

Statement of Dr. David A. Cockrell
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Competition Policy and Consumer Rights
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Good afternoon, Chairperson Klobuchar, Ranking Member Lee and members of the subcommittee. I am Dr. David A. Cockrell, President of the American Optometric Association and an optometrist in private practice in Stillwater, OK.

The AOA, with more than 36,000 member doctors and affiliated associations representing each state, DC and our armed forces and federal service optometrists, is the national voice for the optometric profession, the tens of millions of patients who depend on us and the cause of access to eye health care.

Thank you very much for the opportunity to participate in today's hearing and to discuss the high quality care being provided by the nation's Doctors of Optometry to our patients, particularly those who wear contact lenses.

Optometrists provide a full range of primary eye health and vision care to our patients, including children, working adults and seniors. In my own practice, we see patients ranging in age from babies just a few months old to centenarians. Within that group, our contact lens patients range in age from two to more than 90.

Some patients wear contact lenses to correct their vision while others choose them for cosmetic reasons. Younger patients and patients with differing types of eye disease wear contacts for therapeutic reasons. It's for this group that contact lenses are sometimes not just the best option to have functional vision; they are the only option to achieve functional vision.

The AOA represents optometrists practicing across the full spectrum of eye care delivery, including private offices, retail settings, health centers, clinics and hospitals. Other doctors work in health agencies or are engaged in academic research and teaching.

My own office's main focus is on management and treatment of all vision related problems and eye diseases. As a team of four primary eye care physicians, we regularly see patients with conjunctivitis, cataract, glaucoma, diabetic retinopathy and macular degeneration. Also, we perform surgery for lid procedures as well as laser surgeries for glaucoma and secondary cataract.

Often we are working closely with our ophthalmologist colleagues to ensure that every patient gets the care he or she needs. Many ophthalmology practices also prescribe and dispense contact lenses for the same reasons optometrists do, and there is considerable agreement between the respective national organizations on appropriate patient care, eye health and consumer safety concerns.

The advancement of optometry to the role of the nation's frontline provider of eye health care services is tied to advances in the scope and quality of optometric education. It includes four years of undergraduate pre-medical education and successful completion of four years of optometric education – including didactic and clinical studies – at an accredited U.S. college of optometry. A one to two year residency may be pursued, commonly in specific areas of study such as pediatrics, vision rehabilitation, hospital based care and care of contact lens patients. There are also increasing opportunities for post-graduate fellowships. Board certification for optometry is also a recognized credential and the Maintenance in Certification program is approved for use in Medicare quality and performance incentives.

Optometric education is certified by the Accreditation Council on Optometric Education (ACOE), a panel recognized by the U.S. Department of Education. All Optometrists must successfully pass national and state board examinations and secure and maintain state licensure.

Given the topic of today's hearing and the AOA's role in educating the public, it's essential to state that contact lenses have been recognized in law and regulation since the 1970s as a medical device. A doctor's supervision and care for their proper and safe use is required. However, since contact lenses are so widely and successfully used by consumers, I've been asked from time to time why physician supervision is needed and what it consists of.

It is important to note the great deal of information in the lay press as well as scientific literature addressing the fact that a patient's vision and overall health are at risk with improper lens wear, care or fit. In fact, the consequences can be severe and permanent.

In my own experience, I've seen unsupervised or non-prescribed contact lens use result in:

- **Corneal neovascularization** – A corneal condition where oxygen deprivation and corneal stress cause abnormal blood vessels to grow into the normally clear, transparent cornea. This is a permanent/irreversible condition that will continue to cause increasing sight threatening damage unless detected and resolved.
- **Giant papillary conjunctivitis** – This is a very uncomfortable condition and not only makes it difficult to wear contacts over time but also makes it uncomfortable for the patient when they are not wearing lenses due to the damage and scarring that occurs on the inside surface of the lids. It is caused by a variety of reasons, all having to do with the fit of contact lenses as well as the material from which the contact lenses are manufactured.
- **Corneal infection, ulcer, infiltrate/inflammation** – Can occur due to the improper fit of the contact lenses as well as bacteria or fungal accumulation on the surface of the lens due to abuse of the correct wearing schedule, contact lens cleaning and care, or the use of a contaminated solution or cosmetic.
- **Corneal scarring** – A result of any of those things I just mentioned and it's similar to having a large blurred spot on a window that cannot be removed. The only cure in some cases is a corneal transplant – which I consider to be a very last resort for patients. Within the past year the doctors in our office have treated two patients with significant, essentially blinding scarring; a direct result of

improper contact lens wear. In both cases, the only resolution was a corneal transplant. Corneal transplants are expensive, painful and sadly, rarely leave the patient with vision as clear as they had before the incident (which brought about the need for the transplant.)

- **Permanent loss of vision** – Sometimes loss of vision can be reversed with discontinuation of the contact lens and medical treatment. Sometimes special types of therapeutic hard contact lenses can resolve vision issues but can be uncomfortable for the patient. Sometimes vision loss simply cannot be reversed by any means

As an eye doctor, what I find so profoundly tragic is that the majority of these situations are preventable.

Doctors have several criteria to evaluate patients for contact lenses to be sure they are safe and effective for long term vision and health. I'm pleased to offer a brief review of the criteria and steps to fitting contact lenses:

- a. Patients will inquire about contact lenses either before or after a comprehensive eye examination. If they don't inquire and they are candidates for healthy contact lens wear, doctors will commonly ask if they prefer to wear glasses or contact lenses or if they prefer other refractive options, so these can be considered during the examination.
- b. A comprehensive eye exam is usually done first (if not completed within the last 12 months) to rule out any eye disease or potential vision problems and to determine the best corrected visual acuity (BCVA) refraction -spectacle and/or contact lens prescription. During this time, corneal health is also evaluated, along with lid hygiene and general tear assessment. Once the comprehensive eye exam is complete, a contact lens fitting is the next step.
- c. A full evaluation of the tear film and corneal surface are completed to determine dry eye, tear osmolarity and tear evaporation rates as a first indication of the lens material that may be most suitable for the patient. For example, a faster tear evaporation rate (less than 10

seconds after blinking) may require a lens with lower required water content to remain comfortable and healthy for the patient (it won't absorb all the tears and will leave some leftover with each blink for lens movement).

- d. Measurements of the corneal surface (the front of the eye surface that the contact sits on) are done to determine curvature and minimum patient diameter requirement for the lens.
- e. A determination is made regarding the most compatible lenses and lens types for the patient with the following considerations:
 - i. Oxygen transmission
 - ii. Water content
 - iii. Lens thickness
 - iv. Corneal curvature
 - v. Corneal diameter
 - vi. Prescription needs available (Myopia- nearsightedness, Hyperopia – farsightedness)
 - vii. Toric fitting needs - astigmatic/astigmatism parameters of the lens to meet visual specific prescription needs)
 - viii. Specialty fit lens needs- might include but are not limited to, specialty gas permeable lenses for the treatment of corneal thinning problems (Keratoconus) and temporary post-surgical or pharmaceutical delivery lenses and amblyopic needs.
 - ix. Extended wear versus daily wear is determined based on the patient's needs and ability of the patient to be compliant with care of the lenses.
 - x. Determination of the lens use and environment in which the lenses will be worn- dusty work environment, dry office spaces, near vision work (at a desk), far vision work (a driver), and whether they will be worn with or without spectacle lenses over the contact lenses.
- f. A trial fit is then performed. Doctors may choose several lens types by various lens manufacturers to try on the patient's cornea for best fit and comfort. Once the lens is on the cornea, we examine the fit using a biomicroscope (slit lamp), and we look for the following:

- i. The lens needs to move on the eye – it cannot be too tight on the cornea, because the cornea has no blood vessels and uses the tear and atmosphere to obtain nutrients and oxygen. Lens movement is needed to pump an adequate amount of tear liquid under the lens with each blink.
 - ii. The lens can't be too loose, or too flat on the eye, or else the lens will move too far out of place with each blink, causing poor vision and discomfort.
 - iii. If the patient has astigmatism, then the astigmatic power must be located in the proper axis (area for power) and return to that location after each blink.
 - iv. The lens has to not absorb all the tears (low enough water content) to remain comfortable for longer wear.
 - v. The lens surface is examined to determine whether there are excess protein deposits on the lens from the tears. Protein bonds/adheres to the lens surface and can eventually cause problems to the inside lids. If deposits are seen early, then a lens with a different coating may be considered.
 - vi. Visual acuity is tested again to determine if slightly more or less power is needed for the "best controlled visual acuity.
 - vii. At this point, the best "first" lens for the patient is determined and we are ready to dispense the lenses.
- g. Prior to dispensing the lenses, patient education must take place either by the doctor or office technician to teach the patient about lens care – how to insert the lenses, apply makeup when worn, and lid and hand hygiene for handling lenses.
 - i. We review insertion and removal of lenses and observe the patient completing this several times to be sure they can wear the lenses correctly (right side out for a soft lens) and most importantly can remove them safely when needed.
 - ii. We review lens care – how to apply wetting solution for insertion and how to wash and store a daily lens.
 - iii. We provide a fitting schedule to the patient to build up their wear time for comfort and corneal health – usually several hours to all day and/or extended wear use.

- iv. We review supplemental tear types and use with the patient (when to use, how to use, what types are compatible with the lens, i.e., preserved, non-preserved tears).
- v. We ascertain smoking status of the patient, including exposure to second-hand smoke. We provide information on increased prevalence of adverse contact lens events to the patient along with smoking cessation information.
- vi. We provide warning and risk information to the patient so they know what to look for in case they have problems - signs of inflammation, discomfort, and eye discharge versus normal tearing (signs of infection versus normal tearing).
- h. A follow up visit with the patient is scheduled to check for longer wear fit and eye health. This is a fast but very important doctor visit to determine whether the lenses are *compatible* with the patient's cornea: the lens is comfortable for the time the patient wears the lenses, they are remaining in place but retaining movement over wear time (not becoming tight with time), the lenses don't have excessive protein buildup, and the patient is not showing any signs of inflammation or infection (patient exhibits properly handling the lenses).
- i. At this point in time, we determine the final lens prescription – will it be the first lens we have fit onto the patient, or is another lens type or lens size/material needed?
- j. We write the final lens prescription and present it to the patient, which includes the manufacturer's name, the base curvature numbers, the diameter and the prescription/power of the lenses and an expiration date of the prescription.

Accordingly, my colleagues and I want and, frankly, insist on the very best contact lens products to meet our patient's needs. There have been historic innovations in these medical devices over the last three decades which I believe have benefitted patients in three key ways:

- First, innovation in the contact lens industry has enabled more patients to use contact lenses for a greater proportion of their vision needs. Because of innovations in materials and designs, many patients who were simply not

correctable with conventional eyeglasses now can experience normal vision with contact lenses.

- Second, innovation has improved the quality of contact lenses so that they are easier for patients to use with less risk of harm to the eye. We now have a large variety of true daily disposable lenses (lenses that are worn for one day and then disposed of as well as improvements in lenses that can be safely worn for up to 30 days without removal. Each of those technologies fills significantly different needs for the patients who use them. These quality improvements help with comfort, safety and compliance. But oversight from the patient's eye doctor remains a critical component to success and safety of contact lenses. Simply put, while contact lens choice is greater than ever, all contact lenses do not meet all patient requirements. It's our job to match the appropriate lens with each patient's individual needs. .
- Third, innovation has created healthy competition among contact lens manufacturers to bring higher quality products and competitive pricing to consumers. As a doctor, I observe that there are more choices than ever before that I am able to discuss with my patients.

The priority for the AOA is to support best practices and high standards to benefit the tens of millions of Americans who entrust their vision and eye health to my colleagues and to me. On the subject of competition generally, the AOA believes strongly that competition in the contact lens industry is positive and needed.

As I understand it, I share this table with executives representing the largest manufacturer of contact lenses in the United States and the largest seller of contact lenses in the world. They are in a better position than am I to describe and discuss their own pricing strategies, marketing initiatives and business objectives. Suffice it to say that in my experience of over thirty years of prescribing these devices, my contact lens patients have never had more choices, products of a higher quality or greater affordability in their options.

Using my practice as an example, we have four ODs and currently use contact lenses on a monthly basis from typically 10-15 manufacturers, each with multiple

lens types and parameters. My colleagues and I make independent, patient-centered decisions on which lens type and parameters are the best for the patient in question, depending on the patient's needs. We then work with the patient to help achieve the best outcome without regard to any other factor.

More broadly on the issue of competition, I know that the Federal Trade Commission (FTC) released a report in February 2005, which reached the conclusion that the market for contact lenses is highly fragmented and competitive. The FTC report also concluded that optometrists prescribe multiple brands of contact lenses. This is our understanding as well – optometrists prescribe the lens that is best for the patient and select from among many brands. We've seen nothing that calls into question these findings nor anything that would cast them in a different light, though we will listen carefully to the testimony and discussion today.

The health, well-being and safety of our patients is the foundation of my practice and the practices of AOA members from coast to coast. As the national voice of 36,000 Doctors of Optometry – notably including Senator John Boozman, a longtime Doctor of Optometry in private practice and AOA and Arkansas Optometric Association member – and the tens of millions of patients we serve, we work to educate the public about the safe use of contact lenses as a medical device and the dangers posed by unscrupulous sellers.

In 2005, at AOA's urging, Congress passed and the President signed legislation [Public Law 109-96] that closed a harmful loophole in Federal law by requiring even non-corrective contact lenses to be regulated as a medical device. This has helped safeguard the eye health and vision of many young Americans who were easily and openly purchasing and using decorative contacts without the care and instruction of an optometrist or ophthalmologist.

This significant safeguard and stepped-up enforcement is no guarantee for our patients though. As a member of the state board of examiners in Oklahoma I continue to see patients grievously harmed after purchasing contact lenses from illegal vendors.

With consumers still facing risks, the AOA is partnering with the Food and Drug Administration on a new national public health awareness campaign to alert teenagers and young adults to the dangers connected to the improper use of

contact lenses. I commend the FDA for listening so closely to concerned optometrists and the AOA and for making this urgent public health problem the priority it needs to be. For up to date information on the FDA-AOA contact lens safety campaign, please visit FDA.gov or directly access the recent consumer update at www.fda.gov/ForConsumers/ConsumerUpdates/ucm402704.htm.

Again, thank you for the opportunity to be here and participate in today's important discussion. I look forward to answering any questions you may have.