as other professionals, including several pharmacists.

In July, I offered to meet with Ms. Wingfield to discuss the draft TPA- Formulary that my firm has prepared *on behalf of* the YOA. Although Ms. Wingfield declined to meet with me in light of her role as counsel to the Board of Optometry, based on my previous discussions with her and our reading of the Virginia Code, we believe the draft TPA Formulary fully complies with Virginia

law.

{HAND OUT draft TPA-Formulary}. The VOA supports the draft that is being circulated and would ask you to consider adopting the draft as your recommendation to the Board of Optometry.

I will be present throughout this meeting today. If you have any questions at Time, I would be happy to offer my thoughts on behalf of the VOA.

Draft TPA Formulary, Recommended by the TPA Formulary Committee

August 9, 2004

18 V AC 105-30-70. Therapeutic pharmaceutical agents.

- A. A TPA-certified optometrist, acting within the scope of his practice, may procure, administer and prescribe the following pharmaceutical therapeutic agents (or any therapeutically appropriate combination thereof) appropriate to treat diseases and abnormal conditions of the human eye and its adnexa within the following categories:
1. Oral Analgesics:
 - a. Schedule III narcotic and non-narcotic oral analgesic preparations;
 - b. Schedule IV narcotic and non-narcotic oral analgesic preparations; and
 - c. Schedule VI oral analgesics within the following categories:
 - Steroidal and Non-steroidal anti-inflammatory agents; and
 - Centrally acting analgesics.
 2. Topically administered Schedule VI agents:
 - a. Alpha-Adrenergic Blocking Agents;
 - b. Anesthetics (including Esters and Amides);
 - c. Anti-allergies (including Antihistamines and Mast Cell Stabilizers);
 - d. Antifungals;
 - e. Anti-glaucoma;
 - f. Anti-Infectives (including Antibiotics and Antivirals);
 - g. Anti-Inflammatories (including Steroidal and Non-steroidal);
 - h. Cycloplegics and Mydriatics;
 - i. Decongestants;
 - j. Hypotensive Agents (including Carbonic Anhydrase Inhibitors and Hyperosmotics); and
 - k. Immunosuppressive Agents.
 3. Orally administered Schedule VI agents within the following categories:
 - a. Aminocaproic Acids (including Antifibrinolytic Agents);
 - b. Anti-allergies (including Antihistamines and Leukotriene Inhibitors);
 - c. Antifungals;
 - d. Anti-glaucoma;
 - e. Anti-Infectives (including Antibiotics and Antivirals);
 - f. Anti-Inflammatories (including Steroidal and Non-steroidal);
 - g. Decongestants;
 - h. Hypotensive Agents (including Carbonic Anhydrase Inhibitors and Hyperosmotics) and
 - i. Immunosuppressive Agents.

- B. The following drugs are excluded from the list of pharmaceutical therapeutic agents: Any Schedule I, U or V drug. *[List any other drugs to be excluded]*
- C. Over-the-counter topical and oral medications appropriate to treat the eye and its adnexa may be procured for administration, administered, prescribed or dispensed.
- D. Any optometrist may prescribe and dispense contact lenses for therapeutic purposes.
- E. A TPA-certified optometrist may inject epinephrine intramuscularly for emergency treatment of anaphylactic shock.

Suggested Reference Materials: Ophthalmic Drug Facts®, published by Wolters Kluwer Health, Inc., edited by Jimmy D. Bartlett, OD, DOS, DSC (Hon).

Attachment 3

A TPA-certified optometrist, acting within the scope of his practice, may procure, administer and prescribe therapeutic pharmaceutical agents (or any therapeutically appropriate combination thereof) to treat diseases and abnormal conditions of the human eye and its adnexa within the following categories:

1. Oral analgesics
Schedule III, IV and VI narcotic and non-narcotic agents
2. Topically administered Schedule VI agents:
 - a. Alpha-Adrenergic Blocking Agents
 - b. Anesthetic (including Esters and Amides)
 - c. Anti-allergy (including antihistamines and Mast Cell stabilizers)
 - d. Anti-fungal
 - e. Anti-glaucoma(including carbonic anhydrase inhibitors and hyperosmotics)
 - f. Anti-infective (including Antibiotics and Antivirals)
 - g. Anti-inflammatory
 - h. Cycloplegics and Mydratics
 - i. Decongestants
 - j. Immunosuppressive Agents
3. Orally administered Schedule VI agents:
 - a. Aminocaproic Acids (including Antifibrinolytic agents)
 - b. Anti-allergy (including antihistamines and Leukotriene Inhibitors)
 - c. Anti-fungal
 - d. Anti-glaucoma(including carbonic anhydrase inhibitors and hyperosmotics)
 - e. Anti-infective (including Antibiotics and Antivirals)
 - f. Anti-inflammatory (including steroidal and non-steroidal)
 - g. Decongestants

B. Schedule I, II and V drugs are excluded from the list of therapeutic pharmaceutical agents.

C. Over-the-counter topical and oral medications for the treatment of the eye and its adnexa may be procured for administration, administered, prescribed or dispensed.