

COLORADO CHALLENGE: THE COURT BATTLE FOR THE PRESCRIBING OF SOFT CONTACT LENSES, THE USE OF THE TONOMETER, AND THE DIAGNOSIS OF GLAUCOMA

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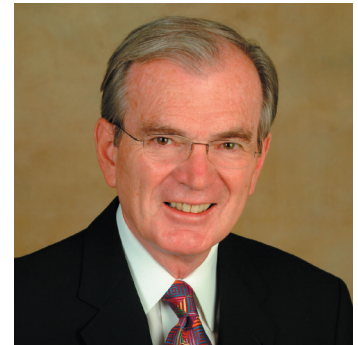
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Dr. Jerry Pederson (Image courtesy Dr. Jon Pederson)

EDITORIAL NOTE

This paper was originally published in 2012 in the Colorado Optometric Association's newsletter, Viewpoints. It is reprinted here with permission of the Colorado Optometric Association.

INTRODUCTION

There have been many challenges to the profession of optometry at both the state and federal level during its 110 years of legalized existence. These challenges have involved the passage of the original state practice acts, clarification of the original optometry laws, passage of state board rules and regulations and efforts to eliminate commercialism. This was followed by the expansion of state optometry practice acts authorizing the use of diagnostic drugs, therapeutic drugs or other clinical procedures. Additional challenges have been federal in nature and therefore broader in scope but still of great importance for the profession.

Colorado is unique in that the Colorado Optometric Association (COA) defended optometry's right to use the tonometer and fit soft contact lenses in a lawsuit that had national implications. If this defense had not been successful, it is likely other states would have been confronted with similar litigation. The following is an historical account of this challenge and its outcome.

BACKGROUND

From its inception in Minnesota in 1901, optometry was a profession that became legalized in a relatively short period of time. By 1924 all 48 states, the District of Columbia and two territories (Hawaii and Alaska) had enacted optometry practice acts.¹ Colorado was the 30th state to pass an optometry practice act in 1913. Optometry was very proud of its drugless heritage and had utilized this fact to distinguish itself from medicine in its establishment as a separate and distinct profession.

The scope of optometric practice, however, had not changed in almost 70 years. Those in leadership positions were beginning to sense a growing level of discontent, especially among more recent

graduates, with the confined scope of practice and the increase in pre-optometry and professional program curricular requirements for the doctor of optometry degree.

An informal, yet historic, meeting was called by Dr. Alden N. Haffner, director of the Optometric Center of New York, in 1968. Those optometrists invited to attend this meeting were Drs. Gordon Heath (Indiana University), William Baldwin (Massachusetts College of Optometry), Richard Hazlett (Massachusetts College of Optometry), Norman Wallis (University of Houston) and Spurgeon Eure (Southern College of Optometry) all affiliated with optometric education in one form or another. Optometrists from private practice invited to this meeting were Drs. Irvin Borish, Charles Seger and Milton Eger all involved in some capacity in organized optometry. This meeting was held on January 16, 1968, in a hotel at LaGuardia Airport in New York City.²⁻⁴ The individuals attending this meeting did not come representing any organization or group but were there because of a sincere concern for the future of the profession. Each attendee had personally funded the expense for this trip.

The consensus of this group, after intense debate and discussion, was that the profession must expand its scope of practice responsibilities and discard the original concept of a drugless profession. Dr. Haffner articulated this notion of an expanded scope of practice within the context of an evolving American health care system during a keynote address to the New England Council of Optometrists on March 17, 1968.⁵

Dr. Haffner's message particularly excited the imagination of several optometrists from the State of Rhode Island who were in the audience for the address. Dr. Haffner had met with Dr. Morton Silverman before, during and after the New England Council meeting. Led by Drs. Morton Silverman, David Ferris and Richard Albert, the Rhode Island Optometric Association, after three years of effort, passed the first law that specifically authorized the use of drugs for diagnostic purposes.^{6,7} This bill was signed into law on July 16, 1971. West Virginia passed the first therapeutic drug act on March 4, 1976.⁸

To most optometrists, the passage of this legislation was a success that seemed to come out of nowhere but had a tremendously positive impact on the profession. It served as the event that began the change from the drugless profession of the past. It had been 70 years since the first optometry law was passed. At the present time, 183 legislative enactments have been passed since the first Rhode Island diagnostic drug law was enacted 40 years ago.⁸ Each of these state laws has increased the scope of practice of optometry. No other health care profession has undergone such a scope of practice metamorphosis as optometry. The State of Pennsylvania passed the second such diagnostic drug act in 1974 and Oregon, Maine, Louisiana and Delaware in 1975.⁸

LAWSUIT IN COLORADO

Stimulus for Lawsuit

The passage of legislation in Rhode Island did much to generate opposition from organized medicine, especially by those in ophthalmology. Among the practitioners who opposed optometry's attempt to expand its scope of practice were such ophthalmologists as Drs. Charles Jakel, James Allen, Ralph Ryan, Bernard Campbell, Eugene Wiggs and Lawrence Winograd. Dr. Jakel was an optometrist who later became an ophthalmologist and was very antagonistic toward optometry. This was not an unusual or unexpected response for those individuals who had made such a professional transition. Many of those practitioners were active in the Physicians Education Network (PEN), a newspaper that detailed supposed optometric diagnostic misadventures, reported lawsuits against optometrists and denigrated optometry in general and optometric education in particular. It was a form of "yellow" journalism popular around the turn of the 20th century and designed to inflame and injure the profession of optometry. It was circulated to many academic medical schools as well as to most ophthalmologists. Although it was uncomfortable or distasteful to read from an optometric viewpoint, in the long term, the PEN did not have its intended effect in the medical and health care community.

On Wednesday, January 10, 1973, Dr. Winograd later joined by Drs. Campbell and Wiggs filed a suit in Denver District Court against C. E. Johnson, O.D. and "all persons similarly situated"⁹ This latter phrase meant all optometrists practicing in Colorado. The suit specifically asked the court to stop all optometrists from fitting soft contact lenses and "from holding themselves out to the public as persons qualified to diagnose the presence or absence of glaucoma." The court was further requested to enter immediately a temporary restraining order and preliminary injunction.

The reason for naming Dr. Johnson was apparently based on statements made by Dr. Johnson to a patient related to his ability to "measure intraocular pressure or diagnose glaucoma." Other reasons that may have been a factor in this decision were Dr. Winograd's desire to denigrate optometry or be viewed as an important figure in ophthalmology on the state and national level. Perhaps all of the above or even other reasons could explain his motives. Dr. Winograd and his colleagues were hoping to set a precedent for the nation.

Contact Lenses

If they could stop optometrists from fitting soft contact lenses, they would be able to reduce or eliminate optometry's ability to examine the eye and fit this revolutionary new contact lens. Ironically, it had been optometry that had been most responsible for the success of rigid contact lenses. Many ophthalmologists were opposed to and did not recommend contact lenses to their patients and a few even reported they caused blindness in patients who wore them. Nevertheless, from the early 1950s through the 1960s, contact lenses grew in popularity with the public. However, with the introduction of the cross-linked hydrophilic polymer, or soft contact lens, in 1971 the potential for the contact lens market was going to grow even larger. It is not clear if ophthalmology wanted to increase its share of this market or stop optometry from being able to increase its market share of contact lens patients. The ophthalmologists thought that the Food and Drug Administration's (FDA) designation of soft contact lenses as a drug would preclude its use by optometry. This designation was used by the agency for testing and certification purposes only. The ophthalmologists reasoned that optometrists did not have a right under Colorado law to use drugs and therefore it would be illegal to fit this type of contact lens. This portion of the lawsuit was important since it was the first challenge of any type to the prescribing and fitting of contact lenses by optometrists made from this material. Unfortunately, some state optometry laws did not include the fitting of contact lenses in their law. However, Colorado was not among these states.

Tonometry

If ophthalmology were successful in blocking the use of tonometry for the measurement of intraocular pressure, then optometry would be at a competitive disadvantage in its ability to perform a comprehensive eye examination. At this point in time, the understanding of the diagnosis of glaucoma included patient history, intraocular pressure measurement, cup-to-disk ratio assessment and visual field measurement with a tangent screen or other kinetic visual field instrument. However, the first among equals was the measurement of intraocular pressure. Glaucoma was equal to high intraocular pressure rather than intraocular pressure being one of several risk factors as it is considered today. Without this technique, optometry would surely be portrayed as less than capable of delivering quality eye care.

Prior to the late 1950s, intraocular pressure had been measured by various instruments utilizing a weight that indented either the corneal or scleral tissue. Schiotz had introduced his indentation instrument in 1905. Unfortunately, scleral indentation tonometry was found to be inaccurate. Usually, to the extent the technique of tonometry was performed, ophthalmologists performed it on the cornea and optometrists on the sclera. This was because ophthalmology had the right to use corneal anesthetics and optometry did not.

Goldmann introduced the applanation tonometer in 1954 and by the late 1950s this instrument was becoming the technique of choice. The Goldmann tonometer required a corneal anesthetic.

In 1958, Elwin Marg, O.D., Ph.D. of the University of California, Berkeley School of Optometry was on sabbatical leave in Stockholm, Sweden. During this time, he met R. Stuart Mackay, Ph. D., a physicist from the same institution who was also on sabbatical leave. Mackay and Marg discussed the theoretical basis

for a new electronic tonometer and by 1959, they had convinced the university to take out a patent for this instrument. The Mackay-Marg electronic tonometer was introduced in 1962.¹⁰ To ascertain the accuracy of this new instrument, a joint OD/MD study was conducted at Berkeley.¹¹ The study revealed a high correlation between intraocular pressures measured by Mackay-Marg and Goldmann tonometers. With both tonometers, the procedure was performed on the cornea surface, but the Mackay-Marg instrument did not require an anesthetic.

Schools and colleges of optometry renewed their emphasis on the topic of glaucoma detection and diagnosis using the Mackay-Marg instrument and its successor, the noncontact tonometer (NCT). The NCT used a small burst of air to achieve a predetermined area of corneal applanation.¹² These instruments helped optometrists in their movement toward a more health-oriented role. In fact, it is usually agreed that contact lenses and tonometry first brought the optometrist into direct contact with the eye.

PROCEEDINGS RELATED TO THE LAWSUIT

Initial Hearing

The first proceeding of the lawsuit was a motion by the plaintiffs requesting the court to issue a temporary restraining order and preliminary injunction against the optometrists from claiming they could detect or diagnose glaucoma.

On Wednesday, January 12, 1973, the case was set for a hearing on the preliminary restraining order and temporary injunction. This hearing was scheduled for Monday, January 22, 1973. During the two-day hearing, arguments against the request as well as testimony from members or representatives of the optometric profession were presented. This case was heard in the court of Judge Robert Kingsley. Counsel for the COA was the law firm of Akolt, Dick, Rovira, DeMuth and Eiberger. Mr. Jack Akolt presented the case for the optometrists.

On January 23, 1973, the following were in attendance at the hearing: Drs. C. E. "Buzz" Johnson, Ron G. Fair, John A. Ordahl, C. Edward Williams, George W. Tull and Mr. William O'Rourke, executive director of the COA. The only witness who testified on behalf of the COA was Dr. Fair and his testimony concerned a paper he had published in the *American Journal of Optometry* and can be found in the Archives of the American Academy of Optometry. This paper, which was published in 1972, was entitled *Incidence of Glaucoma in Optometric Practice-An Eight Year Evaluation of 6,580 Tonograms*, and described the prevalence and incidence of glaucoma suspects or glaucoma in an optometric practice.¹³

Dr. Fair deserves great credit for the time and effort spent in collecting and analyzing the data and writing this report. It may be one of the most fortuitous and timely clinical research reports in the history of the profession. Dr. Fair collected data on patients over the age of 40 years between April 1963 and January 1971. This paper contained a description of the clinical technique of the use of the Mackay-Marg tonometer as well as establishing criteria for determining patients who were glaucoma suspects and criteria for referral or the diagnosis of glaucoma. Dr. Fair was

questioned extensively about this study and its results during the initial hearing.

On January 26, 1973, following several sessions in chambers with the COA general counsel and the attorney for the ophthalmologists, the court issued an order. The court order denied the request for action on soft contact lenses. It restrained optometrists from "holding forth to the public as being qualified to diagnose the presence or absence of the disease known as Glaucoma." The court did not place any restriction on the use of tonometers by optometrists. When the language of the court order was compared to the language of the Colorado law regulating the practice of optometry, the order simply restated what was already a matter of law. This order merely interpreted the statutes of the State of Colorado as they had existed for many years. This temporary injunction would remain in effect until the suit was brought to trial.



Dr. Ron Fair (Image courtesy Dr. Fair)

Preparations for Trial

Over the next two years, the COA prepared for this trial set for January 1975. In the background was Mr. Ellis Lyons the general counsel for the American Optometric Association (AOA). Mr. Lyons had a very distinguished legal career and had served in the U. S. Attorney General's Office during the Korean conflict.

Mr. Lyons' opinion regarding eye examinations performed by optometrists was the following: "I start with the proposition that anyone licensed to examine the eye should have available the best possible means for doing so, including every device, instrument and drug in use. I believe that as an optimum goal, professionals charged with examining the eyes should be free to use or not use every diagnostic aid available." Mr. Lyons did qualify this as an assumption on his part, but he felt that as a general proposition it was sound, quite apart from whether the use of drugs in diagnosis is indispensable, which was a technical question beyond his scope as an attorney. Mr. Lyons' statement

served to set the course for future actions by the COA as well as for optometric legislation across the nation.

Mr. Carl F. Eiberger was the COA's general counsel and Mr. Edmundo A. Gonzales was the Legislative Counsel. The attorneys for the ophthalmologists were Mr. Leonard N. Waldbaum and Mr. Lawrence F. Hobbs. This suit was classified as a "class action" suit. This meant each individual optometrist had to decide whether to "opt in" or "opt out" of the suit. If the optometrist decided to "opt out" of the suit, he or she would not be obligated for the legal expenses. However, even if the optometrist "opted out," he or she would still be bound by the court's ruling. Fortunately, most Colorado optometrists elected to remain in the suit.

Ultimately the lawsuit expenses cost the COA approximately \$165,000. Colorado optometrists were asked to pledge \$1,000 each to be paid over a year's time. A fund termed CATAPULT, which stood for "Continuous Action to Achieve Professional Acceptance and Ultimate Legal Triumph," was established to solicit Colorado optometrists as well as appeal to colleagues nationwide. At that time, there were 219 optometrists licensed in Colorado and they contributed \$55,000. Dr. Ronald Solomon, COA president, headed the CATAPULT drive and sent a letter to all optometrists in the nation. This appeal by Dr. Solomon raised additional funds which, when combined with COA operational and reserve resources, the association was able to retire the indebtedness of the legal fees. Interestingly, those optometrists who attended or testified in this trial paid their own expenses. The AOA was not officially involved in the lawsuit because of the implications a negative court decision would pose for this national organization.



Dr. Ronald Solomon (Image courtesy Dr. Solomon)

THE TRIAL

The trial began on January 9, 1975 at Denver District Court in the court of Judge Robert Kingsley. Kingsley was the district judge who had presided over the initial hearing on January 22, 1973. The optometrists had witnesses from the Colorado State Board of Optometric Examiners, Colorado Vision Services, officers of the COA, a general practice physician and two ophthalmologists. The ophthalmologists presented testimony from four community

ophthalmologists and two from academic ophthalmology. Dr. Fair had presented the majority of the testimony in the initial hearing for the temporary injunction in 1973 but was not called as a witness in the trial.

Defense of Soft Contact Lenses

Evidence was presented by the COA on behalf of the state's optometrists that soft contact lenses were a device under federal law. The FDA labeled the soft contact lens a "new drug" so it had greater ability to regulate the manufacture of the new contact lens. The soft contact lens prescribed by Colorado optometrists was not used for any disease treatment. The soft contact lens was for vision correction only. The question of who could actually prescribe a contact lens was a matter of state law and Colorado optometrists had the authority to prescribe contact lenses. Clearly Dr. Winograd and his colleagues had a serious misunderstanding about the classification of the FDA regarding new products.

Defense of Tonometry

The Colorado optometrists also stated that as a matter of public health they should be permitted to use a tonometer. Various nationwide statistics indicated that 70% of the U. S. population consulted an optometrist for their initial eye care. This accessibility gave patients who otherwise would not receive such care the opportunity to have their eye pressure measured as part of a routine comprehensive eye examination. It was established that there were tonometers that did not require a corneal anesthetic. Both optometric and medical experts testified that these tonometers were as reliable and accurate for measuring intraocular pressure as those which did require corneal anesthetic. It was also established that optometrists did not use and did not claim to use any tonometer requiring the use of corneal anesthesia. Also, optometrists did not diagnose glaucoma or any other eye disease but had a duty under the law to detect or recognize any signs or symptoms exhibited by a patient and to refer the patient to the appropriate physician for diagnosis and treatment. This was a requirement of the Colorado optometry practice act at this time.

To summarize, the following three factors were admitted or claimed by the optometrists:

1. Optometrists did not use soft contact lens for disease treatment.
2. Optometrists did not use a tonometer that required the use of an anesthetic eye drop.
3. Optometrists did not diagnose glaucoma.

But the optometrists did claim the right to fit and prescribe soft contact lenses as these are contact lenses and are not drugs under Colorado law. Also, optometrists had the right to use a tonometer which does not require an anesthetic eye drop and they had the right and duty to recognize any signs or symptoms of a disease exhibited by a patient as well as making an appropriate referral to a physician.

THE DECISION

On February 5, 1975, after a 10-day trial in Denver District Court, Judge Robert Kingsley agreed with the position of the

optometrists. Judge Kingsley accepted the optometrists' positions completely as to what the optometrists could and should do in discharging their duties as a matter of public health under the Colorado optometry practice act. Judge Kingsley also accepted what the optometrists stated they did not do in terms of discharging their professional responsibilities.

Soft Contact Lens Decision

Judge Kingsley found that Bausch and Lomb's soft contact lens was a contact lens and may be prescribed by optometrists for correction of visual acuity but not for the treatment of eye disease. The court said that optometry was not bound by the Food and Drug Administration's categorization of soft contact lens as a "new drug." This ruling was consistent with what Colorado optometrists had been doing since the inception of contact lenses in this ophthalmic market.

Tonometry Decision

Judge Kingsley further ruled that optometrists could use a tonometer which does not require anesthetic eye drops in examining their patients. The court agreed with the optometrists in their claim that they did not diagnose the presence of glaucoma. However, in no way should this be construed or interpreted to limit the optometrists' right and duty to refer or direct a patient to a physician whenever it comes to the optometrists' attention that such a patient exhibits signs or symptoms of a disease requiring treatment by an ophthalmologist or other physician.

These decisions of the court raised some questions because of the terminology that was used in the decision. Therefore, motions for clarifications were filed by the optometrists. Not surprisingly the ophthalmologists subsequently filed a motion for a new trial.

After a hearing, the court issued a modified decision with modified findings of fact and order on April 2, 1975. This decision rendered again was in agreement with the optometrists' claims and positions.

SUMMARY

The lawsuit had taken 25 months from the time it had been filed in January 1973 until the final decision was rendered in April 1975. It had been a time of great uncertainty and anxiety on the part of the Colorado optometrists. The expense of the preparation, hearings and trial for the lawsuit had been substantial and was borne largely by the COA. As with most issues of this nature, much of the effort and expense was shouldered by the minority of the membership. Fortunately, the COA had the benefit of outstanding and farsighted leadership.

Although the lawsuit was unsuccessful from Colorado ophthalmology's point of view it had clearly validated the position of the profession of optometry. Undoubtedly Dr. Winograd was unfamiliar with the FDA's language regarding new products and caught completely off guard by Dr. Fair's clinical research that used an instrument with which Winograd must have been unfamiliar or was unaware it existed.

This lawsuit did serve to make Colorado optometrists realize the COA, especially its leadership, needed to develop, support and pass legislation that would change the Colorado optometry practice act. This would serve to make the COA proactive rather than reactive to a lawsuit. Perhaps if any good came from this it was the realization of the importance of having the word "diagnosis" in the Colorado optometry practice act.

To achieve a change in the optometric practice act would require a political grassroots effort on the part of the COA. Then Executive Director William B. O'Rourke was active in local Democratic politics and also had experience in the Colorado legislature as a lobbyist. He began to educate the Colorado optometrists on how to become involved in legislative campaigns at the local and state levels. O'Rourke emphasized the importance of becoming involved in candidates' campaigns early and be willing to do "grassroots" work for the candidate. If the candidate was successful in being elected to the legislature, then the optometrist would be able to have access to the legislator. In this manner, he or she could explain optometry's proposed legislation and why it was in the best interest of the citizens of Colorado.

Although the lawsuit was emotionally and financially troublesome for Colorado optometrists, it resulted in a very united COA. As a result of the rural nature of Colorado and the distribution of legislators, optometry had a significant advantage of impacting the outcome of legislation. Like many states, it had really failed to grasp the significance of this advantage until adversity brought it into focus. The lawsuit may have delayed the COA by a few years in its quest to receive authorization to use pharmaceutical agents for diagnostic and therapeutic purposes. However, it did help the organization and its leadership understand what was necessary to increase the scope of practice for the profession of optometry. This would ultimately result in more accessible and therefore less expensive care for the citizens of Colorado.

ACKNOWLEDGEMENT

The authors want to express their appreciation to all of those optometrists, past and present, who supported this effort by the COA to win this important case. Clearly this case would have had national implications for the profession had the outcome been different. They also thank John F. Amos, O.D. for his assistance in reviewing and writing portions of this paper.

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Appendix. Index of Witnesses

For the Plaintiffs

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