Approved 2-17-87
Date

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE.

The meeting was called to order by SENATOR ROY M. EHRLICH at
Chairperson

10:00 a.m./~~p.m.~~ on February 12, 1987 in room 526-S of the Capitol.

All members were present except:

Committee staff present:

Bill Wolff, Legislative Research
Norman Furse, Revisor of Statutes Office
Clarene Wilms, Committee Secretary

Conferees appearing before the committee:
Ron Hein, Representative Counsel for Kansas State Ophthalmological Society
Frank Griffith, M.D., Salina, Kansas
Arthur D. Snow, Jr., M.D., President, Kansas Academy of Family Physicians
Albert N. Lemoine, Jr., M.D., Certified by the American Board of Ophthalmology and a Fellow of the American College of Surgeons
Written testimony by Perry Schuetz, M.D., President, Kansas State Ophthalmological Society
Written testimony by Patricia L. Turner, M.D.
Written testimony by Norma Shoemaker, Counselor

Others attending: see attached list

Ron Hein introduced himself, stating that he and the Kansas Ophthalmology Society were appearing in opposition to SB-113. It was further explained that the conferees were appearing in an order to accomodate those from out of town.

Frank H. Griffith testified and presented written testimony opposing SB-113. Dr. Griffith reviewed his education which included both optometry and ophthalmology, consequently he felt qualified to speak from his own experience. He stated that SB-113 expanded the scope of practice giving an optometrist permission to treat glaucoma and then went on to list other reasons for denying such scope of practice. He stated optometrists in the state of Pennsylvania have been denied the privilege of expansion of their practice act. It was felt that while the use of therapeutic and related studies such as biology, physiology, pharmacology, and clinical experience were receiving more emphasis in optometric education than in the past even optometrists who have recently attended an optometric college did not have sufficient education to use therapeutic drugs fully at their discretion. Dr. Griffith stated that as an optometrist he felt that he was equal to the task of treating eye disease and felt that medical school and residency were redundant to his optometric education. He found there was a vast body of general medical knowledge that is used on a day to day basis in his ophthalmology practice. Because this knowledge is unknown to the optometrist, he does not realize it exists, or even more important, that it may be crucial to treating disease. (attachment 1)

Arthur Snow, Jr., testified and presented written testimony in opposition of SB-113. Dr. Snow stated that Family Physicians are well qualified to handle diagnosis and treatment of eye disease. The American Family Academy of Family Physicians was the first to require 50 hours of CME per year to continue membership, but also requires passing a written recertification test every 7 years. It was also stated that Family Physicians are available through out the state and are appropriately trained in all aspects of medical care, diagnostics and therapeutics. (attachment 2)

Albert N. Lemoine, Jr., M.D., testified opposing SB-113. Dr. Lemoine is a licensed M.D. in the states of Kansas and Missouri, certified by the American Board of Ophthalmology and Fellow of the American College of Surgeons. It was stated that he has supported and continues to support optometrists' use

of drugs for diagnostic purposes in over 29 states. He stated that he was opposed to optometrists or any other health care providers being given the legal right to prescribe drugs for therapeutic purposes or perform surgery to treat eye diseases until their educational experiences include the direct management of patients under adequate supervision. Dr. Lemoine pointed out the bar graphs (attachment 3) to compare professional education, hours of classroom pharmacology, pharmacology education and patients treated in training. It was further stated that lines 0037 to 0039 in SB-113 were of primary concern. It was stated that glaucoma is most difficult to treat and follow, it is even difficult to make a diagnoses. Also of concern was that optometric competence is controlled by their own peers. (attachment 7)

Written testimony was received from Dr. Perry Schuetz opposing SB-113. Dr. Schuetz will testify February 13, 1987. (attachment 4)

Written testimony was presented to the committee in opposition to SB-113 from Patricia L. Turner, M.D. (attachment 5)

Written testimony by Norma Shoemaker, Counselor, in support of SB-78 was presented to the committee. (attachment 6)

Chairman Ehrlich recognized his pages, Heather Deel, Barbara Zwick and Charity Bradford from Sterling.

The Committee will continue hearings on SB-113 February 13, 1987, at 10:00 a.m. in room 526-S.

The meeting adjourned at 11:04 a.m.

SENATE
PUBLIC HEALTH AND WELFARE COMMITTEE
DATE 2-12-87

(PLEASE PRINT) NAME AND ADDRESS	ORGANIZATION
HAROLD C. PITTS	KCOA
Jim Yonally	KOA
A. Snow MD	Kans Acad Fam Phys & Dr for a Day
Perry Hickert MD	Kansas State Ophthalmological Society
Albert N. Lemon Jr	" " "
Frank H Griffith MD	K. S. O. S.
Mark Glenn	KOA
HAROLD E. KIENM	Ks. Assn of Osteopathic Assn
Walt Bettis	Ks. Academy of Family Physicians
KOA Lobbyists	Kansas State Optom Soc
Jim Bell	Kans St. Oph. Soc.
Donald E Beahm MD	Ks Councillor American Academy of Ophthalmology
David Beahm	Visitor
Larry E Hamm, OD	Ks Optometric Assn
KEITH R LANDIS	CHRISTIAN SCIENCE COMMITTEE ON PUBLICATION FOR KANSAS
Phil Anderson	BUDGET DIVISION
Mike Hinds	Ks. Resp. Care Society
Jerry Slaughter	KS MEDICAL SOCIETY
Rebecca Crenshaw	KSOS

SENATE
PUBLIC HEALTH AND WELFARE COMMITTEE
DATE 2/12/87

(PLEASE PRINT) NAME AND ADDRESS		ORGANIZATION
Ron Hein	Topeka	KSOS
Bill Henry	Topeka	Kansas Optometric Assn
LARRY LUTTJOHANN	TOPEKA	Ks. Optometric Assn.
CHARLES BEIER	"	Optometrist
Gordon A. Hammerschmidt	"	"
Dean McSweeney	" "	Optometrist
Kevin B. Wickliff	Lawrence	Sen. Mulich
Richard Harmon		visitor
Ken Schafer	Topeka	KS Pharmacists Assoc.

FRANK H. GRIFFITH, M. D.
Practice Limited To Ophthalmology
1493 EAST IRON AVE.
SALINA, KANSAS 67401

Telephone (913) 827-0488

February 12, 1987

TESTIMONY ON SB-113

"Optometric Therapeutic Bill"

Mr. Chairman, Members of the Committee, Ladies and Gentlemen:

My name is Frank H. Griffith. I am a medical doctor specializing in eye disease and have practiced in Salina, Kansas since 1978. I feel that I have a somewhat unique perspective to offer regarding SB-113. I have been a licensed optometrist in the state of Kansas and was also an instructor for two years on the faculty of the University of Houston College of Optometry. My Doctor of Optometry degree was obtained in 1969, two years prior to the start of my medical education. I graduated from the University of Texas Medical School at San Antonio, Texas and took my ophthalmology residency at the University of Kansas Medical Center.

I am a Diplomate of the National Board of Examiners in Optometry; I am Board certified by the American Board of Ophthalmology and I am a Fellow in the American Academy of Ophthalmology. I have a clinical faculty appointment as a Preceptor in the Department of Surgery of the University of Kansas School of Medicine--Wichita.

As you can see from my preceeding statement, I have a double background both in optometry and ophthalmology.

I have come before this Committee to voice my opposition to the proposed expansion of optometric practice contained in SB-113. The proposed Bill would allow optometrists to use topical therapeutic drugs; perform surgical removal of embedded foreign bodies of the eye that are not intraocular; and specifically expand their privileges to include treatment of chronic glaucoma (one of the most blinding diseases in ophthalmology).

As an optometrist, I was not trained to treat eye diseases; current optometric graduates are <u>not</u> trained to treat eye diseases.

During my four years of optometric training, I examined a total of approximately 300 patient's eyes; most of them were normal or only required glasses or contact lenses. I only saw a few eye diseases and these were referred for final diagnosis and treatment. However, during my medical training and ophthalmology residency, I spent extensive time periods with repetitive exposure to thousands of sick patients with sick eyes. The medical and surgical management of these patients were under the direct supervision of qualified physicians and surgeons.

Optometrists are trying to equate their clinical training as being equivalent to a dentist's clinical training. However, dentists and podiatrists use therapeutic drugs only after both classroom and clinically supervised experience with their use. My optometric training had absolutely <u>no</u> supervised treatment of any type of eye disease. Yet many of my former optometric classmates and students are here asking this Committee for your approval to treat eye disease with medication and surgery even though they have no prior medical education and no clinical experience treating

SPHW
2-12-87
Attachment 1

eye disease. The following is an excerpt from an editorial statement written by Stan Herrin, managing Editor of Review of Optometry, April, 1986. He states: "Treating glaucoma while frustrating, is also good for optometrists. When optometrists treat glaucoma, they can keep more patients under their care, avoiding one way referrals. Glaucoma patients make a steady source of income since they must return frequently for care. And the ability to treat glaucoma further enhances optometry's standing in the health care community."

As an optometrist, I felt that I was equal to the task of treating eye disease and felt that medical school and residency were redundant to my optometric education. Unfortunately, I was wrong. I found there is a vast body of general medical knowledge that is used on a day to day basis in my ophthalmology practice. Because this knowledge is unknown to the optometrist, he does not realize it exists, or even more important, that it may be crucial to treating disease.

This Bill takes a very narrow view of medical eye care. It focuses on treatment of the eye as an isolated organ, to the exclusion of the rest of the body systems. A further assumption is made that treatment with topical drugs is somehow different or separate from other forms of treatment. Some topical eye drops can have potent side effects that may require immediate treatment to reverse their effects. I have personally had to treat some of these side effects. Optometrists make no claim to have any general medical training. It is not in the best interests of our citizens to have potent medications prescribed by non-medical practitioners who will be unable to detect, diagnose, and treat their side effects.

It might be argued that the treatment of some eye problems are sufficiently simple to preclude the requirement for a complete medical education. However, there is the question of whether or not one can separate the treatment of "mild" eye disease from "serious" eye disease. Theoretically, this concept has some appeal, but it assumes that the boundary between simple and complex is readily apparent and sharply defined. This boundary is very often ill defined and a "simple" eye condition can rapidly deteriorate into a sight-threatening problem. It does take all the years of medical training to prepare one to make proper judgments about the potential severity of an eye problem and institute proper therapy. Optometrists do not have the clinical experience necessary to make the distinction of which cases they should and which cases they should not try to treat. It is as important to know when not to treat as it is to know when to treat. It is not satisfactory to try topical medications first, and then wait and if the patient does not get better, then refer him for more definitive and extensive treatment. This is not fair to you, your constituents as patients, or the final treating physician.

The proponents of this Bill state that eye care will be made cheaper and more available to Kansans. However, there are no patients that are not within two hours driving time from an ophthalmologist's care in Kansas or an adjacent state. This also ignores the presence of 1800 primary care physicians in the towns and cities across Kansas. Therefore, optometrists are not more accessible than existing family physicians, internists, or pediatricians. These physicians treat common eye problems and readily refer more difficult problems to an ophthalmologist. Most importantly, they are trained in general medicine and are prepared to responsibly handle all the potential side effects of these medications. Some ophthalmologists also provide medical eye care to many communities without a full-time ophthalmologist on a weekly basis, often in direct cooperation with the

town's local optometrists. Many times, these patients are seen in the local optometrist's office. Therefore, medical eye care while at times may be somewhat inconvenient, is readily accessible to Kansans even in the Northwest corner of the State.

Allowing optometrists to treat with drugs will not save Kansans money. Surveys have found that optometrists have generated almost twice as many eyeglass prescriptions from the same number of patients examined (Medical Economics 1981). In January, 1986, a telephone survey of optometric and ophthalmologic charges for routine eye exams were done in the Salina, Hays, Wichita, and Johnson County areas. It is interesting to note that the fees charged were comparable and in several instances, the optometric fees were higher than the ophthalmologist charges even without the use of therapeutic drugs. There is absolutely no documented evidence that expanding the role of optometry to include the use of drugs and surgery is cost effective. Optometrists only provide care to approximately 32% of Medicare age patients while ophthalmologists provide 68% of the eye care of these citizens. (Optometric Management, February, 1987). The American Academy of Ophthalmology introduced a National Eye Care Project in Kansas on March 31, 1986. This program has aided many Kansans over 65 who can least afford medical care. Free treatment of their eye disease has been provided if these patients do not have any insurance.

Any time a profession expands its scope of practice, their malpractice costs rise after a short grace period. These higher malpractice costs will be passed on to their parents. Kansas optometrists are included in the Health Care Stabilization Fund and increased optometric malpractice claims will further strain the nearly depleted fund. In fact, malpractice insurance for optometrists will be more difficult to obtain. State Farm Fire and Casualty Insurance Company will not insure optometrists in states with therapeutic laws. Optometrists currently provide Kansans with a valuable service in the prescription and dispensing of glasses and contact lenses. There is no documented need to expand their services.

Ophthalmology's concern is that Kansans will continue to receive care from those who are best qualified by education and clinical training to precisely diagnose and properly treat eye disease as well as follow a patient's disease through the best possible recovery. This law would permit delay in diagnosis, offer the patient false reassurances, and could cause loss of vision. This is not an economic turf battle but concerns the maintenance of quality eye care for the citizens of Kansas. Do not allow political pressure to provide a short cut to education. This is an untried area and other states do not have a long enough track record to document the safety of allowing optometrists to treat eye disease. Do not let the citizens of Kansas have their eyesight placed at risk by an unproven practice of allowing non-medical practitioners to treat eye disease. Dr. George Weinstein has testified before the West Virginia Legislature of at least 40 cases of optometric mismanagement, some of which involved life threatening conditions such as cancers of the eye and eyelids. Other cases resulted in permanent loss of vision. Obviously, there is no truth to the claim that there have been no problems with diagnostic and therapeutic drugs used by optometrists in West Virginia. Optometry may point to a number of instances in which problems arise during treatment of eye disease by ophthalmologists. I feel badly for those patients but this simply points out that treatment of eye disease can be difficult even for ophthalmologists. How can optometrists hope to treat eye disease with a brief afterthought course in disease treatment.

At this time, every citizen in the state of Kansas who has an eye disease is guaranteed that he will be treated by a physician. The eyesight of every citizen of Kansas is too important to risk for the benefit of a few optometrists who wish to treat eye disease without the proper medical education. Consider what you would do for your family. If you do not believe that a few additional hours of training in pharmacology will qualify a person with only six years of non-medical education to practice medicine and surgery, then vote against this bill. It will not make eye care better. It will not make eye care cheaper. It could be dangerous. This Bill is not worth the risk of the sight of even one Kansan. Weigh my testimony and if you agree, please vote against Senate Bill 113. Thank you for your time and attention.

Sincerely,

Frank H Griffith OD, MD

Frank H. Griffith, O.D., M.D.

FHG/sks

Kansas Academy of Family Physicians

818 Carriage Parkway, P.O. Box 20597 • Wichita, Kansas 67208 • (316) 651-2238

Walter D. Bettis
Executive Director

February 12, 1987

Mr. Chairman and Members of the Committee:

My name is Art Snow. I am a practicing family physician in Shawnee Mission, Kansas. I received my M.D. from the University of Kansas in 1975. (I am also your Doctor-for-a-Day today, so if I can be of any service to you or your staff today, please let me know.)

I come to speak to you today as the President of the Kansas Academy of Family Physicians regarding SB 113, an act concerning optometrists. The optometrists want to diagnose and prescribe medications to treat eye disease. As training for this, some optometrists have taken a course taught by opthalmologists. Another large contingent of ophthalmologists do not feel this training is adequate. (I'm sure you have heard many details of these arguments.) The real issue here is quality eye care for the patients of the state of Kansas.

There are approximately 80 ophthalmologists in Kansas who unquestionably are the best trained in the diagnostics and therapeutics of diseases of the eyes.

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2-12-87
attachment 2

There are approximately 300 optometrists in the state. By numbers, they are clearly more available. However, debate continues regarding their training.

There are approximately 735 family physicians across Kansas. There are 126 residents in family practice training programs in Kansas. There are 350 medical students who are student members of the Kansas Academy of Family Physicians. These physicians are geographically well distributed throughout the state of Kansas and are the best qualified people to deliver medical services for the diagnosis and therapy of eye diseases.

Family physicians are very adequately trained in all areas of medicine. Our training includes four years of medical school and three years of post-graduate training after receiving the M.D. degree. Diagnosis and treatment of eye disease is taught very well at both the undergraduate and the post-graduate level in the Family Practice Program at K.U. in Kansas City (and in all other programs I have had contact with).

As a family physician, I see, diagnose, and prescribe medications daily for numerous eye problems. Many lectures, articles, and other Continuing Medical Education materials are available and used by family physicians to continually update their knowledge. Recall that the American Academy of Family Physicians was the first specialty to not only require 50 hours of CME per year to continue membership, but also requires passing a written recertification test every seven years.

Gonorrhea, tuberculosis, herpes infections, chickenpox, German measles,

infectious mononucleosis, mumps, measles, various fungal infections, histoplasmosis, toxoplasmosis, syphilis, and a systemic granulomatous disease--sarcoidosis--are all diseases requiring a full medical history and physical examination to diagnose and treat. All can present as "eye disease". Sjogren's syndrome is a chronic connective tissue disease that can be manifested by a conjunctivitis-like finding. Giant cell arteritis can be manifested by eye findings and can result in total permanent blindness. A severe acute inflammatory disease--erythema multiforme--or a chronic generalized systemic disorder--systemic lupus erythematosus--can present themselves as eye disease. Neurologic diseases--myasthenia gravis and multiple sclerosis, an arthritic disease--rheumatoid arthritis, and many more systemic diseases can present as eye disease. These are all diseases that require specialized medical knowledge to diagnose and treat. A limited practitioner must not be allowed to be responsible for the diagnosis and treatment of eye diseases when the eye may only be one manifestation of an illness.

Medications used in the eye can and do provide not only relief from the diagnosed condition, but also can and do lead to other nondesired, occasionally dangerous side effects. These additional problems do not affect only the eye. Complete medical training is necessary to adequately diagnose and prescribe for treatment of eye disease. Otherwise, the practitioner cannot be expected to diagnose or treat in the most effective, safest way possible.

There is no need to offer to the residents of the state of Kansas anything less than the best in eye care (or any other medical care, for that matter).

Family physicians are,

1) available throughout the state of Kansas

2) appropriately trained in all aspects of medical care--diagnostics and therapeutics

and should remain the primary provider of quality eye care.

Please do not lessen this care.

Thank you.

Arthur D. Snow, Jr., M.D.
President
Kansas Academy of Family Physicians

ADS:jg

Attachments

REVIEW ARTICLE

Systemic Effects of Topical Ophthalmic Medications

BEATRICE L. SELVIN, MD, Baltimore, Md

ABSTRACT: Ophthalmic drugs topically applied have significant systemic absorption, which may result in widespread adverse side effects. All physicians involved in the care of patients receiving these drugs should be cognizant of such actions, interactions, and toxic effects. They should also be familiar with the prevention, diagnosis, and treatment of these effects, as well as the mechanisms of systemic drug absorption.

OPHTHALMIC DRUGS, topically applied, are intended to exert a local effect on the eye or penetrate the cornea and act on some internal ocular structure. However, after being placed in the conjunctival sac, a significant amount of drug is available for systemic absorption and may result in adverse systemic side effects.[1,2] These effects are frequently not anticipated, recognized, or treated appropriately. The patient's routine history may not even reveal the use of eye drops. Neither ophthalmologist, other physicians involved in patient care, nor the patient himself may appreciate the magnitude of milligram dosage contained in one to two drops of medication or associate early, acute, or chronic symptoms with this drug therapy. If an operation is planned, both the ophthalmologist and the anesthesiologist may fail to consider the potential actions and interactions of eye drops "routinely" administered in the perioperative period.

Systemic absorption occurs by several routes:

Nasal mucosa: The puncta of the eye and the nasolacrimal duct afford access to the nasal mucosa. The rate of drug absorption across mucous membranes is extremely rapid and comparable to intravenous administration.[3-6] The structure of the superficial nasal vessels, especially in the turbinates, has a striking resemblance to the parallel pipes of a heating or cooling system and supports this rapid absorption.[7] The nasal mucosal route has even been effectively used to administer drugs for the treatment of diabetes insipidus[8,9] and air sickness.[7]

Gastrointestinal tract: If the drug can survive the acidity of the stomach, the gastrointestinal tract is a major pathway for absorption, as well as elimination, of ocularly applied drugs. Access to the gastrointestinal tract occurs by swallowing the drug after it has traversed the nasolacrimal duct and the nasopharynx.

Circulation: Diffusion into the circulation is effected by conjunctival, episcleral, and intraocular vessels, which drain by way of the ophthalmic and facial veins and the cavernous sinus into the superior vena cava and right atrium.[10]

Although there are many reports of systemic effects of ocularly applied drugs, evaluation of toxicity is difficult because of the lack of quantitative data on amounts absorbed and many other variables. Amounts absorbed can be altered by overflow, waste, and dilution caused by blinking, reflex tear production, and simultaneous use of other eyedrops. Differences in eyedroppers and drop size (15 to 40 drops/ml) result in different milligram per drop dosage. Less of a drop is retained in the conjunctival sac of the younger age group, whereas the lax eyelids of the older population allow more retention.[11] Different patient populations have varying susceptibility to the medications.[12-14] Pediatric and geriatric patients are inclined toward increased toxicity.[1,15-17] The eye that is dry (as occurs under general anesthesia), hyperemic, or diseased will allow increased systemic absorption of drug.[18,19] Patient position alters the amount of drug absorption; a tenfold loss of drug occurs in the upright position.[20]

From the Department of Anesthesiology, University of Maryland Hospital, Baltimore.
Reprint requests to Beatrice L. Selvin, MD, Department of Anesthesiology, University of Maryland Hospital, 22 S Greene St, Baltimore, MD 21201.

Systemic Effects of Eye Drops

Alan G. Adler, MD; Guy E. McElwain, MD; Geno J. Merli, MD; John H. Martin, MD

• Eye drops are a common form of medication that has been reported to cause a wide range of substantial systemic effects, as reviewed herein. A greater awareness of potential eye drop–related complications is important since these complications are frequently not taken into consideration in a patient's drug history and neglected in a differential diagnosis of adverse reactions.

(*Arch Intern Med* 1982;142:2293-2294)

Until 1964, a search of the general medical literature disclosed only one article containing a warning of toxic reactions from eye drops.[1] Since that time, there have been multiple, scattered reports describing serious, systemic side effects of various eye drops and ointments, primarily in the ophthalmologic literature. Unfortunately, few nonophthalmologists consider systemic absorption of eye drops as a possible cause when evaluating the condition of a patient with unexplained cardiovascular, pulmonary, autonomic nervous system, or CNS dysfunction. It is essential for all physicians to have an expanded knowledge of the possible consequences of eye medications since they are in such common use.

Following installation into the conjunctival sac, systemic absorption occurs through the conjunctival capillaries, as well as via the nasal mucosa, oral pharynx, and gastrointestinal (GI) tract after passage through the lacrimal drainage system. Mucosal hyperemia enhances absorption. Symptoms can often be avoided by digital pressure on the nasal canthus, thereby occluding the puncta. Reactions to ointment are less frequent than eye drops because of reduced absorption by the conjunctiva and lack of lacrimal duct passage.

To illustrate the total dose of a drug administered by topical application, consider a drop of 2% solution of epinephrine hydrochloride in each eye. Assuming that there are 15 drops/mL, more than 2.5 mg of the drug is introduced in the conjunctival sacs.[2] As little as 10% absorption could result in doses of 0.2 to 0.3 mg, known to produce cardiac effects in many patients when given intravenously or subcutaneously.

For practical purposes, adverse reactions will be discussed in relationship to the cardiovascular and pulmonary systems, the autonomic nervous system, the CNS and miscellaneous side effects.

Cardiovascular and pulmonary effects of the adrenergic and antiadrenergic eye preparations have been well documented. Sympathomimetic agents such as phenylephrine hydrochloride are used to produce dilatation of the pupil. Thirty-three cases of notable adverse reactions possibly associated with ocular use of 10% phenylephrine as reported to the National Registry of Drug-Induced Ocular Side Effects have been detailed.[3] These cases include 15 myocardial infarctions (11 that were terminal) and seven additional cases requiring cardiopulmonary resuscitation. Severe hypertensive reactions following administration of 10% phenylephrine have also been reported,[4] including one case of a subarachnoid hemorrhage caused by severe hypertension.[5] Kim et al[6] reported that patients with partially denervated, sympathetic nervous systems (such as diabetics with autonomic neuropathy or those patients on a regimen of reserpine or guanethidine sulfate) are at a greater risk of hypertensive reactions to phenylephrine because of a denervation hypersensitivity. Furthermore, we have recently reported a case of coronary artery spasm in a diabetic induced by 10% phenylephrine eye drops.[7] Substantial elevations of BP precipitated by 1% and 2.5% phenylephrine drops have been reported, but, in both cases, patients had been on a regimen of clonidine hydrochloride for hypertension, which had been abruptly stopped.[8]

Epinephrine drops, frequently used in the treatment of glaucoma, have been reported to produce an increased incidence of ventricular extrasystoles in approximately 8% of all patients.[9] Although the incidence of more serious reactions, eg, palpitations, hypertension, tachycardia, and anxiety is rather low,[10] these reactions may be detrimental to the patient with borderline cardiac symptoms.

Timolol maleate, a nonspecific β-adrenergic blocking agent, became available for treatment of glaucoma several years ago. Serious adverse reactions involving the cardiopulmonary system (as well as the autonomic nervous system and CNS) have been proved. Charan and Lakshminarayan[11] reported the occurrence of acute bronchospasm in a previously asymptomatic patient with asthma following topical use of timolol. A second challenge of the patient with 2 drops of 0.5% timolol maleate resulted in a 25% decrease in forced expiratory volume at 1 s, and another challenge with 4 drops caused a 47% decrease.[11] An episode of congestive heart failure in an elderly patient with known rheumatic disease has also been linked to taking timolol eye drops.[12] Further demonstration of the systemic effects of timolol has been provided by McMahon et al[13] who studied 165 patients who had been started on a regimen of timolol eye drops. Of these, eight patients had symptoms or signs related to the cardiovascular system, including bradycardia, palpitations, hypotension, and syncope. Syncope was the most serious reaction reported by three patients, although 39% of all patients had small, asymptomatic reduction in their pulse rates. Three patients had respiratory symptoms after timolol therapy was initiated—two of the three were mild exacerbations of underlying disease, while the third was an acute asthma attack in a 12-year-old boy with only one previous, brief episode of asthma as a child.

The autonomic nervous system may also be adversely affected by the systemic effects of eye drops. Toxic reactions may be produced by cholinergic drugs such as pilocarpine hydrochloride, but more commonly may be produced by anticholinesterase agents such as echothiophate iodide and demecarium bromide.

Symptoms of nausea, vomiting, abdominal cramps, diarrhea, sweating, salivation, rhinorrhea, respiratory distress, muscular fasciculations, and weakness have occurred from overdoses with topical pilocarpine, usually given for an acute glaucoma attack.[14,15] However, therapeutic low-dose topical pilocarpine has also been reported to induce GI

Accepted for publication Aug 12, 1982.

From the Department of Medicine, Thomas Jefferson University Hospital, and Will's Eye Hospital, Philadelphia.

Reprint requests to Department of Medicine, Thomas Jefferson University Hospital, Philadelphia, PA 19107 (Dr Adler).

The Effect of Topical Ophthalmic Instillation of Timolol and Betaxolol on Lung Function in Asthmatic Subjects[1-4]

THADDEUS L. DUNN, MICHAEL J. GERBER, ANTHONY S. SHEN, ENRIQUE FERNANDEZ, MICHAEL D. ISEMAN, and REUBEN M. CHERNIACK

SUMMARY The propensity of systemic beta-adrenergic blockers to cause bronchoconstriction in patients with reactive airway disease is well recognized. A study was carried out to determine the prevalence of sensitivity to ophthalmic timolol in 24 asthmatic subjects at our institution and to determine the effect of ophthalmic betaxolol, a cardioselective beta-blocker efficacious in the treatment of glaucoma, in 8 subjects who were timolol-sensitive. Subjects received topical timolol 0.5%; ventilatory function, blood pressure, and heart rate were monitored over a 90-min period. The mean FEV_1 fell from 2.47 to 1.93 L by 30 min after drug treatment to a minimal value of 1.86 L (−27.8%). There was a corresponding fall in FVC from 3.68 to 3.09 L by 30 min with a minimal value of 3.00 L (−20.7%). FEV_1/FVC ratio also fell from 66.9 to 61.0% by 30 min, reaching a minimum of 60.0%. In 14 subjects (58.3%), the fall in FEV_1 was ≥ 20%, with a mean fall of 38.7% by 30 min and a maximal fall of 44.9%. The severity of timolol-sensitivity correlated with the extent of reduction in baseline percent predicted FEV_1 and FVC and with exercise-induced bronchospasm. In addition, the administration of timolol reduced the bronchodilator response to below the pretimolol value. In 8 of the timolol-sensitive patients who underwent a double-blind crossover challenge with ocular instillation of betaxolol 1% and saline, betaxolol was well-tolerated and did not affect ventilatory function over a 4-h observation period. In addition, it did not prevent the FEV_1 response to inhaled bronchodilator. Thus, sensitivity to ophthalmic timolol was common in our patients with asthma and correlated with the severity of airway obstruction and reactivity. Betaxolol, on the other hand, was well tolerated in the timolol-sensitive asthmatics, suggesting that it may prove to be a useful adjunct in the management of glaucoma in patients with reactive airway disease.

AM REV RESPIR DIS 1986; 133:264-268

Introduction

It has long been recognized that administration of systemic beta-adrenergic inhibitors may result in bronchoconstriction in susceptible persons (1-5). More recently, it has become clear that ocular topical beta-antagonists, such as timolol maleate, widely used to reduce intraocular pressure in open angle glaucoma/ocular hypertension, may also cause a worsening of respiratory function (6-16). By 1984, 16 fatal cases of status asthmaticus and more than 200 major reactions had been reported to the National Registry of Drug-Induced Ocular Side Effects (17). Our purpose here is to report the prevalence of sensitivity to timolol in patients with asthma at our institution and to characterize and relate the timolol response to other parameters of airway function. In addition, we report a comparison of the pulmonary response to ophthalmic timolol and betaxolol (18), a cardioselective beta-blocker, which has been demonstrated to be comparably effective to equal concentrations of timolol in the reduction of intraocular pressure (19, 20), and which has also been reported to be well tolerated in asthmatic patients with (21) and without (22) glaucoma.

Methods

Twenty-four subjects (11 men and 13 women: 21 patients at the National Jewish Center for Immunology and Respiratory Medicine and 3 staff members) with a mean age of 40.4 yr (range, 20 to 66 yr), all of whom had an admitting diagnosis of asthma or a history compatible with reactive airway disease, were the subjects of this study (table 1). Institutional Review Board approval had been obtained as was informed consent.

In all, inhaled beta-agonists were withheld for 4 to 6 h before the onset of the study. Clinical status, heart rate, brachial blood pressure, FEV_1, and FVC were recorded before and 30, 60, and 90 min after the instillation of 1 drop per eye of timolol maleate 0.5% (Timoptic 0.5%; Merck, Sharp & Dohme, West Point, PA). When the potential marked rapidity of the timolol response was noted, a 15-min physiologic assessment was added as well in the final 12 patients tested. The study was terminated prematurely if lung function deteriorated rapidly and/or marked wheezing developed. When this occurred, inhaled beta-agonists were administered as needed. Measurements of lung function were carried out after the inhaled bronchodilator in 12 subjects demonstrating timolol sensitivity. In addition, as part of a concurrent study at our institution, within 3 wk of timolol challenge, 19 subjects were evaluated with respect to baseline bronchodilator responsiveness, i.e., percent increase in FEV_1 after inhaled beta-agonist, usually metaproterenol (Alupent Inhalant Solution 5%; Boehringer Ingelheim Ltd., Ridgefield, CT), and 17 subjects underwent testing for exercise-induced bronchospasm (percent decrease in FEV_1 after 4 to 5 min of treadmill exercise at 80 to 85% of maximal predicted heart rate).

In 8 of the patients who exhibited a significant (≥ 20%) fall in FEV_1 after the ocular instillation of timolol (Patients 2, 8, 9, 12, 16, 19, 23, and 24), the effect of the topical betaxolol on lung function was determined. These patients did not differ from the entire group of timolol reactors on the basis of age, baseline spirometry, or degree of timolol sensitivity. In this study, inhaled bronchodilators were once again withheld for 4 to 6 h before the onset of the study. Clinical status, heart rate, brachial blood pressure, FEV_1, and FVC were determined before and 15, 30, 60, 90, 120, 180 and 240 min after the ocular instillation of either betaxolol hydrochloride 1% (Alcon Laboratories, Fort Worth, TX) or normal saline, 1 drop per eye in a double-blind crossover fashion, the alternate solution being administered ≥ 72 h later. In 5 of these subjects, inhaled bronchodilator was administered at the end of the study, and measurements of lung function were carried out.

In general, data did not significantly differ from the normal distribution (univariate

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[1] From the Department of Medicine, National Jewish Center for Immunology and Respiratory Medicine, Denver, Colorado.

[2] Supported by a grant from Alcon Laboratories, Fort Worth, Texas.

[3] Presented in part at the meeting of the Western Section of the American Federation for Clinical Research, Carmel, California, February 7, 1985.

[4] Requests for reprints should be addressed to Reuben M. Cherniack, M.D., Director, Pulmonary Physiology Unit, National Jewish Center for Immunology and Respiratory Medicine, 1400 Jackson St., Denver, CO 80206.

2-7

OCULAR BIOAVAILABILITY AND SYSTEMIC LOSS OF TOPICALLY APPLIED OPHTHALMIC DRUGS

THOMAS F. PATTON, PH.D.,
AND
MICHAEL FRANCOEUR
Lawrence, Kansas

The bioavailability of topically applied pilocarpine nitrate as a function of instilled volume has been reported.[1] By using a pharmacokinetic treatment, this study showed that as the instilled volume was decreased, the fraction of dose absorbed into the interior of the eye increased. Since drainage of instilled solutions into the nasolacrimal duct is a function of instilled volume,[2] the potential for systemic loss of drug should also be minimized by administering doses in volumes smaller than are commonly used.

When a drug is applied locally to an area of the body, the intent is to affect the immediate area of application. Topically applied ophthalmic drugs are intended to exert some local effect or to penetrate the cornea and act on some internal ocular structure. Loss of drugs to other areas of the body and particularly into the general systemic circulation could cause toxic side effects. Such systemic drug loss could be especially harmful in both pediatric and geriatric patients because these age groups may be less able to tolerate large doses of systemically absorbed drug.[3-5]

Much effort in recent years has been devoted to evaluating topical ophthalmic drug delivery in an attempt to optimize ocular bioavailability. The development of solid drug delivery devices[6-12] has been a major advance in this direction. However, the instillation of drugs in drop form continues to be the major method of applying drugs to the eye. Therefore, systematic examination of the factors responsible for drug distribution after this form of drug delivery is essential to place ophthalmic dosage regimens on a more rational basis.

Most investigators have concerned themselves with vehicle influences on drug penetration.[13-19] In this study, our aim was to maximize drug concentration in the eye while simultaneously minimizing systemic drug loss.

MATERIAL AND METHODS

Commercially obtained pilocarpine nitrate USP was used without further purification. Tritiated pilocarpine (specific activity 4.1 Ci/mM) in ethanol solution was evaporated several times before use[20] to remove any solvent that had become tritiated by exchange. All other chemicals were of analytical or reagent grade and were used as received.

All rabbits used were male New Zealand albinos, 18 to 23 days old. Before experimentation, rabbits were housed in standard laboratory animal cages and allowed food and water at will.

Pilocarpine nitrate solutions were prepared in isotonic Sorensen's phosphate buffer at a pH of 6.24. Solutions were filtered for clarity but not sterilized, and were prepared fresh for each experiment. The amount of tritiated pilocarpine added was chosen to insure adequate counting accuracy, but in no case was it sufficient

From the Department of Pharmaceutical Chemistry, University of Kansas, Lawrence, Kansas. This study was supported by grants from the University of Kansas General Research Fund and the Children's Eye Care Foundation. Mr. Francoeur was the recipient of a 1977 University of Kansas, College Honors Program, Undergraduate Research Award.

Reprint requests to Thomas F. Patton, Ph.D., Department of Pharmaceutical Chemistry, University of Kansas, Lawrence, KS 66044.

Systemic Absorption of Topical Ocularly Applied Epinephrine and Dipivefrin

Janet A. Anderson, PhD

• **The systemic absorption of two drugs, epinephrine and dipivefrin hydrochloride, was determined to be from 55% to 65% of the ocularly applied dose. Although dipivefrin is much more readily absorbed into the eye than epinephrine, the systemic absorption of the two drugs was similar. After ocular treatment, the drugs were slowly absorbed into the body over a period of several hours. The metabolism of epinephrine in the body did not appear to be different whether the drug was applied ocularly or injected intravenously. The metabolism of dipivefrin showed some difference depending on route of administration. The tissue distribution of radioactive material after ocular treatment with epinephrine tagged with carbon 14 was quite different than that observed after intravenous treatment. A major pathway for systemic absorption of ocularly applied material appears to be through the walls of the gastrointestinal tract.**

(*Arch Ophthalmol* 98:350-353, 1980)

Many reports in the ophthalmic literature describe systemic effects of ocularly applied drugs. One problem encountered in evaluating the possible systemic toxicity of topical ocularly applied drugs is the varying susceptibilities of different patient populations.[1-3] Another barrier to understanding the systemic effects of ocularly applied drugs is the lack of extensive quantitative data on the amount of a topically applied drug that is systemically absorbed.

In some studies, systemic absorption of substantial amounts of a topically applied drug can be inferred from the extent of the observed systemic effect, for example, the adrenal suppression seen after ocular steroid administration,[4] the extensive reduction of intestinal cholinesterase activity found after echothiophate iodide treatment,[5] and the marked reduction of serum glucose after ocular insulin application.[6] In a more quantitative study of systemic absorption, Janes and Stiles[7] measured the distribution of radioactivity in the body after ocular application of radioactively labeled cortisol. Thirty minutes after treatment, they found 20% to 35% of the applied dose in the body tissues and fluids (not including the eye). Since only a few tissues (liver, gallbladder, kidney, and adrenal glands) were examined in their study, actual systemic absorption of cortisol was undoubtedly greater than that reported.[7]

In the following report, the recovery of radioactivity in body tissues, urine, and feces was determined 96 hours after the application of radioactively labeled drugs to the eye. The results are compared to those obtained after intravenous injection of the same drugs in order to determine what effects the mode of drug application might have on elimination patterns. The two drugs studied were epinephrine and a prodrug of epinephrine, dipivefrin. Dipivefrin is hydrolyzed to epinephrine in the eye[8] and acts like epinephrine in the reduction of intraocular pressure.[9] Dipivefrin is more lipophilic than epinephrine and, as a consequence, is more readily absorbed into the eye.[8]

The systemic absorption of these two compounds was compared to determine whether increased absorption by the eye would affect systemic absorption. Ninety-six hours after drug administration, practically all of the applied drug was excreted in the urine and/or feces. To compare the tissue distribution of an ocularly applied drug with that of the same drug given intravenously, the tissue concentrations of radioactivity were determined 15 minutes and one hour after radioactive epinephrine treatment.

MATERIALS AND METHODS

Female New Zealand white rabbits ranging in weight from 2.0 to 3.6 kg were used in these studies. Epinephrine bitartrate tagged with carbon 14 (molecular weight 333, 33 mCi/mmole), untagged epinephrine bitartrate, and dipivefrin hydrochloride tagged with carbon 14 (mol wt 388, 1 mCi/mmole) were used.

In the long-term (96-hour) studies, rabbits were injected over a period of one minute in the peripheral ear vein with 127 μg/kg of ^{14}C-epinephrine bitartrate or 110 μg/kg of ^{14}C-dipivefrin hydrochloride. Ocularly treated animals were given either 0.1% ^{14}C-epinephrine bitartrate or 0.1% ^{14}C-dipivefrin hydrochloride in 0.01N acetate buffer, pH 4.0. The drop was applied to the eye above the cornea and allowed to spread over the surface of the eye, and then the eye was gently held closed so no blinking occurred. Both eyes were treated with a single 50-μL drop at 30-minute intervals until a total of four drops had been delivered to each eye. Blood samples were taken from the ocularly treated animals every 30 minutes for the first four hours, then hourly for the next four hours. Animals were kept in metabolic cages during the 96 hours after treatment, and urine and feces samples were collected at regular intervals. After 96 hours, the animals were killed by pentobarbital sodium injection. Tissues were taken from the ocularly treated animals for determination of radioactivity. The tissues taken were adrenal gland, brain, cornea, fat, heart, intestine, kidney, liver, lung, skeletal muscle, ovaries, pancreas, pituitary, spleen, and uterus.

Radioactivity of urine was measured by placing 1-mL samples in a vial with 15 mL of scintillation fluid in a liquid scintillation counter. The samples were counted and corrected for quenching with use of the external standard channels ratio. Radioactive contents of tissue and feces samples were determined by oxidizing weighed samples in a materials oxidizer. The radioactive carbon dioxide was collected in a carbon dioxide trapping scintillation fluid. The samples were counted in the scintillation counter and corrected for recovery from the oxidizer by comparison with a standard sample and for quenching as described above.

The rates of elimination of radioactive material from the body were calculated from the equation for loss of material: $\ln(dU/dt) = K - k_e t$, where dU/dt = the change in urine concentration with time; K is constant; k_e, the elimination rate constant; and t, time. When $\ln (dU/dt)$ is plotted against time, the slope is equal to k_e.

Urine samples for the chromatographic studies were collected for 24 hours after ocular or intravenous treatment of rabbits

Accepted for publication June 4, 1979.

From the Department of Ophthalmology, California College of Medicine, University of California at Irvine.

Read in part before the spring meeting of the Association for Research in Vision and Ophthalmology, Sarasota, Fla, May 3, 1978.

Reprint requests to Department of Ophthalmology, California College of Medicine, University of California at Irvine, Irvine, CA 92717 (Dr Anderson).

ADVERSE EXTERNAL OCULAR EFFECTS OF TOPICAL OPHTHALMIC THERAPY: AN EPIDEMIOLOGIC, LABORATORY, AND CLINICAL STUDY*

BY *Fred M. Wilson II,* MD

INTRODUCTION

FOR CENTURIES THE ART OF MEDICINE HAS BEEN OF GREAT IMPORTANCE AND VALue to patients and practitioners alike. When specific remedies were few, physicians relied heavily, and often successfully, on physical and environmental therapy, placebos, prognostication with reassurance and support, and the Hippocratic principle of first doing no harm.

More recently, as the science of therapeutics has advanced, we have come to rely progressively more on the seemingly wondrous capabilities of our drugs and less on the art of our profession. As a result, and because no drug is entirely safe, we may sometimes subject our patients to treatment which does more harm than good.

In general medicine, the importance of adverse reactions to drugs has been the subject of some controversy. The preponderance of evidence and opinion suggests that we live in an overmedicated society and that adverse reactions constitute a problem of considerable magnitude.[1,2] The opposing view is that the problem has been overemphasized and that inappropriate fear of undesirable effects can reduce unacceptably the benefits to be derived from medications.[3] Despite this difference of opinion, all agree that the problem is not a trivial one; that no drug is completely safe; that drug reactions can be clinically confusing or even serious when they develop; that they are never acceptable when they can be prevented; and that every effort should be made to minimize their occurrence.

*From the Corneal and External Ocular Disease Service, Department of Ophthalmology, Indiana University School of Medicine, Indianapolis. Supported in part by a grant from Research to Prevent Blindness, Inc, New York and by Indiana University Computing Center Grant No 350706.

2-10

CLINICAL EVALUATION OF TRIMETHOPRIM-CONTAINING OPHTHALMIC SOLUTIONS IN HUMANS

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Lubbock, Texas

THEODORE BUKA, M.D.
Cincinnati, Ohio

AND
GAIL M. KNOWLTON, M.S.
Lubbock, Texas

We studied trimethoprim in combination with sulfacetamide and polymyxin B and also in combination with polymyxin B alone (without the sulfacetamide) to determine the efficacy and safety of these new antibiotic combinations in the eyes of patients with bacterial conjunctivitis or blepharitis. Patients were selected for the study if they showed at least three of the following criteria: (1) symptoms of a surface ocular infection; (2) a purulent discharge; (3) a polymorphonuclear neutrophilic response on Giemsa stain; (4) a history of recent exposure to an infected individual; (5) a history of an inadequately treated surface bacterial infection. Trimethoprim-sulfacetamide-polymyxin B and polymyxin B-neomycin-gramicidin (Neosporin, the control) eliminated bacteria from the eyes of patients with conjunctivitis or blepharitis with equal effectiveness. There was no loss of effectiveness when trimethoprim-polymyxin B was compared with trimethoprim-sulfacetamide-polymyxin B, suggesting that the sulfacetamide was not a necessary component. The combination antibiotic containing trimethoprim and polymyxin B appears to be an effective topical antibiotic solution for the treatment of ocular surface infections.

Although trimethoprim has been used as a broad-spectrum systemic antibiotic for several years, its use as a topical ophthalmic solution has only recently been reported.[1,2] Trimethoprim inhibits the synthesis of tetrahydrofolic acid from dihydrofolic acid by binding to and reversibly inhibiting the enzyme dihydrofolate reductase. Trimethoprim is most often used in a synergistic combination with sulfamethoxazole in the treatment of *Pneumocystis carinii* pneumonitis, shigellosis, acute otitis media from *Haemophilus influenzae* or *Streptococcus pneumoniae*, urinary tract infections, and acute exacerbations of chronic bronchitis in adults. It is also administered alone in

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From the Department of Ophthalmology, Cornea Service, Texas Tech University School of Medicine, Lubbock, Texas (Dr. Lamberts and Ms. Knowlton). Dr. Buka is in private practice in Cincinnati, Ohio. This study was supported in part by a grant from Research to Prevent Blindness, Inc., New York, New York, and by Burroughs Wellcome Co., Research Triangle Park, North Carolina.

Reprint requests to David W. Lamberts, M.D., Cornea Service, Department of Ophthalmology, Texas Tech University School of Medicine, Lubbock, TX 79430.

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URVEY OF OPHTHALMOLOGY VOLUME 29 • NUMBER 4 • JANUARY-FEBRUARY 1985

THERAPEUTIC REVIEW

STEVEN G. KRAMER AND SAIICHI MISHIMA, EDITORS

Tetracyclines in Ophthalmology

SAMUEL M. SALAMON, M.D.

Combined Program in Ophthalmology, University of Alabama in Birmingham School of Medicine and Eye Foundation Hospital, Birmingham, Alabama

Abstract. Tetracycline and its congeners demonstrate antimicrobial activity against bacteria, *Chlamydiae* and *Toxoplasma gondii*. Ophthalmologists can use these drugs to treat bacterial and chlamydial infections, and also for ocular rosacea and similar disorders. Side effects associated with systemic tetracycline use are most commonly related to the gastrointestinal tract and to signs of yeast superinfection. Minocycline use may be limited by its vestibular toxicity. Temporary growth retardation and staining of erupting teeth may occur with oral use of tetracycline in children under 8 years; these drugs should not be given in pregnancy or to young children. Topical tetracycline application yields good tear and aqueous humor concentrations. **(Surv Ophthalmol 29:**265–275, 1985)

Key words. *Chlamydia* • inclusion conjunctivitis • phlyctenular keratoconjunctivitis • rosacea • tetracyclines • trachoma

The tetracycline antibiotics have many applications, and their effective spectrum crosses bacterial, parasitic, and chlamydial boundaries. his review consolidates current thoughts regardg therapeutic applications of tetracyclines in ophalmology.

The first tetracycline, chlortetracycline, a prodct of *Streptomyces aureofaciens*, was introduced in 948, the result of a systematic search of soil specimens around the world for antibiotic-producing mioorganisms. In 1950 oxytetracycline was made vailable, tetracycline followed in 1952, and others, ncluding semi-synthetic derivatives, have been inoduced in the ensuing three decades.

These drugs were soon found to be effective gainst many gram-positive and gram-negative acteria, rickettsiae, and the inclusion conjunctivis agent. Thus, they are labeled "broad spectrum" ntibiotics. Finland[25] has reviewed the history and evelopment of tetracyclines, and Neu[66] has evaluted the current role of tetracyclines in antimicroial therapy.

Pharmacology

MECHANISM OF ACTION

Tetracyclines inhibit protein synthesis and bind specifically to 30S ribosomes, as do the aminoglycosides.[80] In vitro, tetracyclines are bacteriostatic, but may be bacteriocidal at high concentrations. The disparate members of the class of tetracyclines usually have the same spectrum of activity, but an individual microorganism may be especially sensitive to one or another of these. Variations in sensitivities can be determined only by tests with each drug. Minocycline appears to retain slightly greater activity against strains of *Staphylococcus aureus*[80] and some gram-negative bacilli resistant to other tetracyclines.[32]

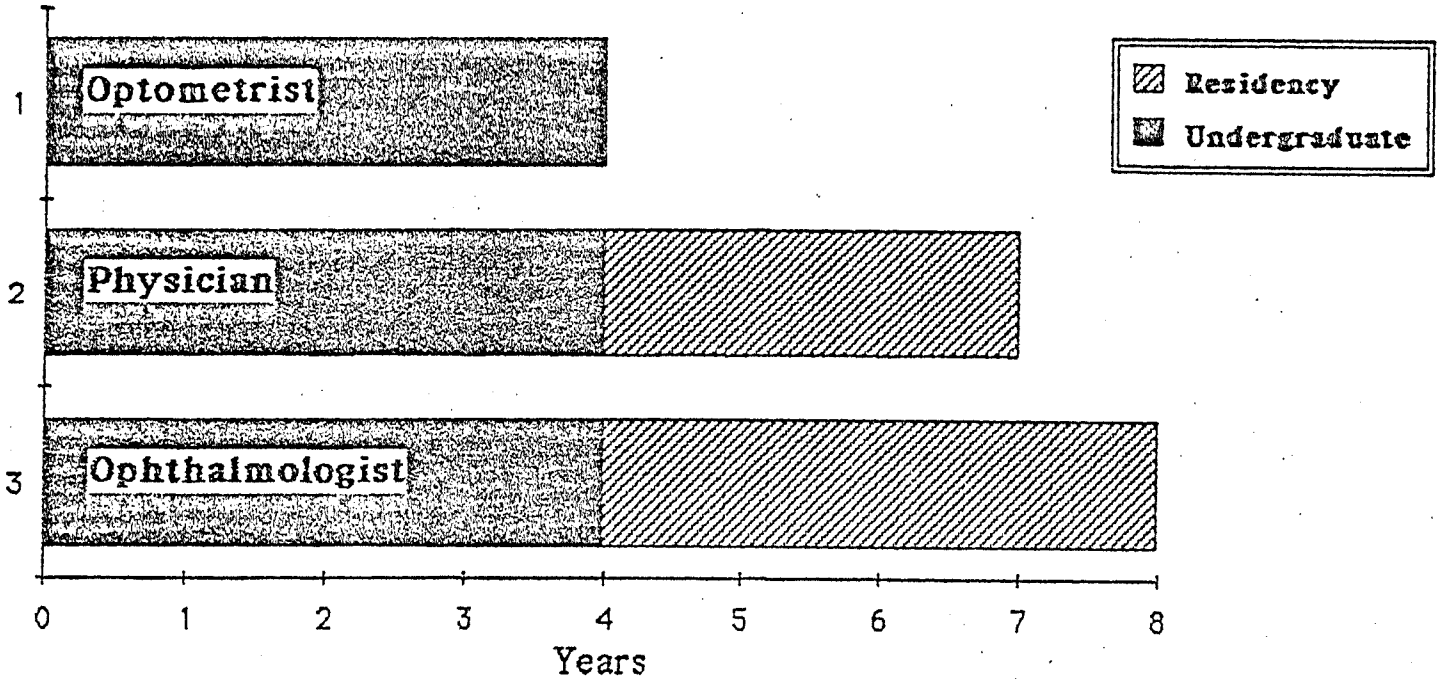
ABSORPTION

Absorption of the tetracyclines takes place in the upper gastrointestinal tract and is best in the fasting state. Various test meals were found to reduce blood levels of tetracycline by 50% (and doxycycline by

2-12

SB 84(a)
2-12-87
Attachment 3

Professional Education



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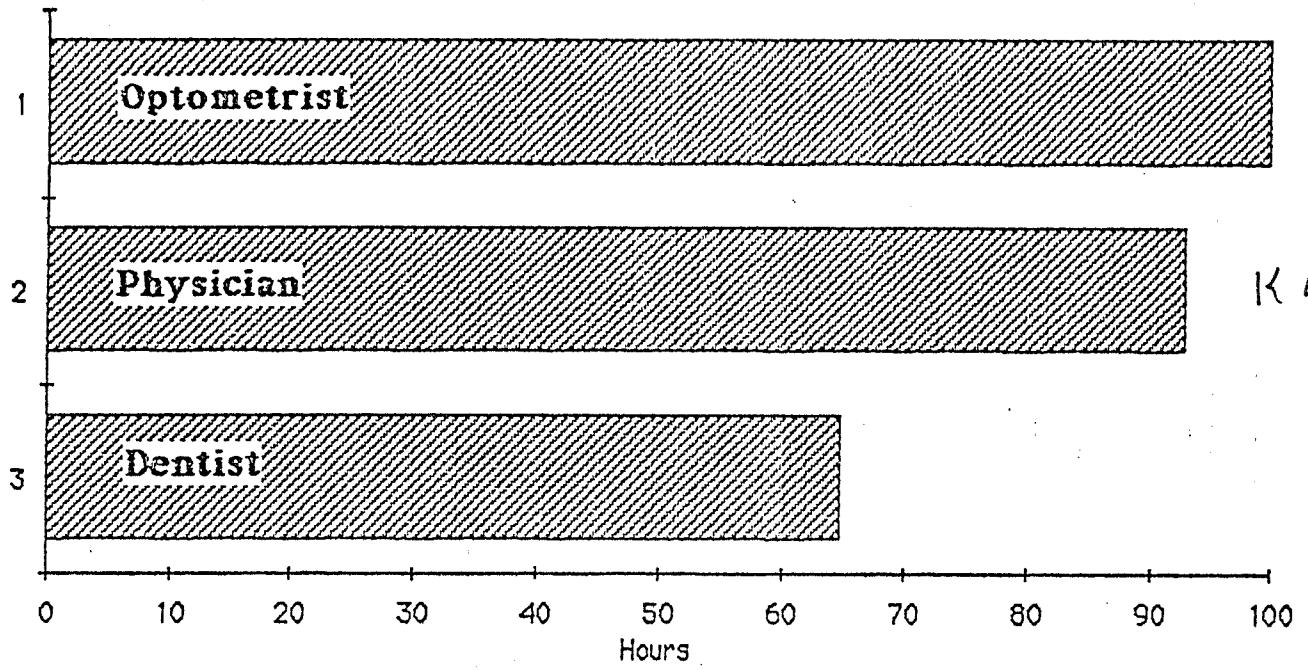

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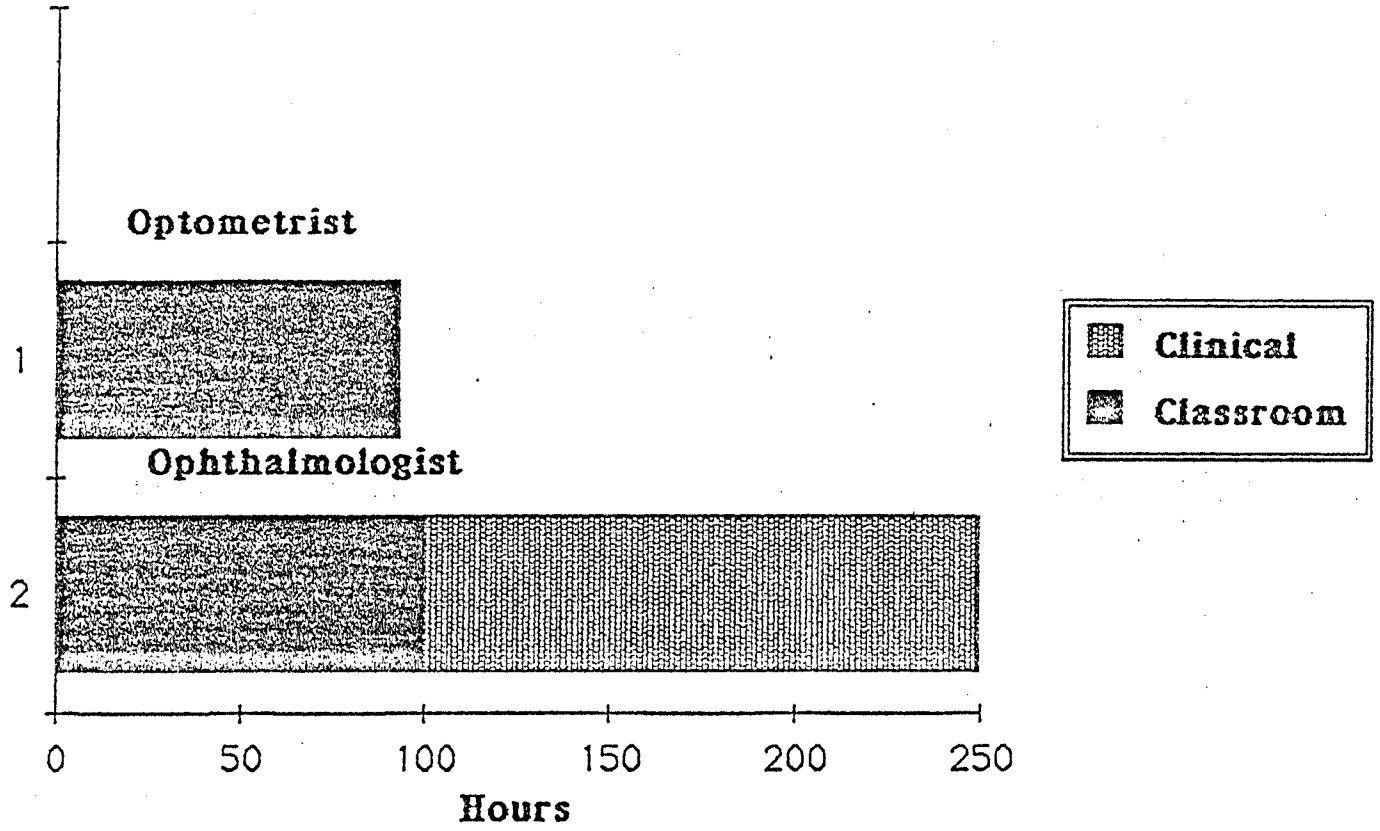
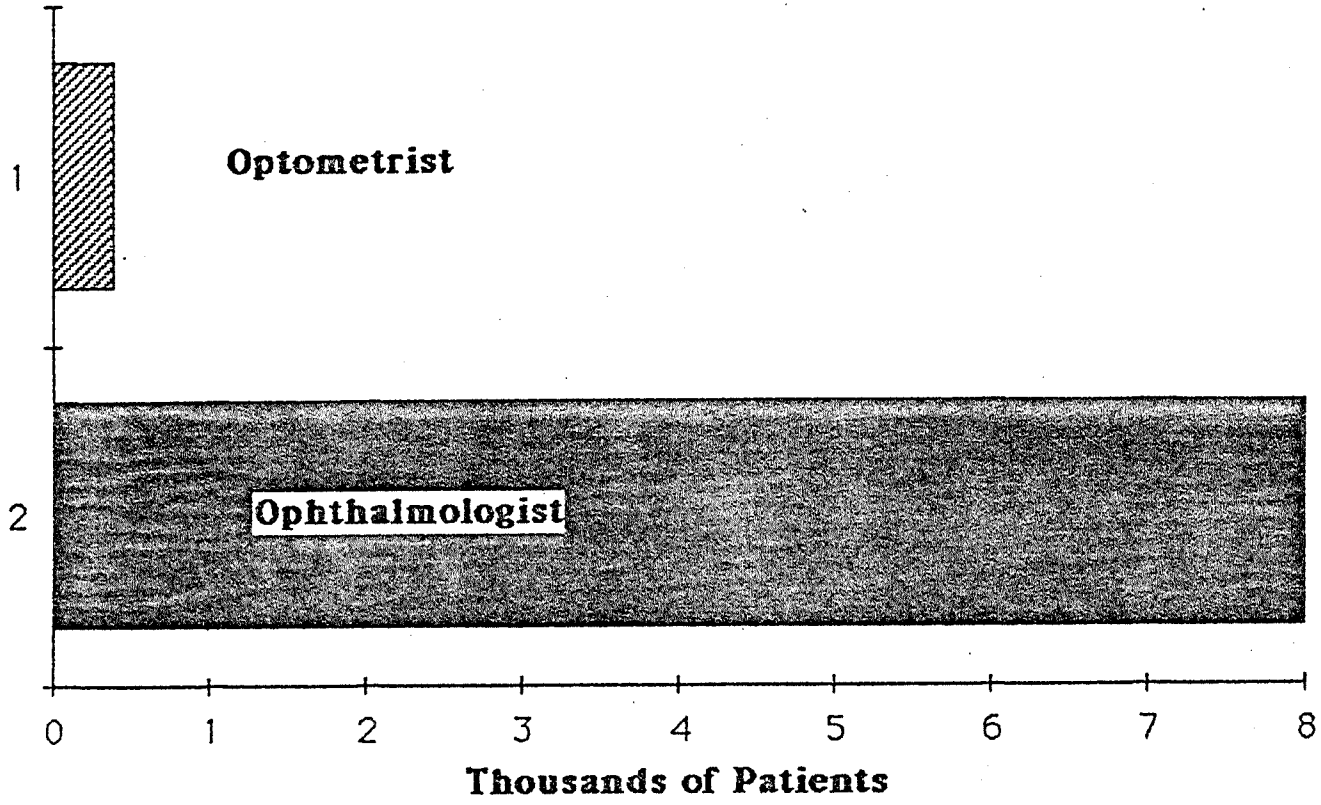
Pharmacology Education



Patients Treated in Training



TESTIMONY OF DR. PERRY SCHUETZ
To the Senate Public Health and Welfare Committee
February 12, 1987
Re: SB 113

Mr. Chairman, Members of the Committee, ladies and gentlemen:

My name is Perry N. Schuetz, M.D., and I am President of the Kansas State Ophthalmological Society (KSOS). I was born and grew up in Great Bend. I graduated from the local high school. I attended the University of Kansas in both Lawrence and Kansas City obtaining a B.A. degree, a doctor of medicine degree, an internship in internal medicine and completion of a residency in ophthalmology. I served in the U.S. Army Reserves as the Chief of the Ophthalmology Clinic at Kenner Army Hospital in Fort Lee, Virginia. For nine years I have practiced general ophthalmology in Great Bend. Over this same period, I also have run the Eye Clinic at Larned State Hospital. I have been elected by my peers, and in January of this year have assumed the title of president of our State society. I am here today to testify in opposition to SB 113.

I would like to make several points today.

1. What is happening nationally? Twelve states have now passed the legislation being considered here today, but several states have encountered technical problems in implementing these laws. Each state is different in the formulation of their law. Insurance companies which have traditionally covered optometry have now refused coverage or dramatically increased their rates in the states where optometric drug therapy is permitted. In optometric journals articles are now appearing exhorting optometrists to be able to treat and not refer glaucoma patients in order to preserve a steady source of income. Other articles speak of optometric surgery as "the next frontier". Health care is being removed from the intellectual and academic spheres to become a political football settled by emotional debate and strong lobbying efforts. Any settlement of a pharmaceutical drug issue will soon be followed by optometry again camping at the Capitol steps desiring either more drugs or surgery.

2. The expansion of one profession into another is basically an antisocial action. If this form of conduct were generalized thought society, chaos and anarchy would be the result. When the executive or judicial branches of government assume a legislative role, the legislature very quickly and firmly tells them that they are out of their place. In the sphere of health care with many paramedical disciplines wishing to expand into medicine, strife will predictably occur each time there is a new invasion of medicine. In most, if not all cases, the educational standard will be lowered. A permissive legislature will signal many groups that now is the time for expansion.

SP&W
2-12-87
Attachment 4

3. There is not a need for this legislation in Kansas. Already two levels of optometric care exist in Kansas--those testing eyes and fitting corrective lenses and those also engaging in diagnosis of eye disease. The law would simply create a third level of optometic care, in addition to the undisputed complete and comprehensive care of ophthalmology. How will the average Kansas citizen know what kind of eye care he is going to receive with four levels of eye care practitioners (not to mention the opticians) presented to the public. Manpower charts showing the location of ophthalmologists and optometrists throughout the state do not take into account the many ophthalmologists traveling to several cities around their local areas, seeing medical and surgical problems within the optometrists' offices. Finally, when has there ever been an outcry from anyone in the public except for organized optometry for this legislation?

4. Optometric education is totally inadequate to practice the medical and surgical eye care as outlined by this bill. This point has been made by two of the other testifiers before the committee today, and it should not need to be reiterated. The lack of education is the single most objectionable point in this whole process. A few decades ago a similar fight was raging between medicine and osteopathy. This dispute was satisfactorily resolved by the implementation by osteopathy of an essentially medical school curriculum followed by licensure involving a common level of testing by a common board. A previous legislature showed very good sense in resolving this issue for the citizens of Kansas without invoking a double standard. A double standard for health care will exist in the specific areas under consideration today when two groups of providers with substantial differences in their qualifications are held before the public as equally capable of providing the same service. This brings me to my next point.

5. An attempt was made last summer to compromise the issue. The optometric position could be characterized by the question: what drugs will you give us? The ophthalmology position could be characterized by this question: what input will you give us into the educational process and the testing process of your participants in order to assure some sort of parity between our two groups? As you have since learned, the drugs which we offered--antihistamines and other non-steroidal anti-inflammatory agents to be used topically--was felt to be insufficient. From the optometric side, we were told summarily that the hundred hour course had been set up and the most that we should expect is a syllabus outlining what would be taught. This was to be sent shortly after our last meeting, and it has never been received by anyone involved in the negotiations on our side. All we know is that we were told that if ophthalmology provided the course and the testing, there would be a great fear that no optometrist could pass.

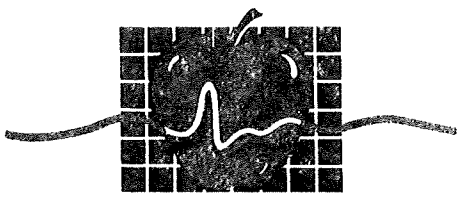
6. A few comments should be made about general medicine and surgery as relating to the eye. A prominent Kansas City cardio-

logist tells me that he has written this committee describing serious cardiac side effects that he has seen produced by timolol. This is one of the most commonly used drugs in glaucoma therapy, and it can be very dangerous even when used by competently trained individuals. He has seen congestive heart failure, a slowing of the heart's rate and even complete stopping of the heart due to this drug and similar agents. He is very concerned. Similarly, all physicians know that the cortisone class of drugs can produce cataracts and glaucoma as well as promote the worsening of most infections; a large array of side effects from the hormonal action of these drugs occur including high blood pressure, fluid retention, softening of the bones, abnormal growth and development of infants and children, and shrinkage of part of the adrenal and pituitary glands. Also, the notion that glaucoma is a short term disease which can be treated for a few days, then forgotten needs to be corrected; in most instances, this is a lifelong disease, which can only occasionally be cured by surgical intervention. The removal of a superficial foreign body from the cornea is also not so simple if the penetration goes deeper than the glue layer that holds on the first layer of cells on the front of the eye. An injury deeper than this frequently produces a recurring ulcer or erosion which can take days to weeks to heal; also varying degrees of scarring occur as the wound goes deeper; iron containing foreign bodies usually have a surrounding toxic layer of rust which gradually erodes its way into the deeper layers of tissue; vegetable material embedded in the eye usually carries along a host of saprophytic microorganisms which can potentially cause serious infections of the eye. Regarding antibiotics, every medical school graduate has seen most antibiotic induced complications: this can be anything from a local rash like posion ivy to a permanent stoppage of the body's producing blood cells or loss of hearing or injury to internal organs. These are but a few of the concerns.

7. In looking at the present bill before us, there is what I would like to call the "adnexa problem". Removal of foreign bodies from the ocular adnexa would not be considered surgery in the proposed bill. What is the "adnexa" of the eyeball? Both Dorland's and Stedman's medical dictionaries have similar definitions: "<u>adnexa oculi</u>--the eyelids, lacrimal apparatus, and other appendages of the eye." Sir Stewart Duke-Elder's fourteen volume <u>Systems of Ophthalmology</u> devotes one volume of 1236 pages to the ocular adnexa. Foreign bodies involving eyelid tissue, the tear drainage system and the bony cavity in which the eyeball is contained are described in detail. The last case of disease mentioned would tax most ophthalmologists' treatment skills. I feel the term <u>human eye and its adnexa</u> in regards to foreign body removal is inappropriate and reflects a lack of understanding of the meaning of the word "adnexa" in SB 113.

8. Finally, after stating that the Kansas State Ophthalmological Society has no intention of compromising in any way or agreeing to the usage by optometrists of this state of therapeutic drugs, I would like to make some suggestions. If, in spite of our insistence that this is not in Kansans' best interest, the Kansas State Legislature feels compelled to pass this legislation, then some safeguards should be added to reduce the many inherent hazards. First, the treatment of any and all forms of glaucoma should be eliminated. Second, a mandatory referral for all medical conditions not responding after one week of therapy should be added. Third, foreign bodies impinging on the ocular surface or the conjunctival surface surrounding the eye could only be removed if they are non-embedded and not associated with a rust ring. Fourth, the drugs permitted for usage by optometry should be limited to those offered last summer--topical antihistamines and other non-steroidal, anti-inflammatory preparations. Fifth, the State Legislature must insist on an equal standard of care between the medical and optometric professions. Finally, a credentialing process should be sought through which an outside third party with greater objectivity and immunity to political pressure might evaluate the two professions regarding this expansion and future expansions.

In closing, I would like to say that I have felt like Elizabeth Taylor's fifth husband on the wedding night. I know what has been expected of me. I only hope that it has seemed new and exciting. Thank you.



PrimeHealth®

January 16, 1986

Re: House Bill 1333

It is with upmost concern that I voice my absolute conviction that it would be gravely detrimental to the practice of medicine, optometry, ophthalmology and the welfare of the unknowing public if this therapeutic bill is passed. I write with a unique insight as Director of Ophthalmology at Prime Health, a growing HMO of 60,000 members in the Greater Kansas City Area where I have worked for the past 19 months. We employ seven highly competent and well respected optometrists, all of whom work under my direct medical supervision.

We utilize a strict and limited medical protocol and we share constant clinical exchange. They refer patients suspected of having medical eye problems to ophthalmology for evaluations and second opinions. I greatly respect these optometrists as professionals and value them as colleagues but at the same time I have come to know the limits of optometric training and their limited knowledge of pharmacology and general medicine.

Intuitively it would seem reasonable that optometrists would be qualified to prescribe therapeutic medicines for the eye as outlined in House Bill 1333. They, after all, spend four years studying the eye, contact lens fitting, refraction and the like. However, the drugs used in the treatment of eye problems have primary effects in other body systems. Their use requires a broad knowledge of medicine and pharmacology. It would be a simple matter if drug effects could be restricted to a single predictable organ or organ system. The concerns of the ophthalmic community about the proposed legislation would be greatly reduced if this were the case. Yet the very opposite is true.

Pharmacology and drug interaction are among the most complicated aspects of the practice of medicine regardless of speciality. Teaching therapeutics and proper clinical judgement in selecting the best drug(s) for a given patient with a specific problem with a given past medical history makes up the overwhelming majority of training in medical school, internship and residency training for all specialities including ophthalmology. Surgery for our speciality is in comparison a small part of the whole and in many respects is easier than medical therapeutics for ophthalmology.

SPHHW
2-12-87
Attachment 5

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Why? Because drugs...ALL DRUGS, even topical drops, HAVE EFFECTS AND SIDE EFFECTS WHICH IMPACT ON THE ENTIRE BODY. In fact it is a true statement that no drug, vitamin, or mineral has only a single effect--all proceed in complicated ways to effect metabolism and physiology throughout the body.

Drugs used in the speciality of ophthalmology are among the most potentially serious in their effects throughout the body. These drugs (both drops and tablets) are powerful and even potentially deadly. Appropriate and prudent use of these medications may be done only with a knowledge of the patients preexisting medical problems, present systemic medications, often with base-line blood values and electrocardiograms where indicated... that is, with general medical assessment and background which is not provided in optometry school.

Even a single drop of one of several drugs used for the treatment of glaucoma can precipitate or exascerbate heart failure, sudden death from arrythmia/ bradycardia in patients with specific cardiac conditions, sudden respiratory arrest or asthmatic respiratory distress. They can effect cardiac contractility, cause wheezing and gastrointestional problems. Other drops for glaucoma have been known to cause detached retina, iris cysts and mental changes to name only a few.

Oral medications for the treatment of glaucoma is an issue unto itself. These tablets ROUTINELY cause acid-base chemical disturbances, they ROUTINELY deplete the body of vital electrolytes which potentially may cause serious or fatal drug interactions with many frequently prescribed medications (eg. digoxin/lanoxin, diuretics, and many more). These antiglaucoma systemic medications COMMONLY cause changes in kidney function, liver metabolism, and may cause irreversible aplastic anemia.

Oral antibiotics are also included in the proposed legislation. The place of oral antibiotics in ophthalmology is almost exclusively limited to infections such as abcess in the orbit or in cases of cellulitis. These are infections of the skin and soft tissues about the eye. With infections so close to the eye, the condition is serious requiring close follow up, blood counts to evaluate possible early elevation of the white blood cells which is a harbinger of sepsis and likely x-ray or CAT scans. Careful observations by a well trained observer is manditory. Spread of infection into the eye or deeper into the orbit might allow microbes easy access into the central nervous system and brain. For this reason post septal cellulitis carries a mortality (death rate) of up to 20% in some series. Correct choice of proper antibiotics, in correct dosages possibly initiation of intravenous antibiotics and rarely emergency surgery are the only chances for salvation in serious cases. The decision when to start oral medications and when infection is spreading is very difficult even for the ophthalmologist. Patients who would need systemic antibiotics need to be in the hands of an ophthalmologist immediately. There is absolutely no justification for the use of oral antibiotics in the practice of optometry.

Oral and topical anti-inflammatory medications are yet another serious issue. One must ask, why does the patient have the specific inflammation? That is often a good question and requires appropriate systemic work up (blood tests, x-rays, skin testing and occasionally biopsy, etc) to uncover a cause. Such evaluations are performed by ophthalmologists now and are essential in diagnosis

of systemic conditions with primary presentation with eye findings. Design of the appropriate work-up is based on a knowledge of medical ophthalmology and general pediatric and internal medicine which is not adequately addressed in the optometric curriculum.

Use of topical and oral anti-inflammatory medicines commonly cause elevation of eye pressure and may predispose to glaucoma. Such medications may be RELIED upon to cause cataracts when used over the long term. Tablets (prednisone and decadron) may have profound effects in causing aseptic necrosis of the femoral head which is a rare but irreversible condition which may occur after the first dose of oral medication and which leaves the patient in a wheelchair permanently. Steroids create diabetes in predisposed individuals or cause a previously well-controlled diabetic to go out of control and possibly into ketoacidosis and/or hyperglycemic coma, 5-10% mortality. They predictably cause osteoporosis or bone thining, myopathy, personality changes and psychosis. They can trigger internal bleeding. Steroids predispose to all types of infection by their very mechanism of action which involves inhibiting the ability to fight infection and mount an immune response. It easily follows that correct use of these powerful medicines must be heavily weighted on a correct diagnosis, complete knowledge of the patients general medical condition past medical history and seasoned clinical judgement. Inappropriate steriod use can cause a painless perforation of the eye and/or unopposed bacterial/ viral infection of the eye which invaribly results in blindness.

I have tried to provide some insight into my reasons for opposition to this bill. I will be delighted to discuss these issues with you at any time. I will be happy to testify in Jefferson City at your convenience. I can promise you that my comments are correct and unfortunately they do not overstate the seriousness of the use of medications by nonphysicians.

I must reiterate my valued association with the optometrists in my practice. I have allowed their carefully supervised use of topical antibiotics and dilute steroids for specific clear cut cases with my constant surveillance. Our optometric group is truely excellent and yet I cannot in good conscience support this bill in whole or in part.

The differences between the ophthalmic and optometric curriculum simply cannot be legislated away.

Respectfully,

Patricia L. Turner, M.D.
Director of Ophthalmology

PLT/rcs

2-4-87

Senator Leroy Hayden
Division of Legislative Administrative Services
Room 511-S Statehouse
Topeka, Kansas 6612-1591

Dear Senator Hayden:

As a school counselor, I have seen a need for some legal recognition and definition for those in the counseling profession. Senate Bill #78, regarding professional licensure for counselors, addresses that need. I would like to solicit your support of this bill for the following reasons:

1. Licensure would protect the public's right to be served by qualified and ethical counselors and the public's right to freedom of choice in selecting mental health services.
2. The public often has a need for mental health services that focus on assisting all people to live more effectively rather than focusing on dysfunction or mental illness.
3. Licensure of counselors would result in more widespread competent provision of mental health services and less restraint of practive and ultimately offer the public greater freedom of choice in services at more competitive cost to the consumer.
4. There is currently no investigation or sanctioning body with the authority to respond to and intervene in harmful or unethical practices perpetrated upon the public in the name of "counseling". Licensure would hold individual practitioners accountable.
5. Licensure will help identify qualified practitioners for the public since the use of the title and the practice of counseling would be limited to persons who meet the the standards for statutory credentialing.
6. While counseling as a profession does exist (professional membership in the national association exceeds 50,000 members), in Kansas counseling has no legal recognition or definition. Anyone can use the title "counselor".
7. Protection of client disclosed information can be provided for through a licensure law. Without privileged communication for the client, there is no assurance that information disclosed in counseling will not be used against the client in court testimony.
8. Eighteen states have passed laws regulating professional counselors since 1979. Included are Oklahoma, Missouri and Nebraska.
9. In an increasing more complex world, the public will benefit from the requirements for professional education and experience and the regulation of ethical practive. Those who seek counseling services are often more vulnerable than

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their usual selves. Counseling is a sophisticated and abstract activity which may not be clearly understood or accurately judged by the consumer.

Decisions made the next few days in regards to this bill are critical. They can have a positive impact not only for those in my profession but for the public as well. Any consideration and support you can give to this bill will most definitely be appreciated.

Sincerely,

Norma Shoemaker

Norma Shoemaker, Counselor
Garden City High School

TESTIMONY OF ALBERT N. LEMOINE, JR.
To the Senate Public Health and Welfare Committee
February 12, 1987
Re: SB 113

Mr. Chairman, Members of the Committee, ladies and gentlemen:

I am a medical doctor, Board certified in Ophthalmology and a member of the usual local, national and international medical societies.

I wish to speak against SB 113 as an individual ophthalmologist and not a representative of the Department of Ophthalmology or University of Kansas School of Medicine.

Since 1950, my professional career has been in academic health centers, providing patient care and teaching students in the diagnosis and treatment of disease of the eye, visual system and adenexae.

From 1950-1980, I was a professor and Chairman of the Department of Ophthalmology with the University of Kansas School of Medicine. Since then, I have been a Professor of Ophthalmology.

I have taught more than 2,500 undergraduate medical students; more than 500 residents in ophthalmology at 21 medical schools in the United States and Canada; more than 7,000 practicing ophthalmologists in the United States, Canada and foreign nations who have taken the Harvard, Lancaster or Scheie Eye Institute courses in clinical anatomy and embryology at the eye and orbit that I have taught.

I have taught over 2,500 ophthalmologists in 40 consecutive courses at the American Academy of Ophthalmology.

I have taught more than 1,500 senior optometry students at 8 schools of optometry.

From 1977 to 1986 I was an Adjunct Professor at the Southern California College of Optometry - teach one week each February - lecture in the morning and pathology clinics in the afternoon.

I have taught approximately 2,000 practicing optometrists in their continuing education courses.

In 1975, the first Optometry Residency in the VA system was established at the KCVA Medical Center. 20 optometrists have completed this one year program. Last week I was asked if I would write letters of recommendations for medical schools by the 2 current optometry residents. At the present time, we have 2 full time optometrists, 2 optometry residents, and 2 senior optometry students from the St. Louis School of Optometry on the KCVA staff.

I have testified for or supported Optometric drug bills that permit optometrists to use drugs for <u>diagnostic</u> purposes in 32 states. From 1965-1980, I was a member of the MD-OD Committee and in 1977, testified in favor of the Kansas diagnostic drug bill.

With this background, it should be apparent, that until the

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last two years, I have been considered Pro-Optometry by my fellow ophthalmologists and have been bitterly critized for teaching optometrists and testify in favor of their use of drugs for diagnostic purposes.

From the beginning in 1975, until now, I have repeatedly stated that optometrists should not be permitted to use drugs for treatment until their education is comparable to the ophthalmologists. I believe that SB 113 is against the public welfare.

I agree with Dean Lews testimony concerning the intellectual ability of optometry students. In my opinion, 85-90% of the optometry students would have no problem in a medical school.

The problem is the method of education in optometry schools. Beginning in 1910 with the Flexner Report, medical education in the United States and the world has shifted from the use of lectures and the classroom to the bedside and individual patient.

Because medicine is not an exact science, it is essential that the clinic training involve the individual students with a single patient, who has complex problem of disease involving both the mind and body. This means that a tutorial type of education is most important.

Please refer to the 4 bar charts that note the professional training of optometrists, primary medical doctors and ophthalmologists.

My two greatest concerns of SB 113 are paragraph (3), line 0037 and (b), line 0040.

(3), line 0037 states "the prescribing, administering or dispensing of topical pharmaceutical drugs for the treatment of insufficiences or abnormal conditions of the human eye and its adnexae". This means that an optometrist could treat cancer of the eyelids, upper face, conjunctivitis, cornea or lacrimal system with the topical application of caustic agents. They could treat corneal or conjunctival ulcers with topical caustic agents. I believe this is clearly dangerous.

(b), line 0040, " the practice of optometry shall not include the management and treatment of glaucoma, except that therapeutic licensees may prescribe, administer, or dispense topical pharmaceutical drugs in the management of open angle glaucoma". In 1945-46, I was a teaching/research Fellow in Neurophthalmology and Glaucoma at Harvard Medical School. As a thesis, I reviewed the records of over 12,000 glaucoma patients seen over a 30 year period at the Massachusetts Eye and Ear Infirmary and since then, have had a particular interest in glaucoma. In my opinion, one of the most difficult disease/processes of the eye to diagnose and manage is glaucoma, if blindness is to be avoided. The above statement suggests that chronic open angle glaucoma is easy to diagnose and treat - it is not. During the last week I reviewed the examination and treatment recommendations of 12 patients seen by the optometry residents or students at the KCVA Hospital. Eight of the

patients had glaucoma and in six of the patients, either the diagnosis or recommended treatment was incorrect. Admittedly, these were unusual, but they represent the problems with glaucoma patients.

You may legislate the right and license to practice, but competence is acquired by education. The public believes that when the state licenses a person, they are competent - this may or may not be true.

If SB 113 is passed, I honestly wonder whether health licenses means competence. Perhaps the time is coming when the only logical thing to do in the health care field is to abolish all licenses and let the public beware. This is especially true when licenses are controlled by Boards composed of only the provider involved.

I urge you to vote against SB 113.

Thank you for your attention.