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CONTACT LENS SALES: IS MARKET REGULATION THE PRESCRIPTION?

HEARING

BEFORE THE

SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

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CONTACT LENS SALES: IS MARKET REGULATION THE PRESCRIPTION?

FRIDAY, SEPTEMBER 15, 2006

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON COMMERCE, TRADE,
AND CONSUMER PROTECTION,
Washington, DC.

The subcommittee met, pursuant to call, at 9:30 a.m., in Room 2123 of the Rayburn House Office Building, Hon Cliff Stearns [Chairman] presiding.

Representatives Present: Stearns, Terry, Schakowsky, and Gonzalez.

Staff Present: David Cavicke, General Counsel; Chris Leahy, Policy Coordinator; Shannon Weinberg, Counsel; Will Carty, Profession Staff Member; Brian McCullough, Professional Staff Member; Billy Harvard, Legislative Clerk; Jonathan Cordone, Minority Counsel; and Jonathan Brater, Minority Staff Assistant.

MR. STEARNS. Good morning, everybody. The subcommittee will come to order.

I am pleased that this subcommittee has found time to revisit the issue of contact lens regulation, an issue we addressed in the 108th Congress which resulted in the creation of a public law. Unfortunately, according to some companies in the contact lens market, including 1-800 Contacts, there remains a problem with regard to how contact lenses are distributed to retailers, from prescribers to wholesale clubs and mail order or Internet retailers, the so-called alternative channels of distribution.

This committee has a long and distinguished history of addressing market failure problems, but only as a last resort, preferring the invisible hand of the free market to work out inequities over government intervention. At the outset, I hope that this will be the case, but I am pleased to have an opportunity to take a closer look at this issue, understand it better, including the status of a 1996 consent decree, and on the alleged evidence of market failure. Therefore, I welcome this opportunity to hear the testimony before us this morning.

My colleagues, with over 36 million Americans wearing some form of contact lens, this is not a small issue. There are essentially two types of mass marketed lenses for consumer purchase, those distributed exclusively to eye care professionals by a contact lens manufacturer and

those distributed freely to all retailers, including eye care professionals and aftercare providers like 1-800 Contacts. The concerns precipitating this hearing arose because of those manufacturers; namely CooperVision, that sell their lenses exclusively to eye care professionals. Aftercare providers feel that such arrangements limit competition and ultimately harm consumers.

So it is important to note that the Federal Trade Commission conducted a study in 2005, as required by legislation passed by this committee, and concluded there was no market failure in the industry. The Federal Trade Commission found exclusive manufacturer-retail relationships pose no threat to competition nor did any harm to consumers. So I look forward to the FTC elaborating on their findings today, and commenting on the case before us.

I am not resigned to a conclusion at this point. My primary concern in holding this hearing is to walk out of this room with a better and clear understanding of the actual problem and how the legislation introduced and referred to this committee will solve it.

I also want to be certain that by solving an alleged commercial problem, we are not in turn creating a health-related problem. Prescription verification is a very important component of doctor-patient-seller interaction in this area, and I want to understand better how aftercare providers like 1-800 Contacts handle that function. So I thank all the witnesses for being here.

The House went out of session yesterday, so perhaps not all the members will be here this morning, but I to want thank the Ranking Member, Jan Schakowsky, for participating and being here--and others that do show--so we can have that hearing this morning. And with that, I recognize the Ranking Member.

[The Prepared Statement of Hon. Cliff Stearns follows:]

PREPARED STATEMENT OF THE HON. CLIFF STEARNS, CHAIRMAN, SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION

Good morning. I'm pleased that this Committee is finding time to revisit the issue of contact lens regulation – an issue we addressed in the 108th Congress, which resulted in the creation of a public law. Unfortunately, according to some companies in the contact lens market, namely 1-800-Contacts, there remains a problem with regard to how contact lenses are distributed to retailers – from prescribers to wholesale clubs and mail order or internet retailers (the so-called "alternate channels of distribution").

This Committee has a long and distinguished history of addressing market failure problems, but only as a last resort – preferring the invisible hand of the free market to work out inequities over government intervention. At the outset, I hope that will be the case here but I'm pleased to have an opportunity to take a closer look at the issue, including the status of the 1996 consent decree, and on the alleged evidence of market failure. Therefore, I welcome the opportunity to hear the testimony before us this morning.

With over 36 million Americans wearing some form of contact lens, this is no small issue. There are essentially two types of mass-marketed lenses for consumer purchase - those distributed exclusively to eye care professionals by a contact lens manufacturer and those distributed freely to all retailers, including eye care professionals and "aftercare providers" like 1-800-Contacts. The concerns precipitating this hearing arose because of those few manufacturers, namely CooperVision, that sell their lens exclusively to eye care professionals. Aftercare providers feel that such arrangements limit competition and harm consumers.

It is important to note that the Federal Trade Commission conducted a study in 2005, as required by legislation passed by this Committee, and concluded there was no market failure in the industry. The FTC found exclusive manufacturer-retailer relationships pose no threat to competition nor harm consumers. I look forward to the FTC elaborating on those findings today and commenting on the specific case before us.

Because I am not resigned to a conclusion at this point, my primary goal in holding this hearing is to walk out of this room with a clear understanding of the actual problem and how the legislation introduced and referred to this Subcommittee will solve it. I also want to be certain that by solving an alleged commercial problem, we are not, in turn, creating a health-related problem. Prescription verification is a very important component of doctor-patient-seller interaction in this area, and I want to understand better how aftercare providers like 1-800-Contacts handle that function.

Again, I thank everyone for joining us this morning and I look forward to the testimony of this distinguished panel.

Thank you.

MS. SCHAKOWSKY. Thank you, Chairman Stearns, for holding today's hearing to examine the status of contact lens sales, now that the Fairness to Contact Lens Consumers Act has been law for nearly 3 years.

As you mention, that bill went through our subcommittee; I am proud to have been a co-sponsor of it. It is a pro-consumer law that guarantees the 36 million contact users in this country--guarantees that they are provided with a copy of their prescription from their doctor so they will have the freedom to shop for the best deal possible if they choose when filling their contact lens needs.

Despite the success for consumers this law represents, reports have been surfacing from eye care practitioners, manufacturers, and contact lens sellers that there are still problems in the prescription lens business. Eye care practitioners are concerned that sellers are abusing the verification system by making it difficult for eye doctors to authenticate prescriptions, and also by filling prescriptions without ensuring their validity. Manufacturers are concerned about legislation that would force them to offer their product to any distributor that wants them, regardless of their reliability. No other manufacturer field has such a restriction. And online distributors claim that because we did not include language in the Fairness to Contact Lens Consumers Act to require that all lenses are made available to them, eye doctors and manufacturers are trying to keep them out of the loop, they say.

Since the passage of the legislation, the Federal Trade Commission has had to issue warning letters in a number of instances. In the early

days of this law, some were issued to eye care practitioners for not providing prescriptions to consumers. In 2004, online sellers were issued warnings for not having open fax lines for eye care practitioners to verify prescriptions or for falsely claiming that cosmetic or color lenses are nonprescription. The FTC has also had to take law enforcement action against sellers who were found to be not verifying prescriptions.

These problems, whether they represent widespread problems or are attributable to a few bad actors, are quite serious. It is consumers' health, safety and choice that are jeopardized by those violations, and it is never acceptable to compromise consumers in the desire to make a buck by a multibillion dollar industry.

As legislators, we have a duty to make sure that consumers' interests are being met, that they have access to safe and affordable contact lenses, and that those principles guide us in whatever we decide to do. And as key players in the eye care industry, it is the practitioners, manufacturers, and sellers' duty to also be guided by those principles and not try to push the law to its limit.

We have run into some bumps in the road, but I believe that since the FTC has been able to take action under the Fairness to Contact Lens Consumers Act, we can't claim that the law is not working or that we need new legislation at this point. Consumers are getting their prescriptions and are able to shop around for their lenses.

I am glad that we are holding today's hearing to investigate these complaints to determine what needs to be done to ensure that we protect consumers' health and safety, and I thank the witnesses here for shedding light on this important issue. Thanks.

MR. STEARNS. I thank the gentlelady.

Mr. Terry.

MR. TERRY. Thank you, Mr. Chairman, for holding this hearing and our witnesses for appearing here today.

My concern, it was brought to my attention and the basis for introducing what is H.R. 5762, the Contact Lens Consumer Protection Act, appears to me to be an anti-competitive, anti-consumer practice that has emerged as a loophole to what some of us fondly refer to as the Burr bill, a contact lens bill of about 3 years ago, of which there was a great deal of discussion and--I won't say angst, but handwringing and compromise that went into this bill to reach a delicate balance. Then there appears to be a system of marketing that gets around what at least the intention of that bill was, and that is to provide consumers the ability to take a prescription and go then to a place where they want to go, whether it is like the Wall Street Journal article that says that this lady wanted to go to Wal-Mart to fill her contact lens or go online. And I think we should give consumers that freedom. That was the intention of

that bill 3 years ago, as well as to ensure the patient's eye safety and health.

So I want to look and explore this tying marketing agreement that appears where a physician can prescribe a contact lens that only that physician sells. So I want to explore that, see if there is health reasons for something like that or whether it is what it appears on the surface, to just simply be a marketing ploy to get around the current law.

With that, Mr. Chairman, I will put my full statement into the record, and if I could also attach a copy of the Wall Street Journal.

MR. STEARNS. By unanimous consent, so ordered.

MR. TERRY. Then I yield back.

[The Prepared Statement of Hon. Lee Terry follows:]

PREPARED STATEMENT OF THE HON. LEE TERRY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEBRASKA

Mr. Chairman, thank you for holding today's hearing.

Recently, I introduced H.R. 5762, the Contact Lens Consumer Protection Act, because I believe legislation is needed to fix a loophole that prevents millions of consumers from having more choices when purchasing contact lenses prescribed by their eye doctor.

In 2003, Congress passed the Fairness to Contact Lens Consumers Act which many of my colleagues on this committee helped write and supported. Under that law, eye doctors are required to hand patients a copy of their prescription after the exam so that the patient can shop around for the most affordable contact lenses. What patients have found is that the brand they were prescribed was only available at the eye doctor's office at a cost much higher than at an alternative distributor. Why is this happening? Because the major contact lens makers were entering into exclusive arrangements with eye doctors requiring patients to buy their lenses from the doctor, and discouraging purchases from alternative contact lens distributors.

By allowing eye doctors to prescribe doctor-only, or limited-distribution lenses, a loophole has been created forcing millions of consumers to buy their lenses only through eye-care professionals. A recent report issued by the Federal Trade Commission showed that an average user of contact lenses can save up to 20% by buying from alternative distributors of contact lenses.

The practice of limiting consumers to the purchase of doctor-only contact lenses has been found to be harmful to consumers by 39 state attorney generals. According to the state attorney generals, the practice of doctor-only prescribed contact lenses "threatens to thwart the purposes" of the Contact Lens Consumers Act and "puts the eye-care providers' profit motive ahead of patient welfare." Those are their words, not mine.

Congress, as well as the medical community, recognizes that a conflict of interest can be created when doctors sell what they prescribe to consumers. That is why when my doctor writes me a drug prescription, I can go to Walgreens, CVS, or a locally owned pharmacy to purchase my prescription. What I want the subcommittee to explore this morning is why should eye doctors not be held to the same business practices?

My legislation makes two simple changes in the current law. First, it would require a manufacturer to make any contact lens it produces, markets, distributes or sells available in a commercially reasonable and non-discriminatory manner to prescribers or other specified alternative channels of distribution. Second, it exempts prescriptions for

lenses that are not mass marketed or produced that are custom designed to meet the different optometric needs of individuals.

Mr. Chairman, I again thank you for holding this hearing and look forward to hearing from our panel of witnesses.

[The information follows:]

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The Backlash Against 'Doctor Only' Contacts

Momentum Builds to Break Eye-Care Professionals' Lock On Sales of Certain Lenses

By Rhonda L. Rundle

WHEN JANE HOLEYWELL tried to refill her 19-year-old son's contact-lens prescription, she was mystified that she couldn't find the lenses online or at Wal-Mart where she usually shops. She had purchased an initial three-month supply last year from the family eye doctor who wrote the prescription, but she didn't want to pay his high prices when the time came to reorder.

"Imagine when I discovered I couldn't buy them cheaper elsewhere," says the retired veterinary receptionist in Houston. It turned out that the Biomedics brand her son needed was available only through an eye doctor. In the end, Ms. Holeywell took a chance and bought a different, cheaper brand that a Wal-Mart salesperson assured her was the same as her son's Biomedics lenses.

Ms. Holeywell had stumbled upon a little-understood segment of the vision-care industry: so-called doctor-only, or limited-distribution lenses that are meant to be sold only through eye-care professionals. The manufacturers, including CooperVision, Hydrogel Vision and Sauflon Pharmaceuticals, sell these lenses only to eye doctors (or chains that employ optometrists, such as LensCrafters). Prices vary, but eye-care professionals typically charge more—often a lot more—than warehouse clubs like Costco, mass merchandisers like Wal-Mart and Web sites like 1-800 Contacts.

Extreme H_2O lenses, *typically $22-$25 per box, are available only through eye-care professionals.*

Eye doctors say the practice is a positive for patients and encourages them to return more frequently to the office for needed checkups. Patients, they say, benefit from buying lenses from someone who regularly examines their eyes and instructs them on proper hygiene and lens care. Some manufacturers say their doctor-only products have special features, such as higher water retention or greater comfort, says Dan Bell, president of the Contact Lens Manufacturers Association, a trade group that represents about 100 lens makers. "Those are marketing tools and the marketplace decides whether those are real benefits or not," he says.

But the practice is sparking complaints from consumers and retailers, who say it's an effort to circumvent a 2003 law meant to encourage competition and make it easier for consumers to shop for the best deal. Under the Fairness to Contact Lens Consumers Act, eye doctors are required to hand patients a copy of their contact-lens prescription after an exam, whether they ask for it or not. Increasingly, consumers are finding that it doesn't matter that they can take their prescription with them, because they still can fill it only with their ophthalmologist, optometrist or optician.

Amid rising complaints, Congress is now considering whether to ban restrictive distribution of lenses. And 39 state attorneys general collectively sent a letter in June to Sens. Robert Bennett of Utah and Patrick Leahy of Vermont, co-sponsors of a bill that would effectively outlaw doctor-only lenses. The practice "threatens to thwart the purposes" of the contact-lens-consumers act and "puts the eye-care providers' profit motive ahead of patient welfare," the letter stated.

While no one tracks just how many of the available lenses are "limited-distribution lenses," re-

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Backlash Against 'Doctor Only' Lenses

Continued From Page D1

tailers and eye doctors generally agree that it's a relatively small portion of the market. But their use is spreading as eye-care professionals seek strategies to hold on to lens sales and bring clients back for regular checkups. Eye doctors still sell two-thirds of all contact lenses, but their turf is under pressure from big-box retailers, optical chains and mail-order companies. It's a significant financial threat to optometrists who earn far more from product sales than from professional services, industry studies show.

According to a Federal Trade Commission study, a six-month supply of contact lenses sold in bricks-and-mortar locations are on average $15 more expensive than those sold online. For instance, one optometrist in Birmingham, Ala., charges $49 for a six-pack box of CooperVision's Proclear Compatible lenses, a popular doctor-only brand. A widely available similar lens, Focus Monthly from CIBA Vision, was on sale last week for $20.95 at VisionDirect.com. The new O_2Optix lens from CIBA Vision, touted as having "five times more oxygen than the leading lens" is available from one California optometrist for $30 a box; it sold last week for $22.45 at 1-800 Contacts and $21.87 at Walmart.com.

Despite manufacturers' policies, doctor-only lenses are sometimes available online because Web sites buy them on the "gray market" overseas or from sources that resell inventory in violation of their agreements with lens sellers. Also, some lens brands that are sold only through doctors are widely sold under different names to mass merchandisers. The lenses inside are identical; only the names on the box are different.

Unlike medical doctors who have no financial stake in the drug scrips they write, eye-care professionals have a conflict because they sell what they prescribe, says Joe Zeidher, general counsel of 1-800 Contacts Inc., the largest Internet vendor. The company is pushing hard for an amendment to the 2003 law that would force lens makers to sell their products through all distribution channels. Bills to that effect were introduced earlier this year in both houses of Congress.

Optometrists and ophthalmologists strongly oppose the measures. And doctors are demanding legal changes of their own to crack down on what they contend are vendor abuses, including sales of large orders that encourage people to go too long without getting their eyes checked. The Federal Trade Commission recently accused three Web sites, including www.lensworld.com, of filling prescriptions without verifying them first. The owner of the sites, Walsh Optical Inc. of New Jersey, paid a $40,000 penalty and signed a consent decree without admitting or denying wrongdoing.

Some consumers who are restricted to buying from an eye doctor say they don't like it.

Under the current "passive verification" rule, a retailer can fill an order eight business hours after contacting the prescriber, unless the prescriber objects. But eye doctors say they don't have enough time to go through the many faxed requests for verification and lodge any objections in time. They maintain that prescriptions should be positively verified, rather than filled by default. "We view this as ultimately a patient-safety issue," says Thomas Steinemann, a Cleveland ophthalmologist and associate professor at Case Western Reserve University.

CooperVision, which last year acquired Ocular Sciences, is one of the largest sellers of limited-distribution lenses. The Biomedics lens prescribed for Ms. Holeywell's son is an Ocular Sciences brand, which has a doctors-only policy. CooperVision, a unit of Cooper Cos., also sells its popular Proclear Compatibles brand to vendors who perform on-site eye exams, including chains such as LensCrafters, but won't sell to online sellers. Other brands sold exclusively through eye-care professionals include some from CIBA Vision, a unit of Novartis AG; Extreme H_2O, made by Hydrogel Vision; and lenses sold by Saufion Pharmaceuticals, a British company.

"We think the free market is working very well and no one should tell us who we can and can't sell to," says Greg Fryling, CooperVision's president and chief operating officer. "Most people know they are paying a higher price when they buy from their optometrist" and choose that option to assure they are receiving a quality product and service. Counterfeit products are a real problem, he stressed. The FTC "hasn't found any abuse with our products," he added, referring to the study the agency published last year that concluded that limited distribution doesn't harm competition.

In its February 2005 study, the FTC issued an opinion that limited distribution doesn't compromise competition, partly because the practice isn't widespread. But that could change. To settle antitrust litigation that had led to the 2003 consumer law, the big contact-lens companies agreed to sell their wares to alternate suppliers, including mail-order houses. Certain aspects of the settlements are expiring soon, however, potentially opening the door to new sales strategies.

Some consumers who are restricted to buying from an eye doctor say they don't like it. "My eye doctor that I've been going to for years recently prescribed Proclear," says Elaine Candiff, a 51-year-old homemaker in Victorville, Calif. "They are giving me good results, but if I had known I could only buy them through an eye-care professional I would have said: Just write a prescription for Acuvue," a common product of Johnson & Johnson's Vistakon, she says.

MR. STEARNS. And I thank the gentleman. And I also, by unanimous consent, put Mr. Ed Whitfield's statement in the record, and anyone else who seeks.

[The information follows:]

PREPARED STATEMENT OF THE HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Thank you, Chairman Stearns for holding this hearing. We have received much interest in this topic and particularly on the various legislative proposals addressing the contact lens market before both chambers. I hope that today's hearing will give us a chance to look at market regulation and how it affects consumers, and at whether now is the time for Congressional action.

Regulation of consumer markets is an area in which the Federal government traditionally treads lightly—and with good reason. However, when conditions command action—when consumers are being harmed by the actions of a particular market participant—Congress has acted.

The Federal Trade Commission reports 36 million Americans wear contact lenses. Assuring fair access to lenses and ensuring healthy competition among lens manufacturers and retailers are important goals. But the matter is not as cut and dried as it seems. There are numerous competing interests here. Manufacturers assert a right to decide with whom they want to do business, and doctors want to protect their businesses. Consumers certainly have a right to choose their optical care providers and to benefit from competition in the contact lens marketplace. Overlaying the issue we have patient health concerns, too. This hearing will examine these arguments. I hope it will help us to determine whether the contact lens business is free and competitive, or whether some intervention is required.

More competition and less government is the ideal, and I believe in it, but occasionally it takes a nudge from people like us to remind competitors that it's their job to compete.

I look forward to the expert testimony our distinguished panel of leaders will provide today. Thank you all for your time today and welcome.

Thank you, Mr. Chairman, and I yield back.

PREPARED STATEMENT OF THE HON. ED. WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KENTUCKY

Mr. Chairman, thank you for agreeing to hold this timely hearing on an issue affecting many of my constituents.

In 2003, the Fairness to Contact Lens Consumers Act (FCLCA) was signed into law, allowing consumers greater access to their prescription records so they can more easily purchase contact lenses from third-party vendors. Under the law, a third-party vendor must confirm the validity of a prescription with the prescribing doctor before dispensing contact lenses to a patient, and a prescribing doctor has up to eight hours to respond to the inquiry. If the doctor does not respond within the allotted time, the vendor may assume the prescription is valid and proceed with the sale.

In practice, the prescription verification requirements of the FCLCA have been routinely ignored and abused by some third-party vendors. Doctors report numerous instances of third-party vendors using automated phone systems that often provide inadequate information for verifying patient prescriptions. Attempts to communicate with these phone systems are frequently met with busy signals, unattended voice mailboxes, and disconnected calls.

Other vendors make no attempt to verify prescriptions at all. In one major instance, a doctor in Texas found that 17 consecutive contact lens sales by a third-party vendor took place for his patients without any verification of his patients' prescriptions whatsoever. The Federal Trade Commission recognizes these problems, and earlier this

year issued warnings to several third-party vendors advising that their practices are illegal and deceptive to consumers.

Contact lenses are regulated medical devices requiring a valid prescription from a licensed doctor. Third-party vendors that overfill prescriptions or who do not verify that the prescriptions they are filling endanger the health and welfare of the customers they purport to serve. Completing contact lens sales regardless of a patient's medical history is an unacceptable business practice and clearly contrary to the best interest of consumers' health and well-being.

Verifying patient prescriptions requires a good-faith effort on the part of both doctors and third-party vendors. There needs to be better communication between these parties, ensuring that patients receive products that are safe and compatible with their documented medical history.

I am currently working on legislation that will create a "Patient Safety Hotline" for optometrists with patient health concerns related to a prescription verification request. A call to the hotline would suspend the transaction until the vendor addressed the specified health concern.

In addition, the bill would allow optometrists to specify to third-party vendors their preference for fax, e-mail or telephone prescription verification purposes. Vendors would then be required to attempt at least two of the three communication choices.

Thank you again for holding this hearing and for your consideration of my remarks.

MR. STEARNS. Yes, sir.

MR. GONZALEZ. Thank you very much, Mr. Chairman, and good morning to one and all. And I know you are saying attendance is not great, but let me explain when we set these hearings, we had folks scheduled for today. Seventy five percent of the Members of the House of Representative do not have their families in Washington, so along with the wonderful old adage of Harry Truman that if you want a friend in Washington, get a dog, if you want a family life, go back to the district. And that is what happens as soon as they tell us we are not going to have votes. So in the way of explanation. But please understand that your testimony is important. Obviously we have someone that is taking it down, and we can always refer to it, and we ask for a copy of the record; but your written statements are actually reviewed by staff and Members of Congress for future use. So don't think for a second that your presence here today is not important because it is. Some of the Members that are here present this morning will have to leave to catch flights and such. I hope I can say for the duration until I have another commitment.

The way I look at this particular issue is really quite simple. I hate for everything to always be one side versus another. Some think it is consumer choice versus health safety concerns. I would like to think that it is going to be consumer choice with health safety concerns. And I understand that we have different advocates here today and that is what you should be doing, but our job really is to kind of sift through it all and see if we can come up with something that really addresses legitimate

concerns that are out there. And for that, I thank you for your testimony today and I yield back.

MR. STEARNS. I thank my colleague.

With that, we will go to our witnesses. And we have Ms. Maureen Ohlhausen, Director of the Office of Policy Planning at the Federal Trade Commission, and we have Mr. Wayne Klein, Assistant Attorney General, Office of the Attorney General, State of Utah. And we have Mr. Jonathan Coon, CEO of 1-800 Contacts. We have Mr. Gregory Fryling, who is Chief Operating Officer of CooperVision, and Dr. Oliver Schein, Burton E. Grossman Professor of Ophthalmology at John Hopkins. And we have Dr. Wiley Curtis, a member of the American Optometric Association.

I thank all of you. And Ms. Ohlhausen, we appreciate your opening statement.

STATEMENTS OF MAUREEN OHLHAUSEN, DIRECTOR, OFFICE OF POLICY PLANNING, FEDERAL TRADE COMMISSION; WAYNE KLEIN, ASSISTANT ATTORNEY GENERAL, OFFICE OF THE ATTORNEY GENERAL, STATE OF UTAH; JONATHAN C. COON, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, 1-800 CONTACTS, INC.; GREGORY A. FRYLING, CHIEF OPERATING OFFICER, COOPERVISION, INC.; DR. OLIVER D. SCHEIN, M.D., M.P.H., PROFESSOR OF OPHTHALMOLOGY, JOHNS HOPKINS UNIVERSITY, ON BEHALF OF THE AMERICAN ACADEMY OF OPHTHALMOLOGY; AND DR. WILEY CURTIS, O.D., MEMBER, AMERICAN OPTOMETRIC ASSOCIATION

MS. OHLHAUSEN. Good morning. Thank you, Chairman Stearns, Ranking Member Schakowsky, and members of the subcommittee. I am Maureen Ohlhausen, Director of the Federal Trade Commission's Office of Policy Planning.

I am pleased to present the Commission's testimony on consumer protection and competition issues concerning the contact lens industry. The Commission's full testimony has been submitted for the hearing record, and my statement and any answers I give to your questions today reflect my own views and not necessarily those of the Commission.

Over the years, the Commission has engaged in a wide variety of activities concerning the eye care industry. These activities include law enforcement, rule making, business and consumer education, and advocating public policies relating to the marketing and sale of eye care goods and services.

The FTC's activities are all directed toward the same fundamental objective, the promotion of vigorous competition and informed consumer choice, thereby increasing consumer welfare.

In 2003, Congress enacted the Fairness to Contact Lens Consumers Act, which we now call FCLCA, to increase competition and computer choice in the sale of contact lenses using an approach similar to that of the eyeglasses rule which also require prescription release. To implement FCLCA, the FTC issued its Contact Lens Rule, which closely tracks the Act's provisions. Since the rule was issued, the Commission has undertaken substantial efforts to educate sellers and eye care practitioners about its requirements. The FTC staff has also issued warning letters to individual companies to alert them that they may be in violation of the rule, and request that they modify their practices as necessary to come into compliance with the law.

In appropriate circumstances, the FTC initiates investigations and takes law enforcement action against those who violate the rule. For example, in August, 2006, the Department of Justice, at the request of the FTC, filed a complaint and settlement agreement with operators of three Websites that sell contact lenses directly to consumers. We alleged that the defendants violated the Contact Lens Rule by selling lenses to consumers without first obtaining prescriptions or verifying prescriptions with the prescribing eye care practitioners. The consent decree requires the defendants to pay $40,000 in civil penalties and, among other things, prohibits them from violating the rule in the future.

When Congress passed FCLCA, it required the FTC to undertake a study to examine the strengthen of competition in the sale of prescription contact lenses, including, in particular, two contact lens distribution policies, private labeling and limited distribution, that some have argued allow prescribing eye care practitioners to lock their patients into lenses that must be purchased from them at inflated prices. The FTC study, released in February 2005, found no evidence that either of these practices was harming consumers.

Regarding private label lenses, data from the FTC study showed average prices for private label lenses to be statistically equivalent to their national name brand counterparts. As for limited distribution lenses, the study found them to be available through many distribution channels, making it unlikely that limited distribution policies are allowing retailers to raise prices.

Specifically, the Commission found that the two most popular limited distribution lenses were available to consumers at most on and offline sellers sampled, including optical chains, discount retailers such as Wal-Mart and Target, warehouse clubs, such as BJs and Sam's, and many of these outlets' Websites. As in the case of private labeling, the

Commission study found no evidence that limited distribution policies are likely to harm consumers.

Because FCLCA requires eye care practitioners to release prescriptions to patients and permit sellers to fill private label prescriptions with either brand name or other private label equivalent, it appears that eye care practitioners face significant competition in the sale of these limited distribution lenses. Moreover, warehouse clubs tend to offer lowest prices, making it even less likely that an eye care provider would be able to raise prices for a limited distribution lens. Thus, consumers who receive a prescription specifying a limited distribution lens do not appear to be forced to purchase that lens from their prescribing eye care provider, and instead have several online and offline options. Consistent with this observation, the Commission's examination of the data did not suggest that limited distribution lenses were sold at prices any higher than similar lenses that were not subject to such a distribution policy.

It is important to note that limited distribution policies, including those that limit online distribution, are common across industries, and often are intended to spur competition among rival manufacturers, which ultimately can lead to greater quality, enhanced variety, or lower prices. It is widely recognized in law and economics that placing limits on distribution can allow a manufacturer who relies on retailers to provide customer service or quality assurance efforts to compete more effectively against rival manufacturers.

Typically, therefore, a supplier's unilateral decision to restrict the distribution channels in which its product is available raises antitrust concerns only if such a restraint is likely to harm competition among rival manufacturers and if this harm outweighs any pro-competitive benefits.

As the Supreme Court has stated, "a manufacturer of course generally has a right to deal or refuse to deal with whomever it likes as long as it does so independently." At the same time, it is important to distinguish unilaterally imposed distribution restraints from those that manufacturers adopt at the behest of a group of retailers acting in concert. Joint efforts by retailers to coerce manufacturers to disadvantage discounters are a per se violation of the antitrust laws because such agreements among competitors suspend the normal give and take of the marketplace.

The Commission remains committed to promoting competition and consumer protection in the contact lens industry. We are willing to assist your subcommittee in any way that we can. Thank you.

[The prepared statement of Ms. Ohlhausen follows:]

PREPARED STATEMENT OF MAUREEN OHLHAUSEN, DIRECTOR, OFFICE OF POLICY PLANNING, FEDERAL TRADE COMMISSION

PREPARED STATEMENT OF THE FEDERAL TRADE COMMISSION

before the

SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION U.S. HOUSE OF REPRESENTATIVES

on

CONSUMER PROTECTION AND COMPETITION ISSUES CONCERNING THE CONTACT LENS INDUSTRY

September 15, 2006

I. Introduction

Chairman Stearns, Ranking Member Schakowsky, and members of the Subcommittee, I am Maureen Ohlhausen, Director of the Office of Policy Planning at the Federal Trade Commission ("Commission" or "FTC").[1] The Commission appreciates the opportunity to provide its views on consumer protection and competition issues concerning the contact lens industry, including views on the practice of contact lens manufacturers limiting the online distribution of some of their products. The FTC's mission is to promote the efficient functioning of the marketplace by enforcing the FTC Act's prohibition on unfair or deceptive acts or practices and unfair competition in or affecting commerce.[2] Pursuant to its statutory mandate, the Commission works to increase consumer choice by promoting vigorous competition. The FTC has extensive experience assessing the impact of regulation and business practices on

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[1] This written statement reflects the views of the Federal Trade Commission. My oral statements and responses to any questions you may have represent my own views, and do not necessarily reflect the views of the Commission or any individual Commissioner.

[2] Section 5 of the FTC Act, 15 U.S.C. § 45.

competition and consumers in many industries, including eyeglasses, contact lenses, and other eye care goods and services.

After providing a brief overview of the contact lens industry, this testimony will discuss the Commission's mission and its history of activity in the eye care industry, and then provide some specific comments on the impact of exclusive distribution contracts on competition and consumers.

II. The Contact Lens Marketplace

Sales of contact lenses have become a multi-billion dollar market in the United States. The most recent data indicate that nearly 36 million Americans – almost 13% of all Americans – wear contact lenses. The industry includes numerous manufacturers of contact lenses and many different channels of distribution, including eye care practitioners (*e.g.*, ophthalmologists and optometrists), national and regional optical chains, mass merchants, warehouse clubs, and mail order and Internet firms.

The contact lens market has changed significantly in recent years. In the past, contact lenses were designed to last for long periods of time and required daily removal and extensive cleaning regimens. Consumers generally purchased contact lenses from their eye care practitioners ("ECPs") after an eye examination and lens fitting, and then replaced them when their prescriptions changed or contact lenses were lost or damaged. Contact lens manufacturers had not developed methods for producing standardized contact lenses.

Beginning in the late 1980s, manufacturers began to market and sell "disposable" and "frequent replacement" soft contact lenses. These lenses are designed to be replaced daily,

weekly, or monthly. Today, replacement soft contact lenses that a patient receives pursuant to a prescription will be the same, regardless of whether the patient buys the lenses from his or her prescribing ECP or another seller.

This development of standardized soft contact lenses has facilitated the growth of sellers other than ECPs, such as Internet, mail order, and pharmacy sellers. Unlike most ECPs, these alternative sellers do not fit lenses or provide eye care services, but instead sell consumers lenses for which ECPs have already fitted the customers. These sellers provide or ship their customers standardized contact lenses that they have purchased from manufacturers in sealed boxes labeled with the relevant specifications.

III. FTC's Activities in the Eye Care Industry

Over the years, the Commission has engaged in a wide variety of activities concerning the eye care industry. These activities include law enforcement, rulemaking, business and consumer education, and advocating public policies relating to the marketing and sale of eye care goods and services. The FTC's activities are all directed toward the same fundamental objective – the promotion of vigorous competition and informed consumer choice, thereby increasing consumer welfare.

A. Law Enforcement

Law enforcement is a critical component of the Commission's activities related to eye care goods and services. First, the FTC investigates and brings law enforcement actions to address unfair or deceptive acts and practices[3] or unfair methods of competition[4] in violation of

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[3] For example, the Commission entered into consent agreements with two of the largest sellers of LASIK eye surgery services to resolve complaint allegations that they made the unsubstantiated claims that LASIK surgery would eliminate the need for glasses for life, and that

Section 5 of the FTC Act. Second, the FTC investigates and brings law enforcement actions to address violations of the Ophthalmic Practice Rules and the Contact Lens Rule. These Rules empower consumers to comparison shop among sellers of eye glasses and contact lenses, thereby promoting competition among these sellers and enhancing consumer choice.

The Commission promulgated the Ophthalmic Practice Rules ("Eyeglass Rule") in 1978 to increase competition and consumer choice in the sale of eyeglasses.[5] The Eyeglass Rule requires ECPs to provide patients automatically, at no extra cost, with a copy of their eyeglass prescriptions after completion of an eye examination. The FTC promulgated this Rule because it found that many consumers were deterred from comparison shopping for eyeglasses because they did not receive copies of their prescriptions. A recent analysis by the Commission concluded that this Rule has "facilitated comparison shopping by consumers, thereby spurring competition and leading to lower prices and more choices for consumers."[6]

In 2003, Congress enacted the Fairness to Contact Lens Consumers Act[7] ("FCLCA") to

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LASIK surgery poses significantly less risk to the ocular health of patients than wearing contact lenses or eye glasses. *LCA-Vision, Inc. d/b/a LasikPlus*, FTC Docket C-4083 (July 8, 2003) (consent agreement); *The Laser Vision Institute, LLC*, FTC Docket No. C-4084 (July 8, 2003) (consent agreement).

[4] *See, e.g.*, *Massachusetts Board of Registration in Optometry*, 110 F.T.C. 549 (1988) (Commission concluded that a state optometry board's regulations restricting advertising of price discounts, the advertisement of affiliations between optometrists and retail optical stores, and the use of testimonials and similar advertising were an unfair method of competition).

[5] 16 C.F.R. Part 456.

[6] Federal Trade Commission, "The Strength of Competition in the Sales of Rx Contact Lenses: An FTC Study," at 45 (Feb. 2005), *available at* http://www.ftc.gov/opa/2005/02/contactlens.htm.

[7] 15 U.S.C. §§ 7601-7610.

increase competition and consumer choice in the sale of contact lenses, similar to what the Eyeglass Rule had done with respect to the sale of eyeglasses. Among other things, under the FCLCA, ECPs must: (1) provide patients with a copy of their contact lens prescriptions immediately upon completion of a contact lens fitting, and (2) provide or verify contact lens prescriptions to sellers of contact lenses. The Act also states that, before providing customers with contact lenses, sellers must either obtain copies of their prescriptions or verify the information in the customers' prescriptions with their prescribing ECPs. The FCLCA does not require that sellers receive affirmative responses to their verification requests before providing lenses to customers. Instead, the Act adopts a "passive verification scheme" – it allows sellers to provide lenses to their customers if ECPs have not responded to their verification requests within eight business hours.

To implement the FCLCA, the FTC issued its Contact Lens Rule (the "Rule"), which closely tracks the Act's provisions.[8] Since the Rule was issued, the Commission has undertaken substantial efforts to educate sellers and eye care practitioners about its requirements. Coincident with issuing the Rule in the summer of 2004, the agency widely distributed consumer education materials to inform consumers of their rights, as well as business education materials to provide guidance to sellers and ECPs about how to comply with the Rule. In late 2005, the Commission issued updated business education materials to address questions that had arisen in Rule compliance, particularly questions related to telephone communications between sellers and ECPs.

In addition to these general efforts to educate sellers and ECPs about their responsibilities

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[8] 16 C.F.R. Part 315.

under the Rule, the FTC staff has issued warning letters to individual companies to alert them that they may be in violation of the Rule and request that they modify their practices as necessary to come into compliance with the law. In 2004, the FTC staff sent warning letters to ECPs who allegedly were not releasing contact lens prescriptions as the Rule requires.[9] In 2005, the FTC staff sent a warning letter to a leading contact lens seller that may have violated the Rule by not providing ECPs with a reasonable opportunity to communicate with the seller regarding verification requests.[10] Specifically, complaints received by the FTC alleged that the seller's fax lines were often busy, and, therefore, the responses of ECPs to verification requests were not getting through to the seller. Finally, in 2006, the FTC staff sent 18 warning letters to online sellers of cosmetic or colored contact lenses.[11] Most of these sellers allegedly falsely claimed that cosmetic contacts are non-prescription or that they do not require a prescription, in violation of the Rule.[12] In addition, most of them did not appear to obtain a copy of the prescription or verify the information in the prescription with ECPs as required by the Rule.

The Commission uses business education and warning letters to encourage voluntary compliance by sellers and ECPs with the Rule. Nevertheless, in appropriate circumstances, the

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[9] *See* Federal Trade Commission, "The Contact Lens Rule and the Eyeglass Rule" (Oct. 22, 2004), *available at* http://www.ftc.gov/opa/2004/10/contactlens.htm.

[10] *See* Federal Trade Commission, "Announced Actions for October 14, 2005" (Oct. 14, 2005) (announcing results of test shop to follow up on warning letters), *available at* http://www.ftc.gov/opa/2005/10/fyi0575.htm.

[11] *See* Federal Trade Commission, "FTC Staff Sends Warning Letters to Marketers of Cosmetic Contact Lenses" (June 30, 2006), *available at* http://www.ftc.gov/opa/2006/06/fyi0643.htm.

[12] In late 2005, Congress amended Section 520 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360(j), to clarify that such lenses are medical devices for which a prescription is required. *See* Pub. L. No 109-96, 119 Stat. 2119 (Nov. 9, 2005).

FTC initiates investigations and takes law enforcement action against those who violate the Rule. For example, on August 3, 2006, the Department of Justice, at the request of the FTC, filed a complaint and settlement agreement against Walsh Optical, Inc., and its owner, Kevin Walsh, in the United States District Court for the District of New Jersey.[13] The defendants operate three Web sites – www.lensworld.com, www.contactmania.com, and www.contactlensworld.com – through which they sell contact lenses directly to consumers. The FTC's complaint alleged that the defendants violated the Contact Lens Rule by selling contact lenses to consumers without first obtaining their prescriptions or verifying the prescriptions with their prescribing ECPs. The consent decree required the defendants to pay $40,000 in civil penalties and, among other things, prohibits them from violating the Rule in the future.

B. State-Imposed Restrictions on Competition from Alternative Sellers

In addition to its law enforcement role, the Commission has long studied the effects of state-imposed restrictions in the optical goods industry and advocated policies for the optical goods industry that would benefit consumers and competition.[14] In October 2002, the Commission held a public workshop to evaluate possible anticompetitive barriers to e-commerce,[15] and in March 2004, the Commission staff issued a report analyzing potential

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[13] *United States v. Walsh Optical, Inc.*, Civ. No. 06-3591 (D.N.J. Aug. 30, 2006) (consent decree entered).

[14] THE EFFECTS OF RESTRICTIONS ON ADVERTISING AND COMMERCIAL PRACTICE IN THE PROFESSION: THE CASE OF OPTOMETRY, FTC BUREAU OF ECONOMICS STAFF REPORT (1980).

[15] 67 Fed. Reg. 48,472 (2002).

barriers to Internet commerce in contact lenses ("Contact Lens Report").[16] The Contact Lens Report expressed concern that state laws and regulations may limit competition in contact lenses, raise consumer costs, and harm public health. For example, the Contact Lens Report noted that licensing requirements may insulate in-state sellers from out-of-state competition, or insulate ECPs from non-ECP sellers. Further, as noted in the report, staff found that health concerns do not appear to justify the costs imposed by these requirements.[17]

The FTC staff also has provided comments to state agencies and legislatures regarding the effects of restrictions on the sale of replacement contact lenses. For example, in March 2002, the Commission staff filed a comment before the Connecticut Board of Examiners for Opticians in a declaratory ruling proceeding on the interpretation and applicability of various statutes and regulations concerning the sale of contact lenses.[18] In that comment, Commission staff concluded that out-of-state sellers should not be subject to state licensing requirements because the possible benefit consumers might receive from increased state protection did not outweigh the likely negative effect from decreased competition. Ultimately, the Connecticut Board of Examiners decided that state law did not require out-of-state sellers to obtain a license to sell

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[16] POSSIBLE BARRIERS TO E-COMMERCE: CONTACT LENSES: A REPORT FROM THE STAFF OF THE FEDERAL TRADE COMMISSION (Mar. 29, 2004), *available at* http://www.ftc.gov/os/2004/03/040329clreportfinal.pdf.

[17] *Id.* at 3.

[18] *See* FTC Staff Comment Before the Connecticut Board of Examiners for Opticians (Mar. 27, 2002), *available at* http://www.ftc.gov/be.v020007.htm; *see also* Letter from Maureen K. Ohlhausen *et al.*, Acting Director, Office of Policy Planning to Arkansas State Representative Doug Matayo (Oct. 4, 2004) (commenting on legislative proposal that likely would have conflicted with the FCLCA's release and verification requirements), *available at* http://www.ftc.gov/os/2004/10/041008matayocomment.pdf.

contact lenses to consumers.[19]

C. Limited Distribution Policies

When Congress passed the FCLCA, it required the FTC to "undertake a study to examine the strength of competition in the sale of prescription contact lenses."[20] This study, released in February 2005, examined, among other things, two contact lens distribution policies – private labeling and limited distribution – that some have argued allow prescribing ECPs to lock their patients into lenses that must be purchased from them at inflated prices.[21] The Commission concluded that "the theory and the evidence examined do not support the conclusion that these distribution practices harm competition and consumers by allowing prescribers to lock in their patients to supracompetitively priced lenses."[22]

The first practice, "private labeling," involves an outlet selling a national name brand lens

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[19] Connecticut Board of Examiners for Opticians, *In re: Petition for Declaratory Ruling Concerning Sales of Contact Lenses*, Declaratory Ruling Memorandum of Decision (June 24, 2003).

[20] 15 U.S.C. § 7609(a). Congress directed the Commission to address the following specific issues: "1) The incidence of exclusive relationships between prescribers or sellers and contact lens manufacturers and the impact of such relationships on competition; 2) The difference between online and offline sellers of contact lenses, including price, access and availability; 3) The incidence, if any, of contact lens prescriptions that specify brand name or custom labeled contact lenses, the reasons for the incidence, and the effect on consumers and competition; 4) The impact of the FTC eyeglasses rule on competition, the nature of enforcement of the rule, and how such enforcement has impacted competition; and 5) Any other issues that have an impact on competition in the sale of prescription contact lenses." *Id.* at (1)-(5).

[21] *See* THE STRENGTH OF COMPETITION IN THE SALE OF PRESCRIPTION CONTACT LENSES: AN FTC STUDY 16-18 (Feb. 2005) ("CONTACT LENS STUDY"), *available at* http://www.ftc.gov/reports/contactlens/050214contactlensrpt.pdf.

[22] *Id.* at 33.

under a different name, sometimes unique to that seller. Wal-Mart, Pearle Vision, Target, and LensCrafters, for example, offer OSI's Biomedics55 lens under the names UltraFlex, Polysoft, Target55, and Versaflex, respectively. In some instances the term private label may be a misnomer, however, because a specific private label brand may be available at multiple outlets. For example, the FTC survey discovered that the UltraFlex private label is available at Wal-Mart, BJ's, Sam's Club, and America's Best. Thus, a private label brand may not be exclusive to a seller in the way that a generic store brand would be.

The FTC study found no evidence that private labeling is likely to harm consumers. Data from the price survey showed average prices for private label lenses to be statistically equivalent to their national name brand counterparts.[23] Further, the FCLCA and the FTC's Contact Lens Rule mandate that ECPs release prescriptions to patients and allow competing retailers to fill private label prescriptions with either national brand-name or private label equivalents.[24] These provisions allow a customer who receives a private label prescription to take it to competing retailers that sell the same lens under either the national brand name or equivalent private label.

The second practice studied involves certain contact lens manufacturers' decisions to limit the online distribution of some of their lenses. For example, some manufacturers limit the distribution of their lenses to outlets that provide eye care services, which necessarily precludes distribution through pure online sellers like 1-800 Contacts or Coastal Contacts.[25] As in the case

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[23] *Id.* at 24-26.

[24] 15 U.S.C. § 7609(4)(f); 16 C.F.R. § 315.2 (A)(8) ("[i]n the case of a private label contact lens, [a contact lens prescription must contain] the name of the manufacturer, trade name of the private label brand, and, if applicable, trade name of equivalent brand name.")

[25] *See* CONTACT LENS STUDY at 15-16.

of private labeling, the Commission's study found no evidence that limited distribution policies are likely to harm consumers.

Limited distribution lenses appear still to be available through many distribution channels, making it unlikely that the limited distribution is allowing retailers to raise prices. The study examined two lenses produced by CooperVision, Proclear Compatible and Biomedics55.[26] Although Proclear and Biomedics55 are not available to online sellers through normal distribution channels, the Commission found them to be available to consumers at most online and offline sellers sampled, including discount retailers, warehouse clubs, and these outlets' Web sites. For example, Biomedics55 – or its private label equivalent – is available from all offline and nearly all online outlets sampled, including all optical chains sampled: Wal-Mart, Sam's Club, BJ's, Target, and Sears. These lenses also are sold on Wal-Mart's, BJ's, and America's Best's Web sites. Proclear lenses were found at 88 percent of online sellers' sites and were available at all but three offline stores (Wal-Mart, Sam's Club, and Pearle), including Target and BJ's.[27] Given that ECPs must release prescriptions to patients under the FCLCA, it appears that they face significant competition in the sale of these limited distribution lenses. Moreover, warehouse clubs like BJ's tend to offer the lowest prices, making it even less likely than an ECP

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[26] CooperVision acquired Ocular Sciences, which produced Biomedics55, in early 2005. CooperVision produces at least eight brands of lenses and several types of lenses within each brand. To the Commission's knowledge, of CooperVision's lenses, only Biomedics and Proclear Compatibles are subject to limited distribution policies. At the time of the Contact Lens Study, Ocular Sciences produced Hydrogenics, which was subject to a limited distribution policy as well. However, this lens does not appear as a lens currently produced by CooperVision. *See* CooperVision Web Site, *at* http://www.coopervision.com/us/patient_browsebyname.asp.

[27] *See* CONTACT LENS STUDY at 39. A recent search shows that Proclear lenses are also available at Wal-Mart's Web site.

would be able to raise prices for a limited distribution lens.[28] Thus, consumers who receive a prescription specifying a limited distribution lens are not forced to purchase that lens from their prescribing ECPs and instead appear to have several online and offline options. Consistent with this observation, the Commission's examination of the data did not suggest that limited distribution lenses were sold at prices any higher than similar lenses that are not subject to limited distribution policies.

It is important to note that limited distribution policies – including those that limit online distribution – are common across industries.[29] Limits on distribution can allow a manufacturer to compete more effectively with rival manufacturers.[30] For example, a manufacturer may depend on the retailer to educate customers about the merits of a particular product. A retailer will be reluctant to expend those resources, however, if consumers can take this information and purchase the good at a lower price from a discounter that charges less because it does not provide any additional services. Additionally, a manufacturer may want its brand associated only with a certain type of retailer to maintain a reputation for quality or may require retailers to perform certain tasks to maintain a level of quality that consumers associate with the manufacturer's

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[28] *See id.* at 43.

[29] *See, e.g..,*Dennis W. Carlton & Judith A. Chevalier, *Free Riding and Sales Strategies for the Internet*, 49 J. INDUS. ECON. 441 (2001) (examining fragrance, DVD, and refrigerator manufacturers' policies regarding online distribution of their products); Robert H. Gertner & Robert S. Stillman, *Vertical Integration Strategies in the Apparel Industry*, 49 J. INDUS. ECON. 417, 428-30 (2001) (describing various apparel manufacturers' online selling policies that are designed to avoid conflict with offline retailers' interests).

[30] *See Cont'l T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 55 (1977) (noting that exclusive territories have the potential to "induce competent and aggressive retailers to make the kind of investment of capital and labor that is often required in the distribution of products unknown to the consumer").

brand. Limited distribution policies are a means by which a manufacturer can compensate retailers for providing such services that consumers value.[31]

When limited distribution makes a manufacturer a more effective competitor against its rivals, that competition can lead to better quality or more variety, all of which benefits consumers. Typically, therefore, a supplier's unilateral decision to restrict the distribution channels in which its product is available raises antitrust concerns only if such a restraint is likely to harm competition among rival manufacturers and that this harm outweighs any procompetitive benefits.[32] A restriction on distribution can harm consumers, for example, if the restraint lessens competition in a relevant market without providing any off-setting benefits like increased

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[31] Ocular Science, producer of the limited distribution lens Biomedics55, and since purchased by CooperVision, stated in its public comment for the CONTACT LENS STUDY that it relied on a limited distribution policy to "encourage eye care professionals and chains to promote its products." CONTACT LENS STUDY at 32. Due to a lack of data, the CONTACT LENS STUDY did not reach any conclusions regarding the role that limited distribution policies played in providing ECPs incentives to engage in promotional activities. *See id.* at 33.

[32] Non-price vertical restraints such as limited distribution policies are judged under the rule of reason, which requires a plaintiff to show that the agreement at issue is likely to have "genuine adverse effects on competition." *Federal Trade Comm'n v. Indiana Fed'n of Dentists*, 476 U.S. 447, 460 (1986). *See also Virgin Atl. Airways, Ltd. v. British Airways PLC*, 257 F.3d 256, 264 (2d Cir. 2001) (plaintiff is required to show that the agreements in question "had an actual adverse effect on competition as a whole in the relevant market"); *Ezzo's Investments, Inc. v. Royal Beauty Supply, Inc.*, 243 F.3d 980, 988 (6th Cir. 2001) (affirming summary judgment for defendant where plaintiff failed to present evidence that defendant had "sufficient market power to affect competition within the relevant market," or that defendant's restrictive distribution polices "had an effect on interbrand competition"); *Generac Corp. v. Caterpillar Inc.*, 172 F.3d 971, 977 (7th Cir. 1999) (to prevail in a rule of reason challenge to territorial restrictions on distribution, a plaintiff "must demonstrate, at a minimum, that its agreement with Caterpillar has an anticompetitive, welfare-reducing effect that is not overcome by any pro-competitive, welfare-enhancing consequences of the agreement"). For challenges to a dominant firm's vertical restraints under section 2 of the Sherman Act, a plaintiff must first show a causal link between the monopolist's actions and its market power. That is, the monopolist's conduct must "reasonably appear capable of making a significant contribution to creating or maintaining monopoly power." *U.S. v. Microsoft*, 253 F.3d 34, 79 (D.C. Cir. 2001) (quoting P. AREEDA & H. HOVENKAMP, III ANTITRUST LAW ¶ 651f (2d ed. 2002)).

information or quality. Indeed, as the Supreme Court has stated, "[a] manufacturer of course generally has a right to deal, or refuse to deal, with whomever it likes as long as it does so independently."[33] At the same time, it is important to distinguish unilaterally imposed distribution restraints from those that manufacturers adopt at the behest of a group of retailers acting in concert. Joint efforts by retailers to coerce manufacturers to disadvantage discounters are a *per se* violation of the antitrust laws because such agreements among competitors suspend the normal give and take of the marketplace.[34]

IV. Conclusion

The FCLCA and the Contact Lens Rule are intended to promote competition and consumer choice in the sale of contact lenses. The Commission will continue to engage in educational and law enforcement activities to encourage compliance with the law to assure that consumers obtain the benefits Congress intended the FCLCA to confer. Limited distribution policies are common in the U.S. market and can provide important benefits to consumers. The FTC's Congressionally-mandated study of the contact lens industry provided no indication that limited distribution policies in the contact lens industry harm consumers.

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[33] *Monsanto Co. v. Spray-Rite Service Co.*, 465 U.S. 752, 761 (1984).

[34] *See, e.g., U.S. v. General Motors Corp.*, 384 U.S. 127 (1966); *In re Disposable Contact Lens Antitrust Litigation*, MDL 1030, 2001 WL 493244 (M.D. Fla. Feb. 8, 2001); *In re Fair Allocation System, Inc.*, FTC Docket No. C-3832 (1998).

MR. STEARNS. I thank the gentlelady.

Mr. Klein.

MR. KLEIN. Thank you, Mr. Chairman.

My name is Wayne Klein, and I represent the Utah Attorney General today. He, unfortunately, was delayed in a flight from overseas and could not be here, and so I ask that my written statement, along with his statement, be included in the record.

MR. STEARNS. By unanimous consent, so ordered.

MR. KLEIN. Helping consumers maximize the value of their contact lens purchases is important both to buyers of the lenses and the creation of a competitive market for the sale of replacement lenses.

I thank this committee for adopting the Fairness to Contact Lens Consumers Act in 2003. I am here to say that more needs to be done to promote consumer choice and to protect buyers of replacement contact lenses. Some competition is the best means of delivering the highest number of goods to consumers at the lowest price, while rewarding innovation and high quality. Removing artificial restraints on competition and computer choice maximizes the number of sellers.

Ten years ago, competition was restrained by collusion among contact lens manufacturers and optometric trade associations who forced consumers to purchase replacement contact lenses from their prescribing optometrist rather than from cheaper suppliers. Consumers paid 20 to 40 percent more. That problem was solved by the Fairness to Contact Lens Consumers Act and the injunction entered in the litigation by the Attorney General's Office. Now we face a new threat.

It is a shame that health care professionals, manufacturers, and their associations are so afraid of competition that they engage in artifices to deny choices to consumers and put their own financial interests ahead of patient interests. Some contact lens manufacturers have grown rapidly by promising optometrists that the optometrists can increase their profits by forcing consumers to purchase high price lenses available only from the optometrist that writes the prescription. This hijacking of consumer interest is possible only because of two factors that are unique to the contact lens industry. First, contact lenses can be sold only by prescription, and that prescription must identify the contact lens by brand name. Second, optometrists not only treat patients, they also sell lenses to those patients. Unlike physicians prescribing medications, optometrists sell what they prescribe. These two factors permit optometrists' business interests to override the optometrist's duty to serve the interest of their patients.

Promoting consumer choice in the health care industry is exceedingly tricky. The difficulty lies in separating medical decisions from the financial decisions. If a way can be found to divorce those two categories from each other, it is possible to maximize the consumer welfare, while leaving medical decisions to health care providers. We want to prevent health care providers from disguising their economic interests as health care concerns. This separation of economic and medical influences can be accomplished in the contact lens market, and this involves three steps: One, separating the demand for prescriptions from the demand for replacement lenses; second, eliminating optometrists' ability to tie the eye exam to the purchase of replacement

contact lenses; third, increasing competition for the sale of replacement lenses. The larger the number of sellers, the lower the prices that will be offered to consumers.

This solution does not limit an optometrist's ability to prescribe the product that is best for the patient. What it does do is limit the optometrist's ability to charge his patient supra competitive prices for a product that is available only from that practitioner. The best way to ensure that an optometrist truly believes that one particular brand is the best product for a patient is to let that patient buy additional lenses from other sellers.

The legislation proposed, H.R. 5762, is a skillful device to separate the medical and financial influences that affect a patient's purchase of replacement lenses. Optometrists would remain free to sell what they prescribe, but it would not be able to prescribe what they alone sell. The bill would increase competition and consumer choice in three important ways: One, increase competition between manufacturers of contact lenses; two, increase competition between prescribers of contact lenses; and, three, increase competition between contact lens sellers who do not prescribe lenses and contact lens prescribers who both prescribe and sell lenses.

Antitrust enforcers seek to eliminate artificial influences that restrain competitive market forces. This bill would accomplish that goal in a manner that would directly benefit and substantially benefit millions of consumers.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Klein follows:]

PREPARED STATEMENT OF WAYNE KLEIN, ASSISTANT ATTORNEY GENERAL, OFFICE OF THE ATTORNEY GENERAL, STATE OF UTAH

My name is Wayne Klein. I am a special Assistant Attorney General prosecuting antitrust violations for the State of Utah. I appreciate the opportunity to testify here today on H.R. 5762. Helping consumers maximize the value of their contact lens purchases is important both to buyers of lenses and to the creation of a competitive market for the sale of replacement lenses. This Subcommittee is familiar with the anticompetitive and abusive practices that have been prevalent in this industry. Thank you for adopting the Fairness to Contact Lens Consumers Act in 2002.

This topic has consumed many years of my professional life as an antitrust enforcer. First was the six-year litigation against the then-dominant contact lens manufacturers. Utah was one of 32 states that sued contact lens manufacturers and others alleging conspiracies to prevent consumers from obtaining prescriptions and conspiracies to prevent discount suppliers of replacement contact lenses from obtaining lenses to sell.[1]

[1] *In re Disposable Contact Lens Antitrust Litigation*, MDL 1030 (M.D. Fla). Additional information about that enforcement case can be found in the testimony of Robert L. Hubbard before this Subcommittee on September 9, 2001 (testifying in support of the Fairness to Contact Lens Consumers Act).

Second was our support for passage of the Fairness to Contact Lens Consumers Act in 2003. Third, in 2004, the Utah Attorney General submitted comments to the Federal Trade Commission on behalf of 31 states urging improvements to the proposed Contact Lens Rule. The FTC adopted our recommendations. Fourth was helping draft the Utah Contact Lens Consumer Protection Act, which is a forerunner to H.R. 5762.

I am here to say that more needs to be done to promote consumer choice and to protect buyers of replacement contact lenses.

Antitrust Laws and Anticompetitive Conduct by Sellers of Contact Lenses

The antitrust laws, often referred to as the Magna Carta of the free enterprise system, are designed to maximize consumer welfare and promote consumer choice. Strong competition is the best means of delivering the highest number of goods to consumers at the lowest prices while rewarding innovation and high quality. Removing artificial restraints on competition and consumer choice maximizes the number of sellers.

Ten years ago, competition was restrained by collusion among the contact lens manufacturers and optometric trade associations who forced consumers to purchase all replacement contact lenses from the prescribing optometrist rather than from cheaper mail-order suppliers. The result was that consumers paid 20-40% more than the competitive price for replacement lenses. That problem was solved by the Fairness to Contact Lens Consumers Act and the injunction entered against the defendants in the states' enforcement action.

Now we face a new threat. It is a shame that health care practitioners, manufacturers, and their associations are so afraid of competition that they engage in artifices to deny choices to consumers and put their own financial interests ahead of patient interests. Some contact lens manufacturers have grown rapidly by promising optometrists that they can increase their profits by forcing consumers to purchase high-priced lenses available only from the optometrist that writes the prescription.

This hijacking of consumer interest is possible only because of two factors that are unique to the contact lens industry. First: contact lenses can be sold only by prescription. That prescription must identify the contact lens by brand name; no substitutions are allowed or generic equivalents. Second: optometrists not only treat patients, they also sell lenses to those patients. Unlike physicians prescribing medications, optometrists sell what they prescribe.[2] The combination of these two factors permits optometrists' business interests to distort the optometrists' duty to serve the interests of their patients. In that situation, the optometrist can charge whatever price the optometrist chooses. This is the antithesis of consumer choice.

Consumer Welfare, Patient Health, and Improper Financial Motivations

Applying the antitrust laws in the health care industry is exceedingly tricky. The difficulty lies in separating the medical decisions from the financial ones. If a way can be found to divorce those two categories from each other, it is possible to use the antitrust laws to maximize the consumer decisions while leaving the medical decisions to the health care providers. We seek to maximize the economic benefits of competition without negatively affecting the *legitimate* health-related decisions. This principle also can be stated in the converse: we seek to prevent health care providers from disguising their economic interests as health care concerns. This concept was stated well in a June 2006 letter from the American Optometric Association to the contact lens manufacturer CooperVision. The letter is attached.

We are very fortunate that this separation of economic and medical influences can be accomplished in the contact lens market. This involves three steps:

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[2] Some research has indicated that the average eye care provider earns more income from the sale of contact lenses than from providing eye examination services.

1. Separating the *demand* for prescriptions from the demand for replacement contact lenses.
2. Eliminating an optometrist's ability to tie eye examinations to the purchase of replacement contact lenses. An optometrist remains free to do both: provide eye examinations and sell lenses. But the optometrist should not be able to force a customer to buy both products from the optometrist.
3. Increasing competition for the sale of replacement lenses. Once a patient is freed from the compulsion of buying lenses only from the examining optometrist, all sellers of those lenses can compete for the customer's business. The larger the number of sellers, the lower the prices that will be offered to consumers.

Health Care Concerns Are Protected

This solution does not limit an optometrist's ability to prescribe the product that is best for the patient. What it does do is limit an optometrist's ability to charge his patient supracompetitive prices for a product available only from that optometrist. Under the Act, an optometrist can prescribe any contact lens brand, so long as the manufacturer of that lens makes that brand available to a reasonable number of other sellers of replacement contact lenses. The best way to ensure that an optometrist truly believes that one particular brand is the best product for a patient is to empower that patient with the ability to buy additional lenses from other sellers – who may compete with the examining optometrist.

Competitive Markets May Increase Health Benefits

In the antitrust conspiracies of the last decade, sellers made the false claim that buying replacement lenses from alternative channels raised the health risks to patients. No evidence was ever presented in support of that claim and the defendants agreed not to make that assertion absent scientific evidence of health risks. State antitrust enforcers believe that lower prices and greater convenience for patients will actually increase the likelihood that patients will replace their lenses at the frequency recommended by their optometrists.

Summary

This legislation is a skillful device to separate the medical and financial influences that affect a patient's purchase of replacement contact lenses. Optometrists would remain free to sell what they prescribe, but they would not be able to prescribe what they alone sell. The bill would increase competition and consumer choice in three important ways:

1. Increased competition between manufacturers of contact lenses;
2. Increased competition between prescribers of contact lenses (optometrists); and
3. Increased competition between contact lens sellers who do not prescribe lenses and contact lens prescribers who prescribe and sell lenses.

Antitrust enforcers seek to eliminate artificial influences that restrain competitive market forces. This bill accomplishes that goal in a manner that will directly and substantially benefit millions of consumers. I urge this Subcommittee to push adoption of this legislation.

[The statement of Mr. Shurtleff submitted for the record follows:]

Mr. Chairman, and Members of the Subcommittee, my name is Mark Shurtleff and I am the Attorney General of Utah. I appreciate the opportunity to appear before you today on these important issues.

For many years, the state attorneys general have fought to provide consumers with lower prices and more choices when purchasing contact lenses. In the 1990s, a majority

of attorneys general sued the American Optometric Association (AOA), the Contact Lens Association of Ophthalmology (CLAO), and the largest contact lens manufacturers for colluding to restrict competition.

Many of these same attorneys general strongly supported the Fairness to Contact Lens Consumers Act (FCLCA), a law that gives consumers a right to their contact lens prescription and the freedom to choose where to buy their lenses.

As part of our long-standing efforts to protect contact lens wearers, the attorneys general strongly support H.R. 5762. This legislation is necessary to end a practice that threatens competition, threatens ocular health, and threatens to undermine the FCLCA.

Certain manufacturers are limiting distribution of their contact lenses solely to eye doctors. This practice is designed to lock consumers into purchasing contact lenses from the eye doctor writing the prescription.

The so-called "doctors only" marketing scheme puts the eye doctor's profit motive ahead of patient health. It is designed to insulate eye doctors from the increased competition the FCLCA intended to spur and to limit consumer choice.

This same anti-consumer, anti-competitive practice was the subject of the multi-state litigation I previously referenced. The central issue in that case was the manufacturers' refusal to sell contact lenses to retailers not affiliated with an eye doctor.

The attorneys general believe manufacturers engaged in the "doctors only" marketing scheme to entice eye doctors, who also sell the lenses they prescribe, to write prescriptions for restricted lenses. In their dual role as both prescriber and retailer, eye doctors have an inherent conflict of interest which makes them more likely to prescribe lenses that restrict competition and maximize profits.

During nearly seven years of litigation, over 200 depositions, 45 motions for summary judgment, a docket sheet with over 1,400 entries and five weeks of trial before a jury, no evidence surfaced to demonstrate any consumer benefit resulting from limiting distribution of contact lenses only to eye doctors. In fact, the evidence indicated that "doctors only" lenses run counter to the health interests of consumers. Easier access to, and lower prices for, contact lenses encourage patients to replace their lenses more frequently.

To settle this litigation, the named manufacturers agreed to sell their lenses in a commercially reasonable and non-discriminatory manner to mail order, Internet, pharmacies, and other retailers not affiliated with an eye doctor. With these consent decrees in force, competition has flourished and consumers have benefited from lower prices and more choices.

While these consent decrees were a significant victory for consumers, litigation alone cannot address all threats to competition in the contact lens market. Litigation is particularly ineffective in addressing the fundamental structural problem in the contact lens industry – doctors selling the lenses they prescribe.

Congress attempted to regulate this inherent conflict of interest in passing the FCLCA. However, the competitive and consumer protection benefits of the FCLCA are currently at risk.

Since passage of the FCLCA, certain manufacturers have engaged in an aggressive effort to entice eye doctors to prescribe patients lenses only available at the doctor's own store. The attorneys general are concerned that, unless *all* manufacturers abandon these restrictive distribution policies, the effect will be to harm consumers. Consumers will pay more for contact lenses and may suffer adverse health consequences if higher prices cause them to replace lenses less frequently than recommended.

Mr. Chairman, H.R. 5762 is necessary to ensure that all contact lens wearers enjoy the benefits of the FCLCA and the attorneys general litigation. The legislation effectively codifies the consent decrees to prevent manufacturers from engaging in an anti-competitive practice. This will advance the public interest by promoting competition and patient safety.

You will likely hear today that H.R. 5762 will compromise patient health. This argument is baseless, and one more example of the false health claims that the optometric community has made repeatedly over the years.

It bears highlighting that, in addition to suing the contact lens manufacturers, the attorneys general also sued the national associations of optometry and ophthalmology – the same groups testifying here today. Optometry and ophthalmology settled the attorneys general action by paying fines and agreeing not to make claims that consumers could suffer adverse health events if they did not buy contact lenses from their eye doctor.

Specifically, optometry and ophthalmology agree that they:

- (a) will not ask or encourage any contact lens manufacturer to refuse to sell contact lenses to any channel of trade;
- (b) will not make an agreement with any manufacturer to restrict the supply of contact lenses to any channel of trade;
- (c) will resist any invitation by any contact lens manufacturer to enlist the eye doctor's aid in enforcing any manufacturer's distribution policy refusing to sell contact lenses to any channel of trade; and
- (d) will not represent directly or indirectly that increased eye health risk is inherent in the distribution of replacement disposable contact lenses by mail order, or pharmacy or drug stores.

I would like to submit these settlement agreements for the record.

Mr. Chairman, in conclusion, Congress should finish the job it started in passing the FCLCA. H.R. 5762 will ensure that America's 36 million contact lens wearers have the freedom to purchase contact lenses from their chosen supplier, regardless of whether that supplier is affiliated with an eye doctor.

Thank you for considering these views. I would be happy to answer any questions that Members of the Subcommittee may have for me.

MR. STEARNS. Thank you.

Mr. Coon, welcome.

MR. COON. Thank you, Mr. Chairman. My name is Jonathan Coon. I am the CEO of 1-800 Contacts. I started the business in college in 1992, shortly after I began wearing contact lenses. I just felt like someone could offer a better price and better service than I experienced when I got my contact lenses, and as it turns out, I wasn't alone. In the last 14 years we have shipped 15 million orders to more than 5 million customers.

In passing the Fairness to Contact Lens Consumers Act in 2003, this committee clearly intended that prescriptions be more than just a piece of paper. The report this committee filed with the FCLCA read, and I quote, "the consumer's right to a copy of their contact lens prescription means nothing unless consumers can fill that prescription at the business of their choice." And again, that is the report this committee filed with the FCLCA.

Unfortunately, some manufacturers are offering doctors a way to give patients a prescription, but prevent them from buying from the business of their choice. The best illustration of this is the ads that

promote the practice. These are trade ads that are focused at doctors who are supposed to be focused on the health interests of their patient. Clearly this is an intent and effort to get around the release of a prescription. This is an ad on the left paid for by a company called Ocular Sciences, which is now owned by CooperVision. It says, quote, "we would get calls for patients from 1-800 Contacts asking us for their prescription; I wanted to use another strategy to prevent that from happening." So the strategy best described in another ad, "a lens that cannot be shopped around." It is interesting that a doctor would be interested in a lens that cannot be shopped around, but that is because they not only prescribe lenses, they also want to sell them. Another ad is even more explicit. It says since ProClear lenses are only available through your practice, you will get what you are looking for, increased patient loyalty and greater profitability. And that ad bears the headline, "Let's see, you will make more money." And again, that ad is directed to doctors. There is a new entrant that has entered this market recently, and they have adopted the same strategy. In fact, in the last 5 years, no new manufacturer has entered this market with anything other than a purely doctors-only strategy.

The intent of Congress and doctors-only lenses are clearly at odds with each other. The purpose of the law was to allow consumers to choose; the purpose of this practice is to deny them that choice. This doesn't happen with drugs. No one goes to Walgreen's only to find out they can't get their prescription filled because the doctor prescribed something that only the doctor can sell. This committee got it right in the report language, "the prescription means nothing if the patient can't fill it at the business of their choice."

In granting consumers the right to choose where they purchase, Congress was also very clear that third party sellers must verify prescriptions, wait 8 hours to hear from the doctor, cancel an order if the eye doctor tells them the prescription is invalid.

Verification is the single most important thing our company does. Since the law went into effect in early 2004, we have processed and verified prescriptions for 5 million orders. We have canceled 861,000 of those orders. An average order is around a hundred dollars. A single violation of the FCLCA bears a fine of $11,000. There is nothing to be gained by anything less than full and unconditional compliance with the Act.

We employ 50 people in our verification department and have made substantial investment in redundant phone systems, databases, and hardware. We keep detailed records of every verification and every response from the doctor. We go beyond what is required by the law and beyond what is required by the FTC rule. That is why we are able to

respond this morning with the facts about allegations that I learned for the first time last night as I read Dr. Curtis' written testimony.

Dr. Curtis claims that 1-800 Contacts sold lenses with no verification or contact with his office on 17 of the 18 orders he supposedly tracked. We keep detailed records and recordings of every single order and every interaction with the doctor. Our records with Dr. Curtis' office show that in the last 12 months we have received 117 orders from Dr. Curtis' patients. We have made 192 phone calls to Dr. Curtis' office and sent 3 faxes. We spent a total of 8 hours and 32 minutes on the phone with his staff. For each of these 192 phone calls we have a separate digital recording of the person in Dr. Curtis' office answering the phone, so we know who we spoke with.

After navigating Dr. Curtis' automated phone system that answered most of our calls, our agents spoke predominantly with Gail, Kim, Lori, and Liz. I ask to submit for the record a log of all of our communications with Dr. Curtis' office for the last 12 months.

MR. STEARNS. By unanimous consent, so ordered.

[The information follows:]

Mr. Chairman and Members of the Subcommittee:

At last Friday's hearing, I asked to submit for the record copies of our verification history with Dr. Curtis' office and was granted permission to do so. Please find attached copies of our system logs as well as letters from Verizon and Electric Lightwave reaffirming all our calls to Dr. Curtis' office for the last 12 months.

The attached system log includes an invoice number for each order to make it easy to audit and verify should Dr. Curtis provide information that would allow us to identify the 17 orders that he alleged were filled without any calls or faxes to his office. Note that the attached system log also includes an indication of whether or not a call resulted in a complete verification request – meaning that all the information required by the FCLCA was successfully communicated (customer name, lens parameters, business hours, etc).

All 117 of the 117 orders we received in the last 12 months from Dr. Curtis' patients received a successful verification request. In addition to these records, we have digital audio recordings of each call. Dr. Curtis' staff typically greeted our calls using their name, so it is also possible to identify which member of Dr. Curtis' staff received each call.

Our records and call recordings could help Dr. Curtis identify if any one member of his staff is responsible for his misunderstanding about our verification history with his office. Of course, this would require Dr. Curtis or the AOA provide any information (names or dates) that would identify the 17 orders which they allege were filled without verification – which they have refused to do.

Sincerely,

Jonathan Coon
CEO, 1-800 CONTACTS

Verification History - Vision Source / Wiley Curtis OD

1334 East Pioneer Parkway

Arlington, TX 76010
(817) 461-4453

August 01, 2005 - August 31, 2006

Calls were answered by Kim, Lori, Gayle, Jessica, Liz, Melissa, Robyn

Call Record Report	Call Record Duration	Order Number	Date & Time of Order	Verification Date & Time	Verification Successful Y/N	Call Duration		Comments
						Minutes	Seconds	
n/a		20855723	2/8/06 9:16 PM	N/A	N/A			Account had a correct prescription on file, no verification call was made.
n/a		19787900	9/12/05 12:26 PM	N/A	N/A			Customer faxed in Rx.
n/a		19927491	9/30/05 4:35 PM	N/A	N/A			Order deleted by CSR.
n/a		20266419	11/17/05 7:17 AM	N/A	N/A			Customer faxed in Rx.
n/a		20406458	12/7/05 6:02 PM	N/A	N/A			Customer faxed in Rx.
Verizon	0.6	22509079	8/30/06 12:00 AM	8/30/06 11:42 AM	No	1	9	
Verizon	0.9	22509079	8/30/06 12:00 AM	8/30/06 11:43 AM	No	1	19	
Verizon	1.9	22509079	8/30/06 12:00 AM	8/30/2006 11:45AM & 11:45:00 AM	No	4	31	
Verizon	3.1	22509079	8/30/06 12:00 AM	8/30/2006 11:46AM & 11:47:00 AM	Yes	0	42	
Verizon	2.2	22467667	8/24/06 3:44 PM	8/24/06 3:45 AM	Yes	1	2	This was an RMA Order for wrong power. This would have been corrected on the original order had the Doctor responded and corrected the RX
Verizon	1.6	22440384	8/21/06 3:47 AM	8/21/06 3:52 AM	No	2	21	
Verizon	1.3	22440384	8/21/06 3:47 AM	8/21/06 3:54 PM	No	2	55	
Verizon	2.8	22440384	8/21/06 3:47 AM	8/21/06 3:55 PM	Yes	1	22	
Verizon	0.9	22391102	8/15/06 8:54 AM	8/15/06 9:50 AM	No	1	37	
Verizon	2.2	22391102	8/15/06 8:54 AM	8/15/06 9:51 AM	Yes	2	17	
Verizon	3.1	22296633	8/2/06 1:54 PM	8/2/06 2:00 PM	Yes	1	4	
Verizon	2.2	22280965	7/31/06 8:30 PM	8/1/06 7:30 AM	Yes	4	41	
Verizon	2.8	22261898	7/29/06 2:08 AM	7/29/06 8:19 AM	Yes	2	24	
Verizon	2.5	22257398	7/28/06 11:19 AM	7/28/06 11:20 AM	No	2	57	
Verizon	2.5	22257398	7/28/06 11:19 AM	7/28/06 11:23 AM	Yes	2	37	
Verizon	1.2	22249547	7/27/06 11:12 AM	7/27/06 11:53 AM	No	2	40	
Verizon	2.1	22249547	7/27/06 11:12 AM	7/27/06 11:55 AM	Yes	2	10	
Verizon	1.7	22249057	7/27/06 10:25 AM	7/27/06 10:25 AM	No	1	21	This order was deleted and replaced to give an additional discount. The order was replaced and went through verification again.
Verizon	2.1	22249057	7/27/06 10:25 AM	7/27/06 10:27 AM	Yes	2	15	
Verizon	2.1	22241996	7/26/06 12:32 PM	7/26/06 12:33 PM	Yes	1	53	
Verizon	2.3	22225906	7/24/06 4:57 PM	7/24/06 5:28 PM	Yes	2	12	Two Patients on same order
Verizon	2.3	22225906	7/24/06 4:57 PM	7/24/06 5:30 PM	Yes	2	25	Two Patients on same order
Verizon	3.3	22140829	7/13/06 11:00 AM	7/13/06 11:00 AM	Yes	2	29	
Verizon	0.6	22109064	7/10/06 7:24 AM	7/10/06 7:56 AM	No	3	17	
Verizon	1.8	22109064	7/10/06 7:24 AM	7/10/06 7:57 AM	No	2	56	
Verizon	2.9	22109064	7/10/06 7:24 AM	7/10/06 8:06 AM	Yes	1	51	
Verizon	2.3	22062745	7/3/06 10:26 AM	7/3/06 1:50 PM	Yes	0	43	
Verizon	1.4	22049651	6/30/06 2:56 PM	6/30/06 3:12 PM	No	2	49	
Verizon	3.5	22049651	6/30/06 2:56 PM	6/30/06 3:14 PM	Yes	3	39	
Verizon	2.5	22018069	6/26/06 10:44 PM	6/27/06 9:14 AM	Yes	1	39	
Verizon	2.2	21996167	6/25/06 1:54 PM	6/23/06 2:28 PM	Yes	2	40	
Verizon	2.1	21996366	6/23/06 1:55 PM	6/23/06 1:59 PM	Yes	2	21	

Verizon	0.8	21996167	6/23/06 1:54 PM	6/23/06 1:57 PM	No	2	10	
Verizon	0.4	21996167	6/24/06 1:54 PM	6/23/06 1:58 PM	No	0	33	
Verizon	2.6	21942031	6/16/06 6:02 PM	6/17/06 7:32 AM	Yes	0	57	
Verizon	4.7	21808170	5/30/06 10:00 PM	5/31/06 8:22 AM	No	2	40	
n/a	0.04	21766756	5/24/06 11:56 AM	5/24/06 11:57 AM	No	4	49	
Verizon	2.3	21766756	5/24/06 11:56 AM	5/24/06 12:05 PM	Yes	2	25	
Verizon	5.4	21729413	5/19/06 8:20 AM	5/19/06 8:20 AM	Yes	0	3	Short call- does not show up on Verizon's call records.
Verizon	1.3	21713498	5/17/06 9:15 AM	5/17/06 9:25 AM	No	5	28	
Verizon	3.1	21713498	5/17/06 9:15 AM	5/17/06 9:30 AM	Yes	3	14	
Verizon	2.1	21687067	5/13/06 1:35 PM	5/13/06 2:37 PM	Yes	1	22	
Verizon	2.6	21648593	5/8/06 2:09 PM	5/8/06 2:50 PM	Yes	2	9	
Verizon	3.2	21632118	5/5/06 3:29 PM	5/5/06 3:29 PM	Yes	2	42	
Verizon	3.1	21584932	4/29/06 6:41 PM	4/29/06 6:53 PM	Yes	3	30	
Verizon	2.3	21567535	4/26/06 8:45 PM	4/27/06 9:50 AM	Yes	3	14	
Verizon	1.1	21553597	4/25/06 1:58 PM	4/25/06 1:59 PM	No	2	26	
Verizon	1.9	21553597	4/25/06 1:58 PM	4/25/2006 2:15PM & 2:16:44 PM	No	3	41	
Verizon	3.7	21553597	4/25/06 1:58 PM	4/25/06 2:48 PM	Yes	2	8	
Verizon	1.3	21549898	4/25/06 8:53 AM	4/25/06 8:55 AM	No	1	9	
Verizon	1.3	21549898	4/25/06 8:53 AM	4/25/06 8:53 AM	No	1	24	
Verizon	3	21549898	4/25/06 8:53 AM	4/25/06 8:56 AM	Yes	1	23	
Verizon	2.6	21545879	4/24/06 4:54 PM	4/24/06 5:23 PM	Yes	1	24	
Verizon	2.3	21545879	4/24/06 4:54 PM	4/24/06 5:24 PM	Yes	2	36	
Verizon	3.2	21516585	4/20/06 11:44 AM	4/20/06 11:48 AM	Yes	2	23	
Verizon	1.2	21493052	4/17/06 4:04 PM	4/17/2006 4:16PM & 4:17:51 PM	No	3	21	
Verizon	2.4	21493052	4/17/06 4:04 PM	4/18/06 8:01 AM	Yes	2	26	
Verizon	1	21489160	4/17/06 10:42 AM	4/17/06 12:49 PM	No	1	14	
Verizon	1.5	21489160	4/17/06 10:42 AM	4/17/06 1:21 PM	No	2	20	
Verizon	1.1	21489160	4/17/06 10:42 AM	4/17/06 1:51 PM	No	2	4	
Verizon	1.9	21489160	4/17/06 10:42 AM	4/17/06 1:52 PM	No	1	33	
Verizon	2.2	21489160	4/17/06 10:42 AM	4/17/06 1:05 PM	Yes	1	7	
Verizon	3.2	21489081	4/17/06 10:36 AM	4/17/06 12:47 PM	Yes	3	14	
Verizon	2.2	21486267	4/17/06 7:03 AM	4/17/2006 8:36AM & 8:37:42 AM	No	3	15	
Verizon	3.2	21486267	4/17/06 7:03 AM	4/17/06 11:27 AM	Yes	1	28	
Verizon	2.5	21478059	4/14/06 6:33 PM	4/14/06 6:50 PM	Yes	2	32	
Verizon	2.6	21430137	4/8/06 11:52 AM	4/8/06 11:56 AM	Yes	2	42	
Verizon	1	21417730	4/6/06 2:47 PM	4/6/06 2:47 PM	No	1	7	
Verizon	0.6	21417730	4/6/06 2:47 PM	4/6/06 2:50 PM	No	2	2	
Verizon	3.1	21417730	4/6/06 2:47 PM	4/6/06 2:51 PM	Yes	3	8	
Verizon	1.2	21417843	4/6/06 2:26 PM	4/6/06 2:27 PM	No	2	0	
Verizon	1.9	21417843	4/6/06 2:26 PM	4/6/06 2:29 PM	Yes	1	16	
Verizon	1.5	21337843	3/27/06 11:56 AM	3/27/06 1:26 PM		3	18	
Verizon	1	21337843	3/27/06 11:56 AM	3/27/06 1:28 PM		2	16	
n/a	0.02	21337843	3/27/06 11:56 AM	3/27/06 1:47 PM			1	Short call- does not show up on Verizon's call records.
Verizon	2.2	21337843	3/27/06 11:56 AM	3/27/06 1:48 PM		1	1	
Verizon	3.2	21337843	3/27/06 11:56 AM	3/27/06 1:50 PM	Yes	1	37	
Verizon	1.1	21331452	3/26/06 2:39 PM	3/27/06 8:17 AM		2	28	
Verizon	2.4	21331452	3/26/06 2:39 PM	3/27/06 8:49 AM	Yes	1	7	
Verizon	2.5	21326606	3/25/06 12:22 PM	3/25/06 12:25 PM	Yes	2	33	Two Patients on same order
Verizon	2.5	21326606	3/25/06 12:22 PM	3/25/06 12:25 PM	Yes	2	31	Two Patients on same order
Verizon	2.3	21297263	3/21/06 2:41 PM	3/21/06 2:43 PM	Yes	2	26	
Verizon	2.6	21276466	3/19/06 6:49 AM	3/19/06 11:35 AM	Yes	2	38	
Verizon	0.3	21057633	3/7/06 3:53 PM	3/7/06 3:54 PM		2	28	
n/a	0.04	21057633	3/7/06 3:53 PM	3/7/06 4:24 PM		2	0	A call that short would not have shown up on Verizon's call records.

Verizon	1.9	21057633	3/7/06 3:53 PM	3/7/06 4:29 PM		0	3	
Verizon	2.5	21057633	3/7/06 3:53 PM	3/7/06 4:35 PM	Yes (FAX)	0	19	
n/a	0.04	21055131	3/7/06 12:08 PM	3/7/06 12:09 PM		4	4	A call that short would not have shown up on Verizon's call records.
Verizon	2.3	21055131	3/7/06 12:08 PM	3/7/06 12:16 PM	Yes	0	3	
n/a	0.03	21002866	2/28/06 4:41 PM	2/28/06 4:47 PM		2	23	A call that short would not have shown up on Verizon's call records.
Verizon	2.3	21002866	2/28/06 4:41 PM	2/28/06 4:55 PM	Yes	0	3	
Verizon	2	20997759	2/28/06 9:05 AM	2/28/06 10:59 AM	Yes	2	6	
Verizon	2.3	20993612	2/27/06 5:11 PM	2/27/06 5:59 PM		3	0	
Verizon	1.1	20993612	2/27/06 5:11 PM	2/28/06 8:02 AM		1	20	
Verizon	1.2	20993612	2/27/06 5:11 PM	2/28/06 8:03 AM		1	14	
Verizon	2.9	20993612	2/27/06 5:11 PM	2/28/06 8:20 AM	Yes	2	25	
Verizon	1.2	20990663	2/27/06 12:48 PM	2/27/06 1:21 PM		2	58	
Verizon	1.1	20990663	2/27/06 12:48 PM	2/27/06 1:22 PM		1	21	
Verizon	1.2	20990663	2/27/06 12:48 PM	2/27/06 1:25 PM		1	15	
Verizon	2.9	20990663	2/27/06 12:48 PM	2/27/06 1:28 PM	Yes	1	15	
Verizon	1.1	20971311	2/24/06 11:06 AM	2/24/06 11:07 AM		3	30	
Verizon	1.2	20971311	2/24/06 11:06 AM	2/24/06 11:23 AM		1	50	
Verizon	1.8	20971311	2/24/06 11:06 AM	2/24/06 11:24 AM		1	17	
Verizon	3.7	20971311	2/24/06 11:06 AM	2/24/06 11:26 AM	Yes	1	6	
Verizon	0.8	20967946	2/23/06 9:14 PM	2/24/06 6:33 AM		2	28	
Verizon	1.4	20967946	2/23/06 9:14 PM	2/24/06 8:03 AM		2	33	
Verizon	2.4	20967946	2/23/06 9:14 PM	2/24/06 8:20 AM	Yes	0	51	
Verizon	2.3	20956855	2/22/06 2:50 PM	2/22/06 2:50 PM	Yes	2	22	
Verizon	1.2	20956491	2/22/06 2:44 PM	2/22/06 2:45 PM		1	38	
Verizon	2.2	20956491	2/22/06 2:44 PM	2/22/2006 2:47PM 2:48:00PM		2	21	
Verizon	2.3	20956491	2/22/06 2:44 PM	2/22/06 2:49 PM	Yes	1	16	
n/a	0.1	20942859	2/21/06 7:21 AM	2/21/06 8:21 AM		2	30	
Verizon	2.4	20942859	2/21/06 7:21 AM	2/21/06 8:27 AM	Yes	0	4	Short call- does not show up on Verizon's call records.
Verizon	3.8	20912240	2/16/06 2:18 PM	2/16/06 2:19 PM	Yes	3	56	
Verizon	3.1	20901791	2/15/06 11:44 AM	2/15/06 11:45 AM	Yes	3	9	
Verizon	2.5	20854812	2/8/06 2:21 PM	2/8/06 6:35 PM	Yes	2	41	
n/a	0.04	20796481	2/1/06 8:31 AM	2/1/06 8:31 AM		1	51	
Verizon	1.2	20796481	2/1/06 8:31 AM	2/1/06 8:31 AM		3	1	
Verizon	3	20796481	2/1/06 8:31 AM	2/1/06 8:33 AM	Yes	1	21	Two Patients on same order
Verizon	1.8	20796481	2/1/06 8:31 AM	2/1/06 8:37 AM	Yes	0	3	Two Patients on same order
Verizon	3.2	20791084	1/31/06 1:50 PM	1/31/06 1:51 PM		3	30	
Verizon	3.4	20791084	1/31/06 1:50 PM	1/31/06 1:53 PM	Yes	3	15	
Verizon	2.1	20678117	1/16/06 5:06 PM	1/16/06 5:13 PM	Yes	2	13	
Verizon	2.5	20660988	1/13/06 8:03 PM	1/13/06 8:15 PM	Yes	2	37	
Verizon	1.5	20653509	1/12/06 9:38 PM	1/13/06 6:12 AM		2	34	
Verizon	1.9	20653509	1/12/06 9:38 PM	1/13/06 8:05 AM		1	56	
Verizon	2.5	20653509	1/12/06 9:38 PM	1/13/06 8:07 AM	Yes	1	33	
Verizon	1.3	20650318	1/12/06 1:40 PM	1/12/06 1:40 PM		3	3	
Verizon	3	20650318	1/12/06 1:40 PM	1/12/06 1:46 PM	Yes	1	38	
Verizon	2.6	20637004	1/10/06 9:15 PM	1/11/06 6:19 AM	Yes	2	46	
Verizon	2.4	20626679	1/9/06 12:00 AM	1/9/06 6:36 PM	Yes	2	27	
Verizon	2.1	20598660	1/5/06 3:55 PM	1/5/06 3:55 PM	Yes	2	12	
Verizon	3.4	20593890	1/5/06 8:39 AM	1/5/2006 8:39AM & 8:41:00 AM	Yes	3	34	Two calls were made at the same time. Total durations account for both calls.
Verizon	2.3	20582692	1/3/06 8:58 PM	1/4/06 6:46 AM	Yes	2	22	
Verizon	3	20544616	12/29/05 1:34 PM	12/29/05 1:34 PM	Yes	3	2	
Verizon	2.9	20534082	12/28/05 10:54 AM	12/28/05 11:24 AM	Yes	3	3	
Verizon	2.4	20517453	12/26/05 12:22 AM	12/26/05 8:21 AM	Yes	2	26	

Verizon	3.5	20512335	12/23/05 1:17 PM	12/23/2005 1:17PM & 1:18:47 PM	Yes	3	39	Two calls were made at the same time. Total durations account for both calls.
Verizon	0.8	20502310	12/21/05 10:24 PM	12/22/05 6:46 AM	No	2	26	
Verizon	2.4	20502310	12/21/05 10:24 PM	12/22/05 8:04 AM	Yes	0	53	
Verizon	1.1	20479584	12/19/05 8:29 AM	12/19/05 8:29 AM	No	2	8	
Verizon	2.2	20479584	12/19/05 8:29 AM	12/19/05 8:30 AM	No	1	18	
Verizon	1.2	20479584	12/19/05 8:29 AM	12/19/05 8:33 AM	No	2	19	
Verizon	2.5	20479584	12/19/05 8:29 AM	12/19/2005 8:34AM & 8:34:02 AM	Yes	1	14	Two calls were made at the same time. Total durations account for both calls.
Verizon	2.3	20437088	12/12/05 5:10 PM	12/12/05 5:13 PM	Yes	2	23	
Verizon	0.05	20432976	12/12/05 9:58 AM	12/12/05 11:19 AM	No	2	26	Two Patients on same order/Call that short would not have shown up on Verizon's call records.
Verizon	2.3	20432976	12/13/05 9:58 AM	12/12/05 11:19 AM	Yes	2	22	Two Patients on same order
Verizon	2.4	20432976	12/12/05 9:58 AM	12/12/05 11:24 AM	Yes	0	3	Two Patients on same order
Verizon	2	20427361	12/11/05 8:45 AM	12/11/05 10:43 AM	Yes	2	3	Fax was sent to the ECP
Verizon	2.4	20408674	12/8/05 6:13 AM	12/8/05 3:07 PM	Yes	2	31	
Verizon	2.1	20285508	11/19/05 9:53 PM	11/20/05 10:40 AM	No	2	29	
Verizon	2.3	20285508	11/19/05 9:53 PM	11/21/05 8:08 AM	Yes	2	7	
Verizon	1.7	20236837	11/13/05 11:52 AM	11/13/05 12:49 PM	No	2	51	
Verizon	1.7	20236837	11/13/05 11:52 AM	11/14/05 8:06 AM	No	1	18	
Verizon	1.2	20236837	11/13/05 11:52 AM	11/14/05 8:38 AM	No	1	48	
Verizon	0.9	20236837	11/13/05 11:52 AM	11/14/05 8:54 AM	No	0	47	
Verizon	1.2	20236837	11/13/05 11:52 AM	11/14/05 9:25 AM	No	1	42	
Verizon	1.6	20236837	11/13/05 11:52 AM	11/14/05 9:26 AM	No	1	13	
Verizon	0.7	20236837	11/13/05 11:52 AM	11/14/05 9:28 AM	No	0	56	
Verizon	1.7	20236837	11/13/05 11:52 AM	11/14/05 9:59 AM	No	1	18	
Verizon	1.3	20236837	11/13/05 11:52 AM	11/14/05 10:34 AM	No	1	50	
Verizon	2.8	20236837	11/13/05 11:52 AM	11/14/05 11:05 AM	Yes	1	43	
Verizon	1.8	20226138	11/11/05 8:40 AM	11/11/05 8:40 AM	No	2	30	
Verizon	1.2	20226138	11/11/05 8:40 AM	11/11/05 8:40 AM	No	2	37	
Verizon	2.5	20226138	11/11/05 8:40 AM	11/11/05 8:41 AM	Yes	1	16	Two Patients on same order
Verizon	2.4	20226138	11/11/05 8:40 AM	11/11/05 9:27 AM	Yes	1	53	Two Patients on same order
Verizon	2	20116643	10/26/05 8:19 PM	10/26/05 9:56 PM	No	3	0	
Verizon	1.7	20116643	10/26/05 8:19 PM	10/27/05 8:03 AM	No	0	54	
Verizon	0.8	20116643	10/26/05 8:19 PM	10/27/05 8:05 AM	No	1	49	
Verizon	2.9	20116643	10/26/05 8:19 PM	10/27/05 8:36 AM	Yes	2	9	
Verizon	3	20066373	10/19/05 4:25 PM	10/19/2005 4:46 PM & 4:27:12 PM	Yes	3	11	Two calls were made at the same time. Total duration accounts for both calls.
Verizon	2.3	20065146	10/19/05 1:58 PM	10/19/05 1:57 PM	Yes	2	26	
Verizon	0.8	20050477	10/17/05 9:13 PM	10/18/05 6:09 AM	Yes	0	50	
Verizon	2.9	20001914	10/11/05 10:36 AM	10/11/05 12:01 PM	Yes	3	1	
Verizon	2.3	19997357	10/10/05 5:42 PM	10/10/05 7:43 PM	Yes	2	19	
Verizon	3.1	19952202	10/4/05 12:11 PM	10/4/05 12:17 PM	Yes	3	13	
Verizon	1.2	19950866	10/4/05 10:17 AM	10/4/05 10:28 AM	No	2	47	
Verizon	1.2	19950866	10/4/05 10:17 AM	10/4/05 10:29 AM	No	1	13	
Verizon	2.7	19950866	10/4/05 10:17 AM	10/4/05 10:30 AM	Yes	1	18	
Verizon	3.1	19927480	9/30/05 4:41 PM	9/30/05 4:51 PM	Yes	3	11	
Verizon	2.9	19909954	9/28/05 1:29 PM	9/28/05 1:30 PM	Yes	3	0	
Verizon		19904639	9/27/05 8:39 PM	9/27/05 9:15 PM	Yes (Fax)			
Verizon	0.9	19904639	9/27/05 8:39 PM	9/27/05 9:14 PM	No	0	56	
Verizon	2.9	19860978	9/21/05 3:26 PM	9/21/05 3:26 PM	Yes	2	58	
Verizon	3.6	19853544	9/20/05 5:32 PM	9/20/05 5:39 PM	Yes	3	37	
Verizon	1.6	19852417	9/20/05 3:01 PM	9/20/05 3:00 PM	No	2	27	
Verizon	2.3	19852417	9/20/05 3:01 PM	9/20/05 3:01 PM	Yes	2	20	Two Patients on same order
Verizon	2.4	19852417	9/20/05 3:01 PM	9/20/05 3:02 PM	Yes	1	38	Two Patients on same order
Verizon	2.1	19798946	9/13/05 2:02 PM	9/13/05 2:02 PM	No	3	26	
Verizon	1.1	19798946	9/13/05 2:02 PM	9/13/05 2:05 PM	No	1	12	

Verizon	1.8	19798946	9/13/05 2:02 PM	9/13/05 2:06 PM	No	1	17	
Verizon	1.2	19798946	9/13/05 2:02 PM	9/13/05 2:08 PM	No	1	54	
Verizon	1.1	19798946	9/13/05 2:02 PM	9/13/05 2:09 PM	No	1	12	
Verizon	3.3	19798946	9/13/05 2:02 PM	9/13/05 2:11 PM	Yes	2	15	
Verizon	3.2	19785710	9/12/05 12:12 PM	9/12/05 3:01 PM	Yes	3	19	
Verizon	2.5	19772430	9/9/05 4:40 PM	9/9/05 6:03 PM	Yes	2	37	
Verizon	2.6	19759568	9/8/05 9:46 AM	9/8/05 11:08 AM	Yes	2	43	
Verizon	2.5	19684030	8/29/05 1:23 PM	8/29/05 3:05 PM	Yes	2	32	
Verizon	1.8	19676708	8/28/05 2:15 PM	8/28/05 3:36 PM	No			
No		19676708	8/28/05 2:15 PM	8/28/05 3:38 PM	Yes (Fax)	1	53	
Verizon	2.4	19670935	8/27/05 9:11 AM	8/27/05 10:04 AM	Yes	2	32	
Verizon	2.6	19666114	8/26/05 12:38 PM	8/26/05 1:13 PM	Yes	4	5	
Sprint	2.4	19618023	8/20/05 10:54 AM	8/20/05 1:16 PM	Yes	2	33	
Sprint	2	19600326	8/18/05 6:41 AM	8/18/05 8:10 AM	No	3	30	
Sprint	1	19600326	8/18/05 6:41 AM	8/18/05 8:12 AM	No	1	52	
Sprint	1.8	19600326	8/18/05 6:41 AM	8/18/05 8:13 AM	No	1	9	
Sprint	3.4	19600326	8/18/05 6:41 AM	8/18/05 8:31 AM	Yes	2	3	
Sprint	2.6	19568104	8/14/05 1:58 PM	8/14/05 5:19 PM	Yes	2	40	
Sprint	2.5	19565499	8/13/05 6:13 PM	8/14/05 8:27 AM	Yes	2	38	
Sprint	2.3	19564160	8/13/05 1:23 PM	8/13/05 2:54 PM	Yes	2	24	
Sprint	3.4	19556436	8/12/05 11:03 AM	8/12/2005 11:10AM & 11:13:00 AM	Yes	3	32	
Sprint	0.9	19533772	8/9/05 6:05 PM	8/9/05 6:15 PM	No	3	57	
Sprint	1.9	19533772	8/9/05 6:05 PM	8/10/05 8:01 AM	No	1	11	
Sprint	1.1	19533772	8/9/05 6:05 PM	8/10/05 8:03 AM	No	1	57	
Sprint	3	19533772	8/9/05 6:05 PM	8/10/05 8:04 AM	Yes	1	0	

257 E 200 South
Salt Lake City, UT 84111

September 19, 2006

1-800CONTACTS
66 Wadsworth Park Dr. 3rd Fl
Draper, UT 84020

To Whom It May Concern:

Below is a log of all calls to (817) 461-4453 from our customer 1-800 CONTACTS from August 1st, 2005 to August 31st, 2006.

August 2005

Date	Time	Number Dialed		City, ST		Min.
0808	08:36	(817)461-4453	I	ARLINGTON	TX	1.4
0808	09:10	(817)461-4453	I	ARLINGTON	TX	1.7
0826	13:11	(817)461-4453	I	ARLINGTON	TX	0.3
0826	13:12	(817)461-4453	I	ARLINGTON	TX	1.3
0826	13:13	(817)461-4453	I	ARLINGTON	TX	2.6
0827	10:04	(817)461-4453	I	ARLINGTON	TX	2.4
0828	15:36	(817)461-4453	I	ARLINGTON	TX	1.8
0829	15:05	(817)461-4453	I	ARLINGTON	TX	2.5

September 2005

0914	11:27	(817)461-4453	I	ARLINGTON	TX	4.9
0909	18:03	(817)461-4453	I	ARLINGTON	TX	2.5
0913	14:05	(817)461-4453	I	ARLINGTON	TX	1.1
0913	14:06	(817)461-4453	I	ARLINGTON	TX	1.8
0913	14:08	(817)461-4453	I	ARLINGTON	TX	1.2
0920	15:00	(817)461-4453	I	ARLINGTON	TX	1.6
0920	15:01	(817)461-4453	I	ARLINGTON	TX	2.3
0920	17:34	(817)461-4453	I	ARLINGTON	TX	1.1
0920	17:39	(817)461-4453	I	ARLINGTON	TX	3.6
0921	15:26	(817)461-4453	I	ARLINGTON	TX	2.9
0927	21:14	(817)461-4453	I	ARLINGTON	TX	0.9
0928	13:30	(817)461-4453	I	ARLINGTON	TX	2.9
0930	16:51	(817)461-4453	I	ARLINGTON	TX	3.1
0908	11:08	(817)461-4453	I	ARLINGTON	TX	2.6
0912	15:01	(817)461-4453	I	ARLINGTON	TX	3.2
0913	14:11	(817)461-4453	I	ARLINGTON	TX	3.3

0913 14:02 (817)461-4453	I	ARLINGTON	TX	2.1
0913 14:09 (817)461-4453	I	ARLINGTON	TX	1.1
0920 15:02 (817)461-4453	I	ARLINGTON	TX	2.4

October 2005

1019 12:18 (817)461-4453	I	ARLINGTON	TX	2.2
1019 15:35 (817)461-4453	I	ARLINGTON	TX	1.1
1010 19:43 (817)461-4453	I	ARLINGTON	TX	2.3
1018 06:09 (817)461-4453	I	ARLINGTON	TX	0.8
1019 13:58 (817)461-4453	I	ARLINGTON	TX	2.3
1019 16:26 (817)461-4453	I	ARLINGTON	TX	0.9
1019 16:27 (817)461-4453	I	ARLINGTON	TX	2.1
1026 21:56 (817)461-4453	I	ARLINGTON	TX	2.0
1027 08:03 (817)461-4453	I	ARLINGTON	TX	1.7
1027 08:05 (817)461-4453	I	ARLINGTON	TX	0.8
1027 08:36 (817)461-4453	I	ARLINGTON	TX	2.9
1004 10:28 (817)461-4453	I	ARLINGTON	TX	1.2
1004 10:30 (817)461-4453	I	ARLINGTON	TX	2.7
1011 12:01 (817)461-4453	I	ARLINGTON	TX	2.9
1004 10:29 (817)461-4453	I	ARLINGTON	TX	1.2
1004 12:17 (817)461-4453	I	ARLINGTON	TX	3.1

November 2005

1111 08:40 (817)461-4453	I	ARLINGTON	TX	1.2
1111 08:40 (817)461-4453	I	ARLINGTON	TX	1.8
1111 08:41 (817)461-4453	I	ARLINGTON	TX	2.5
1113 12:49 (817)461-4453	I	ARLINGTON	TX	1.7
1114 08:38 (817)461-4453	I	ARLINGTON	TX	1.2
1114 08:54 (817)461-4453	I	ARLINGTON	TX	0.9
1114 09:26 (817)461-4453	I	ARLINGTON	TX	1.6
1114 09:25 (817)461-4453	I	ARLINGTON	TX	1.2
1114 09:28 (817)461-4453	I	ARLINGTON	TX	0.7
1114 09:59 (817)461-4453	I	ARLINGTON	TX	1.7
1114 10:34 (817)461-4453	I	ARLINGTON	TX	1.3
1114 11:05 (817)461-4453	I	ARLINGTON	TX	2.8
1120 10:40 (817)461-4453	I	ARLINGTON	TX	2.1
1114 08:06 (817)461-4453	I	ARLINGTON	TX	1.7
1121 08:08 (817)461-4453	I	ARLINGTON	TX	2.3
1111 09:27 (817)461-4453	I	ARLINGTON	TX	2.4

December 2005

1212 08:30 (817)461-4453	I	ARLINGTON	TX	1.8
1212 09:44 (817)461-4453	I	ARLINGTON	TX	1.2
1208 15:07 (817)461-4453	I	ARLINGTON	TX	2.4
1211 10:43 (817)461-4453	I	ARLINGTON	TX	2.0
1212 11:19 (817)461-4453	I	ARLINGTON	TX	2.3
1212 17:13 (817)461-4453	I	ARLINGTON	TX	2.3
1213 12:02 (817)461-4453	I	ARLINGTON	TX	1.3

1219 08:33	(817)461-4453	I	ARLINGTON TX	1.2
1219 08:29	(817)461-4453	I	ARLINGTON TX	1.1
1219 08:30	(817)461-4453	I	ARLINGTON TX	2.2
1219 08:34	(817)461-4453	I	ARLINGTON TX	2.0
1222 06:46	(817)461-4453	I	ARLINGTON TX	0.8
1223 13:18	(817)461-4453	I	ARLINGTON TX	2.4
1226 08:21	(817)461-4453	I	ARLINGTON TX	2.4
1229 13:34	(817)461-4453	I	ARLINGTON TX	3.0
1228 11:24	(817)461-4453	I	ARLINGTON TX	2.9
1212 11:24	(817)461-4453	I	ARLINGTON TX	2.4
1219 08:34	(817)461-4453	I	ARLINGTON TX	0.5
1222 08:04	(817)461-4453	I	ARLINGTON TX	2.4
1223 13:17	(817)461-4453	I	ARLINGTON TX	1.1

January 2006

0104 06:46	(817)461-4453	I	ARLINGTON TX	2.3
0105 08:39	(817)461-4453	I	ARLINGTON TX	1.2
0105 08:41	(817)461-4453	I	ARLINGTON TX	2.2
0105 15:55	(817)461-4453	I	ARLINGTON TX	2.1
0109 18:36	(817)461-4453	I	ARLINGTON TX	2.4
0111 06:19	(817)461-4453	I	ARLINGTON TX	2.6
0105 08:39	(817)461-4453	I	ARLINGTON TX	1.2
0105 08:41	(817)461-4453	I	ARLINGTON TX	2.2
0112 13:40	(817)461-4453	I	ARLINGTON TX	1.3
0112 13:46	(817)461-4453	I	ARLINGTON TX	3.0
0113 06:12	(817)461-4453	I	ARLINGTON TX	1.5
0113 08:07	(817)461-4453	I	ARLINGTON TX	2.5
0113 20:15	(817)461-4453	I	ARLINGTON TX	2.5
0116 17:13	(817)461-4453	I	ARLINGTON TX	2.1
0131 13:53	(817)461-4453	I	ARLINGTON TX	3.4
0113 08:05	(817)461-4453	I	ARLINGTON TX	1.9
0131 13:50	(817)461-4453	I	ARLINGTON TX	3.2

February 2006

0201 08:33	(817)461-4453	I	ARLINGTON TX	3.0
0201 08:37	(817)461-4453	I	ARLINGTON TX	1.8
0208 18:35	(817)461-4453	I	ARLINGTON TX	2.5
0215 11:45	(817)461-4453	I	ARLINGTON TX	3.1
0216 11:04	(817)461-4453	I	ARLINGTON TX	2.0
0216 11:03	(817)461-4453	I	ARLINGTON TX	1.1
0216 11:08	(817)461-4453	I	ARLINGTON TX	0.9
0216 14:19	(817)461-4453	I	ARLINGTON TX	3.8
0221 04:26	(817)461-4453	I	ARLINGTON TX	2.4
0222 10:45	(817)461-4453	I	ARLINGTON TX	1.2
0222 10:50	(817)461-4453	I	ARLINGTON TX	2.3
0224 02:32	(817)461-4453	I	ARLINGTON TX	0.8
0224 04:04	(817)461-4453	I	ARLINGTON TX	1.3
0224 07:07	(817)461-4453	I	ARLINGTON TX	1.1

0224 07:24	(817)461-4453	I	ARLINGTON TX	1.8
0224 07:26	(817)461-4453	I	ARLINGTON TX	0.3
0224 07:22	(817)461-4453	I	ARLINGTON TX	1.2
0227 13:57	(817)461-4453	I	ARLINGTON TX	2.3
0228 04:02	(817)461-4453	I	ARLINGTON TX	1.2
0228 04:18	(817)461-4453	I	ARLINGTON TX	2.9
0228 12:52	(817)461-4453	I	ARLINGTON TX	2.3
0224 04:20	(817)461-4453	I	ARLINGTON TX	2.4
0227 09:20	(817)461-4453	I	ARLINGTON TX	1.2
0228 06:59	(817)461-4453	I	ARLINGTON TX	2.0
0216 11:04	(817)461-4453	I	ARLINGTON TX	2.0
0201 08:31	(817)461-4453	I	ARLINGTON TX	1.2
0222 10:47	(817)461-4453	I	ARLINGTON TX	0.7
0222 10:48	(817)461-4453	I	ARLINGTON TX	1.5
0222 10:49	(817)461-4453	I	ARLINGTON TX	1.5
0224 04:03	(817)461-4453	I	ARLINGTON TX	1.1
0224 07:26	(817)461-4453	I	ARLINGTON TX	2.6
0227 09:22	(817)461-4453	I	ARLINGTON TX	1.1
0227 09:23	(817)461-4453	I	ARLINGTON TX	1.2
0227 09:25	(817)461-4453	I	ARLINGTON TX	2.9
0228 04:01	(817)461-4453	I	ARLINGTON TX	1.1

March 2006

0307 08:16	(817)461-4453	I	ARLINGTON TX	2.3
0307 11:53	(817)461-4453	I	ARLINGTON TX	0.3
0307 12:29	(817)461-4453	I	ARLINGTON TX	1.9
0319 07:33	(817)461-4453	I	ARLINGTON TX	2.6
0321 10:41	(817)461-4453	I	ARLINGTON TX	2.3
0325 08:23	(817)461-4453	I	ARLINGTON TX	2.5
0325 08:23	(817)461-4453	I	ARLINGTON TX	2.5
0327 09:50	(817)461-4453	I	ARLINGTON TX	3.2
0327 09:48	(817)461-4453	I	ARLINGTON TX	2.2
0327 09:27	(817)461-4453	I	ARLINGTON TX	1.5
0307 08:14	(817)461-4453	I	ARLINGTON TX	1.7
0327 04:18	(817)461-4453	I	ARLINGTON TX	1.1
0327 04:49	(817)461-4453	I	ARLINGTON TX	2.4
0327 09:28	(817)461-4453	I	ARLINGTON TX	1.0

April 2006

0417 07:26	(817)461-4453	I	ARLINGTON TX	3.2
0417 09:20	(817)461-4453	I	ARLINGTON TX	1.5
0417 09:51	(817)461-4453	I	ARLINGTON TX	1.1
0406 10:26	(817)461-4453	I	ARLINGTON TX	1.2
0406 10:28	(817)461-4453	I	ARLINGTON TX	1.9
0406 10:49	(817)461-4453	I	ARLINGTON TX	0.6
0406 10:50	(817)461-4453	I	ARLINGTON TX	1.3
0406 10:47	(817)461-4453	I	ARLINGTON TX	1.0
0406 10:51	(817)461-4453	I	ARLINGTON TX	3.1

0414 14:48 (817)461-4453	I	ARLINGTON	TX	2.5
0417 04:35 (817)461-4453	I	ARLINGTON	TX	0.8
0417 08:47 (817)461-4453	I	ARLINGTON	TX	3.2
0417 12:16 (817)461-4453	I	ARLINGTON	TX	0.5
0417 12:17 (817)461-4453	I	ARLINGTON	TX	0.7
0418 04:00 (817)461-4453	I	ARLINGTON	TX	2.4
0424 13:23 (817)461-4453	I	ARLINGTON	TX	2.6
0424 13:23 (817)461-4453	I	ARLINGTON	TX	2.3
0425 04:53 (817)461-4453	I	ARLINGTON	TX	1.3
0425 04:54 (817)461-4453	I	ARLINGTON	TX	1.3
0425 04:55 (817)461-4453	I	ARLINGTON	TX	3.0
0425 09:58 (817)461-4453	I	ARLINGTON	TX	1.1
0425 10:15 (817)461-4453	I	ARLINGTON	TX	0.7
0425 10:47 (817)461-4453	I	ARLINGTON	TX	3.7
0427 08:07 (817)461-4453	I	ARLINGTON	TX	3.5
0429 18:53 (817)461-4453	I	ARLINGTON	TX	3.1
0408 07:53 (817)461-4453	I	ARLINGTON	TX	2.6
0417 04:36 (817)461-4453	I	ARLINGTON	TX	1.4
0417 09:52 (817)461-4453	I	ARLINGTON	TX	1.9
0417 09:54 (817)461-4453	I	ARLINGTON	TX	2.2
0420 07:47 (817)461-4453	I	ARLINGTON	TX	3.2
0425 10:16 (817)461-4453	I	ARLINGTON	TX	1.2
0427 08:06 (817)461-4453	I	ARLINGTON	TX	1.3
0427 09:35 (817)461-4453	I	ARLINGTON	TX	5.0
0427 09:50 (817)461-4453	I	ARLINGTON	TX	2.3
0417 08:48 (817)461-4453	I	ARLINGTON	TX	1.0

May 2006

0511 16:14 (817)461-4453	I	ARLINGTON	TX	1.1
0512 14:05 (817)461-4453	I	ARLINGTON	TX	3.2
0505 15:29 (817)461-4453	I	ARLINGTON	TX	3.2
0531 08:22 (817)461-4453	I	ARLINGTON	TX	4.7
0517 09:30 (817)461-4453	I	ARLINGTON	TX	3.1
0508 14:50 (817)461-4453	I	ARLINGTON	TX	2.6
0524 08:03 (817)461-4453	I	ARLINGTON	TX	2.3
0513 10:35 (817)461-4453	I	ARLINGTON	TX	2.1
0517 05:24 (817)461-4453	I	ARLINGTON	TX	1.3
0519 04:20 (817)461-4453	I	ARLINGTON	TX	5.4

June 2006

0617 03:32 (817)461-4453	I	ARLINGTON	TX	2.6
0623 09:57 (817)461-4453	I	ARLINGTON	TX	0.8
0623 09:57 (817)461-4453	I	ARLINGTON	TX	2.1
0623 09:58 (817)461-4453	I	ARLINGTON	TX	0.4
0623 10:28 (817)461-4453	I	ARLINGTON	TX	2.2
0627 05:13 (817)461-4453	I	ARLINGTON	TX	2.5
0630 11:13 (817)461-4453	I	ARLINGTON	TX	3.5
0630 11:11 (817)461-4453	I	ARLINGTON	TX	1.4

July 2006

0713	07:01	(817)461-4453	I	ARLINGTON	TX	3.3
0703	09:50	(817)461-4453	I	ARLINGTON	TX	2.3
0710	03:56	(817)461-4453	I	ARLINGTON	TX	0.6
0710	03:57	(817)461-4453	I	ARLINGTON	TX	1.8
0710	04:06	(817)461-4453	I	ARLINGTON	TX	2.9
0724	17:28	(817)461-4453	I	ARLINGTON	TX	2.3
0724	17:30	(817)461-4453	I	ARLINGTON	TX	2.3
0726	12:33	(817)461-4453	I	ARLINGTON	TX	2.1
0727	10:25	(817)461-4453	I	ARLINGTON	TX	1.7
0727	10:27	(817)461-4453	I	ARLINGTON	TX	2.1
0727	11:55	(817)461-4453	I	ARLINGTON	TX	2.1
0727	11:53	(817)461-4453	I	ARLINGTON	TX	1.2
0728	11:20	(817)461-4453	I	ARLINGTON	TX	2.5
0728	11:23	(817)461-4453	I	ARLINGTON	TX	2.5
0729	08:19	(817)461-4453	I	ARLINGTON	TX	2.8

August 2006

0801	07:30	(817)461-4453	I	ARLINGTON	TX	2.2
0802	14:00	(817)461-4453	I	ARLINGTON	TX	3.1
0815	09:50	(817)461-4453	I	ARLINGTON	TX	0.9
0815	09:51	(817)461-4453	I	ARLINGTON	TX	2.2
0821	15:52	(817)461-4453	I	ARLINGTON	TX	1.6
0821	15:54	(817)461-4453	I	ARLINGTON	TX	1.3
0821	15:55	(817)461-4453	I	ARLINGTON	TX	2.8
0824	15:45	(817)461-4453	I	ARLINGTON	TX	2.2
0830	11:43	(817)461-4453	I	ARLINGTON	TX	0.9
0830	11:42	(817)461-4453	I	ARLINGTON	TX	0.6
0830	11:45	(817)461-4453	I	ARLINGTON	TX	0.7
0830	11:44	(817)461-4453	I	ARLINGTON	TX	1.2
0830	11:46	(817)461-4453	I	ARLINGTON	TX	0.5
0830	11:47	(817)461-4453	I	ARLINGTON	TX	2.6

Angel Espana

Service Manager
Phone 801-575-3176
Fax 801-575-3120

LIGHTSTREAM
communications

Lightstream Communications
240 East Morris Avenue, Suite 325
Salt Lake City, Utah 84115

September 20, 2006

1-800 CONTACTS
66 Wadsworth Park Drive
Draper, Utah 84020

To Whom It May Concern:

Lightstream Communications is an authorized Sprint Agent. Below is a log of all calls to (817) 461-4453 from our customer 1-800 CONTACTS for the months of August 2005 through August 2006.

Date	Time	Location		Number	Minutes
08/09/05	06:15:18 PM	ARLINGTON	TX	(817) 461-4453	0.9
08/10/05	08:01:36 AM	ARLINGTON	TX	(817) 461-4453	1.9
08/10/05	08:03:36 AM	ARLINGTON	TX	(817) 461-4453	1.1
08/10/05	08:04:48 AM	ARLINGTON	TX	(817) 461-4453	3.0
08/12/05	11:10:09 AM	ARLINGTON	TX	(817) 461-4453	1.3
08/12/05	11:11:30 AM	ARLINGTON	TX	(817) 461-4453	2.1
08/13/05	02:54:48 PM	ARLINGTON	TX	(817) 461-4453	2.3
08/14/05	08:27:09 AM	ARLINGTON	TX	(817) 461-4453	2.5
08/14/05	05:18:15 PM	ARLINGTON	TX	(817) 461-4453	2.6
08/18/05	08:10:39 AM	ARLINGTON	TX	(817) 461-4453	2.0
08/18/05	08:12:45 AM	ARLINGTON	TX	(817) 461-4453	1.0
08/18/05	08:13:57 AM	ARLINGTON	TX	(817) 461-4453	1.8
08/18/05	08:30:36 AM	ARLINGTON	TX	(817) 461-4453	3.4
08/20/05	01:15:57 PM	ARLINGTON	TX	(817) 461-4453	0.3
08/20/05	01:16:24 PM	ARLINGTON	TX	(817) 461-4453	0.3
08/20/05	01:16:54 PM	ARLINGTON	TX	(817) 461-4453	2.4

Regards,

Jim Cassell
Account Manager
Lightstream Communications
(801) 326-1001

MR. COON. Thank you, Mr. Chairman. I would also add that if the committee has interest we can also provide copies of our phone bill from Verizon that will match and verify every call, time, and the duration of each of these 192 phone calls to Dr. Curtis' office.

Despite this and other unsupported claims that have been leveled against our company, we want to have a good relationship with eye doctors, and in fact do with most doctors and with most manufacturers. The reason for the conflict today is the same as when I testified before

this committee in 2003, it is that eye doctors sell what they prescribe and they compete with anyone else trying to fill that prescription. That inherent conflict of interest either has to be eliminated or managed in order to ensure that 38 million contact lens wearers don't get caught in the middle.

That said, I believe there is actually more common ground here than it might appear from everyone's written testimony. I thank the committee for your time, and I look forward to your questions.

[The prepared statement of Mr. Coon follows:]

PREPARED STATEMENT OF JONATHAN C. COON, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, 1-800 CONTACTS, INC.

Mr. Chairman and Members of the Subcommittee, my name is Jonathan Coon and I am the CEO of 1-800 CONTACTS. Our company is the largest direct marketer of prescription contact lenses, serving approximately two million consumers.

I appreciate the opportunity to appear before the Subcommittee today. I am grateful to the Subcommittee for investing time on the important issues facing America's 38 million contact lens wearers.

Our company believes that contact lens wearers should be afforded two basic consumer protections:

1. Every contact lens wearer holding a valid prescription should have the freedom to choose where her prescription is filled.
2. Every contact lens wearer should feel confident that her prescription is based on health needs and not influenced by the prescriber's financial interests.

Unlike most pharmaceuticals, contact lenses are regulated medical products that are sold by the prescriber, creating an inherent conflict of interest. Congress reviewed this conflict in detail in the 2003 hearings held before the passage of the Fairness to Contact Lens Consumers Act (FCLCA). In the FCLCA report, Congress recognized this conflict of interest when this committee concluded:

> "Consumers continue to face a difficult time getting prescriptions filled by alternative third party sellers due to prescription verification obstacles. Unlike medical doctors who are prohibited from selling the drugs they prescribe, eye doctors and optometrists ("doctors") are able to fill the contact lens prescriptions they write. This sets up an inherent conflict of interest because third party sellers are forced to compete for the sale of lenses with the individual who is writing the prescription."

The committee recommended, and Congress agreed, that based on an "unusually high number of consumer complaints in states that rely on active verification schemes" that "a passive verification system ensures that consumers are not caught in the competitive tug-of-war between doctors and third party sellers for the sale of contact lenses."

Congress understood in passing the FCLCA that having a copy of the prescription is meaningless if the retailer chosen by the consumer cannot get the prescription verified. For example, when consumers seek to refill their prescriptions for medicines, it's generally a simple process – the consumer goes to his or her local pharmacy, the pharmacy calls into the prescribing physician and the physician's office then promptly

confirms, corrects or rejects the refill. That's the way it should work with refills of contact lens prescriptions – but in most cases it does not.

Since eye care professionals both prescribe and sell contact lenses, verification amounts to the consumer asking their doctor's permission to buy lenses from a competitor. Before the FCLCA, these verification requests were ignored more than half the time. After the FCLCA, these verification requests are still ignored more than half the time, but this lack of response does not prevent the consumer from buying from the doctor's competitor. Several states examined this issue closely and some enacted different verification systems before Congress enacting the FCLCA and created a federal standard. The state laws at the time fell into basically two different verification systems.

1. "Positive verification" requires a competing seller to wait indefinitely for the eye doctor, who sells contacts, to respond to the verification request. The seller must wait until a response is received and the patient has no recourse other than to complain when the doctor refuses to grant permission to a competitor to make a sale. This method has proven to result in a very large number of consumer complaints.
2. "Presumed verification" defines how long an eye doctor has to respond to a verification request when a consumer chooses to purchase from a seller that is not an eye doctor and prevents a doctor from blocking access to competitors by simply ignoring the request. This system requires a seller to verify the prescription directly with the prescriber and gives the prescriber a reasonable time period in which to reply. If the prescriber tells the seller within that time period that the prescription is expired or invalid, the seller must cancel the order. If the prescriber does not respond to the seller within the defined time period, the seller can assume the prescription information is correct and fill the order.

Presumed verification was described by the FTC at the 2003 hearing as a self enforcing system because doctors have a financial interest to enforce the law and prevent invalid prescriptions from being filled by competitors. However, unlike a positive verification system in which the doctor's refusal to respond can stop a patient's order from a third party, a presumed verification system requires the doctor to actively do something to cancel the patient's order.

A positive, or active verification system can work where the prescriber has no conflict of interest and does not compete with others filling the prescription. The verification process, communication methods, and time frame for response between medical doctors and pharmacies are not defined. This system works despite the lack of defined rules because medical doctors do not sell drugs and pharmacies do not prescribe. The roles of medical doctors and pharmacies are defined and limited in such a way that cooperation is not a problem. Pharmacies are not asking a competitor for permission to fill an order. Medical doctors are not losing income by cooperating with pharmacies.

Where positive verification systems have been implemented for the sale of replacement contact lenses, the result has been widespread consumer dissatisfaction. Thousands of consumers waited so long for a verification response that more than half ultimately canceled their orders. Most of these customers give up and went back to the doctor to purchase lenses. Many just kept wearing their old lenses.

In just Texas alone, where an indefinite time period system had been in place for more than a year, our company canceled more than 40,000 customer orders solely for non-response by the eye doctor. Consumers filed more than 4,300 hand-signed complaints with the optometry board. Additional complaints were filed by consumer groups. The optometry board (made up of optometrists) took no action on any of the consumer complaints. The result was an unmitigated disaster for Texas consumers with

more than half of all third party seller orders canceled simply because the eye doctor never responded - in any time period.

A presumed verification system was first called for by the Federal Trade Commission ("FTC") staff in its comments before the Connecticut Opticians Board in 2002. FTC proposed that the right way to deal with the conflict of interest of doctors selling what they prescribe and the competitive relationship between eye doctors and third party sellers was a presumed or passive verification system. The FTC stated that the right verification system for this market was one in which "a valid prescription, communicated to the seller by the patient, can be presumed verified if the doctor is contacted and given sufficient opportunity to correct any errors."

This compromise system was enacted into law in California in 2002. The system was developed with the involvement of ophthalmologists, optometrists, consumer groups, the California Medical Board, and the California Optometric Association. In their written statement supporting the California bill, the California Optometric Association concluded that the law "supports safe and responsible patient access to contact lens prescriptions" and "strikes a reasonable balance between access and accountability." Our Company processed more than several hundred thousand orders under this system before the FCLCA was enacted and did so without any complaints being received by the medical board from consumers, online sellers, or eye doctors.

Based on the above mentioned testimony, evidence and hearings, the FCLCA was enacted and the passive verification system has been the law of the land since December of 2003. To date there has been no meaningful evidence that the law is not working or that passive verification is not the right system to manage the conflict of interest of a doctor selling what they prescribe. Although some on today's panel will probably make unsubstantiated claims to the contrary, Congress did not make a mistake in adopting a passive verification system as there is no evidence to support their assertion that this provision of the law should be repealed and replaced with the already tested and failed positive verification system. Instead, the verification system under the FCLCA has allowed millions of consumers the right to purchase their contact lenses at the retailer of their choice. However, a loophole to the FCLCA has surfaced which threatens to erase all the freedoms Congress gave to consumers as part of the Act.

Unlike pharmaceuticals, contact lens prescriptions are brand specific – with no generic lenses and no substitution allowed.

Once prescribed a specific lens, federal law only allows the patient to be sold the "same contact lens . . . manufactured by the same company" (15 U.S.C. 7603(f)). Unlike pharmaceuticals, the prescriber can specify a lens sold only to doctors and effectively force the patient to purchase lenses at the doctor's store or through an affiliated retailer. Trade advertisements promise these benefits to doctors who prescribe restricted lenses.

To provide patients with basic consumer protections, the FCLCA seeks to provide consumers with the right to purchase from any retailer, including those not affiliated with a prescribing doctor. The Committee report accompanying the FCLCA states that the law "allows consumers to purchase contact lenses from the provider of their choice."

The FCLCA has had many positive impacts on the marketplace, and has provided many consumers with real benefit. Despite the law's fundamental goals, patients prescribed so-called "doctors only" lenses continue to be locked into buying lenses from the prescribing doctor or a doctor-affiliated retailer. This loophole allows a doctor to comply with the FCLCA by releasing the prescription, but avoid the intent of the law by prescribing a lens that is only available from a doctor or an affiliated retailer.

Mr. Chairman, millions of Americans who wear contact lenses have no more right to choose where they buy lenses today than before the FCLCA was passed. We agree with the Committee's report which states that, "The consumer's right to a copy of their contact lens prescription means nothing unless consumers can fill that prescription at the business of their choice."

"Doctors only" lenses are marketed to eye doctors on their ability to increase prescriber profits by limiting competition and compelling patients to return to prescribers for lens purchases. A brochure for Extreme H2O lenses promises doctors "a lens that cannot be shopped around" and "a lens that will retain your replacement business."

An ad for ProClear lenses entices the doctor with its headline, "Let's see. You'll make more money." The ad goes on to explain to the doctor that "since ProClear Compatibles are only available through your practice, you'll get what you're looking for: Increased patient loyalty and greater profitability."

This is the same scheme that 32 state attorneys general sought to stop in bringing multi-district litigation (MDL 1030) in 1997. At the time, 100 percent of the market was "doctors only," with all three major manufacturers maintaining a "doctors only" distribution policy. The lawsuit led to consent decrees with the then three largest manufacturers – Johnson & Johnson, CIBA Vision, and Bausch and Lomb – requiring them to abandon their "doctors only" policies and sell to non-prescribers on the same terms as prescribers.

H.R. 5762, introduced by Congressman Lee Terry, is necessary to assure that all consumers are afforded the protections of these consent decrees and those promised by the FCLCA. The bill codifies the consent decrees, under which 80 percent of all contact lenses have been successfully and efficiently sold since 2001.

Like the consent decrees it seeks to codify, H.R. 5762 would protect consumers and promote competition and would remove the ability of any manufacturer to entice doctors to with offers of increased profits by restricting consumer choice.

Thirty-nine state attorneys general said it best in endorsing the legislation:

> "We are very concerned that, unless all manufacturers abandon these restrictive distribution policies, the effect will be to harm consumers. Consumers will pay higher prices to purchase replacement lenses and may suffer adverse health consequences if the higher prices cause them to replace their lenses less frequently than recommended. Because of these risks, the restrictive distribution policies are undermining both the FCLCA and the MDL 1030 settlements."

Despite the fact that manufacturers market "doctors only" lenses on their utility in restricting competition and locking in consumers, a February 2005 FTC report concluded that the marketing practice does not appear to harm competition and consumers. The FTC study is flawed and best characterized as a snapshot in time of a contact lens market that no longer exists. The reason the FTC study found competition for most lenses is because 32 states sued to stop the three largest manufacturers (at the time) from colluding with eye doctors. H.R. 5762 seeks to codify these settlements before they expire in November of this year. The settlements have worked and have created a competitive market for the lenses made by the companies that are subject to it.

The fundamental flaw in the FTC report is its failure to adequately account for the two defining characteristics of the contact lens market – contact lenses are prescription devices and that eye doctors sell the lenses they prescribe.

We do not dispute the FTC economist's view that a manufacturer offering a retailer increased profits or exclusivity to promote the manufacturer's over-the-counter products is a sound and reasonable marketing strategy for the manufacturer. However, <u>39 state attorneys general do see a problem for consumers when manufacturers offer doctors increased profits to promote and prescribe a prescription product</u>.

The FTC's analysis ignores the fact that Federal law requires that a contact lens prescription is brand specific and must be filled with the same lens made by the same company as that specified by the doctor. Once a patient pays to be fitted and receives a prescription, if the lens is not available from her chosen retailer, there is no opportunity

for the patient to choose another lens made by another manufacturer without paying for another exam and contact lens fitting.

The FTC report is based on the assumption that Internet sellers denied direct access by the manufacture to "doctors only" lenses could obtain these lenses on the so-called "grey" market. Since the report was issued, the "grey" market for "doctors only" lenses has dried up. Every week, our company turns away thousands of consumers with valid prescriptions because we are not able to obtain the "doctors only" lenses prescribed by their doctor.

It is important to note that CooperVision assures doctors that its lenses are not available from non-prescribing retailers while at the same time assuring the FTC and Congress that its lenses are widely available from non-prescriber affiliated retailers.

CooperVision suggests that H.R. 5762 will adversely affect patient safety by requiring manufacturers to sell "doctors only" lenses to retailers not affiliated with eye doctors. The American Optometric Association (AOA) repeatedly made this same unsubstantiated claim in the multi-district lawsuit – in which it was a defendant. This argument was shown to be without merit. In fact, the AOA's settlement, Section 2(h) reads:

> "The AOA shall not represent directly or indirectly that the incidence or likelihood of eye health problems arising from the use of replacement disposable contact lenses is affected by or causally related to the channel of trade from which the buyer obtains such lenses."

In addition, the coordinated effort between CooperVision and the AOA appears to run afoul of the AOA's settlement, which clearly states in Section 2(e):

> "The AOA will resist any invitation by any contact lens manufacturer to enlist the AOA's aid in enforcing any manufacturer's distribution policy refusing to sell contact lenses to any channels of trade."

CooperVision's president, Greg Fryling, is quoted in his company's hometown newspaper, *The Rochester Democrat and Chronicle*, July 25th, 2006:

> "What we are also trying to do is push this more to optometrists and the American Optometric Association and have them present the case," Fryling said. "In our view, it's as much their battle as it is our battle."

It is odd for a manufacturer to publicly invite doctors to defend the manufacturer's restrictive distribution policy. The AOA appears to agree, and sent a letter to CooperVision (attached) regarding "an immediate concern of the American Optometric Association" – namely, "marketing materials for contact lenses that emphasize factors subordinate to what is clinically best for the health of the patient's eyes and vision" and asking CooperVision to "review your company's marketing and advertising policies." Even the AOA recognizes that it cannot openly support CooperVision's offer of financial incentives to doctors to promote and prescribe CooperVision lenses.

Medical doctors know that exclusive distribution deals between doctors and manufacturers are wrong. The American Medical Association code of ethics, 8.063, section 4 states:

> "Physicians should not participate in exclusive distributorship of health-related products which are available only through physician's offices. Physicians should encourage manufacturers to make products of established benefit more widely accessible to patients than exclusive distribution mechanisms will allow."

Despite their settlement with 32 states and the AMA code, the AOA is opposing a bill that would eliminate exclusive distributorships between eye doctors and manufacturers and protect consumer choice.

The AOA stated in a January 31, 2006 letter that "the AOA strongly endorses the idea that patients should be able to purchase their contact lenses from whomever they wish." And yet the AOA "strongly opposes" a bill which would protect the patient's right to do so. The bill does not limit what a doctor can prescribe for any patient. The bill does not limit the doctor's ability to sell any lens to any patient. The AOA cannot have it both ways. If they oppose a bill that has no affect on doctors and protects patient choice, then they oppose patient choice.

We ask the Committee to reaffirm the intent of the Fairness to Contact Lens Consumers Act - to allow consumers to fill their prescriptions for contacts where they choose. Thirty nine state attorneys general have signed a letter expressing the urgent need for this legislation in order to ensure the consumer protection intended by the FCLCA and the 32 state settlements (MDL 1030). Please pass HR 5762 and close this loophole before the settlements expire November 1st.

Mr. Chairman, thank you for the opportunity to testify. I would be pleased to answer any questions you may have.

MR. STEARNS. Thank you.

Mr. Fryling, welcome.

MR. FRYLING. Mr. Chairman, and distinguished members of the subcommittee. My name is Gregory Fryling. I am the Chief Operating Officer of CooperVision, which is the manufacturer of soft contact lenses based in Fairport, New York.

Let me begin by making a few central points about the nature of the competition in our industry. First, the contact lens is one of the most competitive pro-consumer industries in the country. Quality has steadily gone up, and prices, now less than 50 cents per day, have steadily gone down over the past decade.

Second, the contact lens sales at the manufacturing levels are characterized by extremely vigorous competition. We regularly negotiate distribution contracts under intense pressure from our competitors. The result is a wide variety of practices that benefits competition and consumers, such as private labels, discounts, special promotions.

Third, CooperVision has been successful because of our high quality products and our policy of choosing distributors carefully. Other major manufacturers spend a significant amount of money on national advertising to influence consumers, we do not. Consequently, we sell many of our products at lower prices. Our private label programs also allow us to compete against the branded competitors, and these lenses are usually sold at lower prices than the branded product. This competitive dynamic is good for the consumer.

Fourth, like other manufacturers, we choose distributors that preserve the reputation and image of our products for consumers. A Federal law that tends to force CooperVision to sell to all persons in a certain broad category would destroy this ability to control the quality and ensure service.

Finally, some have argued that legal modest restrictions on the distribution have undercut Congress' goal in passing the Fairness to Contact Lens Consumers Act. This claim is far off the mark. The FTC conducted an exhaustive study of the contact lens distribution and found that the evidence does not support the conclusion that these restrictions on the distribution harms competition and consumers. The premise that there is a problem that needs to be fixed in the contact lens is simply not supported by facts, and I am hoping later on that I can give you specific facts that support this rather than assumptions that were being presented earlier.

I want to also address claims that have been made about CooperVision distribution practices, particularly the claim that one popular family of CooperVision lens, ProClear, is sold only to doctors. This claim is false. In addition to sales to prescribers, ProClear is sold to over 30 retail chains, including Wal-Mart, Sears, Costco, and many others which offer lenses to consumers at low prices at over 10,000 convenient locations.

The FTC looked specifically at ProClear Compatibles and found that the data does not support an inference that manufacturing limited distribution strategy affects the pricing of ProClear Compatibles.

CooperVision has been hesitant to sell ProClear lenses to Internet suppliers and the retail outlets that have no relations with prescribers. ProClear has a special FDA approval for late day dryness, and we are very anxious to preserve the reputation of these lenses for high quality.

We have also had the unfortunate experience of sales of counterfeit ProClear lenses on the Internet by 1-800 Contacts. I am not saying that 1-800 Contacts knew these lenses were counterfeit, but they endangered patients' eye health and risked harm to the reputation of this product and the entire company.

Despite this experience, we have recently reviewed our policy of selling ProClear to Internet suppliers and have decided to offer these lenses to certain Internet suppliers, provided that certain assurance of quality and services can be met. For example, we have made an offer to sell these lenses to 1-800 Contacts in the near future, and we are currently in negotiations over this contract.

Let me comment on an important issue of patient safety.

As you know, contact lenses are a medical device regulated by the Food and Drug Administration, and manufacturers must monitor sales and take action if patient safety issues arise. For example, Bausch & Lomb recently recalled a contact lens solution brand due to the risk of fungal infection. And recently in France, CooperVision and Johnson & Johnson worked together with the health and legal authority to stop the sale of counterfeit contact lenses and to trace their source.

Our ability to choose high quality distributors is critical to preventing patient safety problems and to effectively remedy problems that may arise.

I understand that this hearing does not specifically focus on the bill, H.R. 5762, but I would like to comment briefly on the problem with this undoubtedly well-intentioned bill.

A fundamental problem is the attempt to impose intrusive regulations on distribution decisions that have historically been left to the free market. While antitrust laws bar manufacturing from colluding in their choice of distributors, neither the Federal government nor the State governments have required manufacturers to sell to everyone. To do so would surely hurt consumers by undermining quality and service.

Second, the bill undercuts competition. The bill requires manufacturers to sell to everyone in several categories in a nondiscriminatory manner. I cannot stress enough that a law barring discrimination is harmful to competition by potentially foreclosing competitive practices that are followed widely in our industry and many others, including volume discounts, private label arrangement, special promotion, individually negotiated discounts, and so on.

Third, the bill creates regulatory chaos. Manufacturers are required to sell to every mail order company, Internet retailer, pharmacies, buying clubs, department stores, or mass merchandising outlets. None of these terms is defined. Confusion and arbitrary enforcement would be the inevitable result.

Ultimately, bill 5762 represents a solution to a problem that does not exist. It is no surprise that of all the States to have considered similar legislation at 1-800's urging, only Utah, 1-800's home State, has passed the bill. The House rejected 1-800 proposed legislation in 2005 when it was included in the Senate appropriation measure, and I urge the House to do so again.

Thank you for holding this important hearing and allowing CooperVision to participate.

[The prepared statement of Mr. Fryling follows:]

PREPARED STATEMENT OF GREGORY A. FRYLING, CHIEF OPERATING OFFICER, COOPERVISION, INC.

Mr. Chairman and Distinguished Members of the Subcommittee:

My name is Gregory Fryling. I am Chief Operating Officer of CooperVision, Inc., which is a manufacturer of soft contact lenses based in Fairport, New York. CooperVision sells contact lenses throughout the United States and in many other countries. Thank you for this opportunity to discuss possible federal regulation of contact lens distribution.

The Contact Lens Industry

Let me begin by making four central points about the nature of competition in our industry. First, the contact lens industry is one of the most competitive, pro-consumer industries in the country. Quality has steadily gone up and overall wholesale prices have gone down over the past decade. There are literally hundreds of different lenses available to consumers, and the technology for correcting all kinds of vision problems with comfortable, long-wearing lenses has continued to improve.

Second, contact lens sales at the manufacturing level is characterized by extremely vigorous competition. We regularly negotiate distribution contracts under intense pressure from our competitors. These negotiations take place, as they should, behind closed doors so that there is no opportunity for collusion. The result is a wide variety of practices that benefit competition and consumers, such as private labels, discounts, special promotions, and other common practices that economists and antitrust lawyers will recognize are the signposts of a vigorously competitive market. For example, the major proponent of legislation to regulate contact lens distribution, 1-800 Contacts, has recognized the values of private labels and uses them widely in its sales in Europe. That is good for consumers in Europe, but it seems 1-800 Contacts wants to restrict these practices in the United States.

Third, there are four major contact lens manufacturers in the United States and a number of smaller ones, including some foreign firms that sell into the U.S. We started as a small company competing against the large companies. CooperVision has been successful because of our high-quality products and our policy of choosing distributors carefully. The other major manufacturers spend significant amounts on national advertising to consumers. CooperVision does not. Consequently, we sell many of our products at lower prices. Our private label program also allows us to compete against the branded competitors, and these lenses are usually sold at lower prices than the branded products. This competitive dynamic is good for consumers.

Fourth, we want to sell as many lenses as possible, but we also want to ensure that our distributors provide high quality service, comply with all federal and state laws, and preserve the reputation of our lenses for excellent quality at a great price. Like other manufacturers, we choose distributors that preserve the reputation and image of our product for consumers. A federal law that attempts to force CooperVision to sell to all persons in several broad categories would destroy this ability to control quality and ensure service. It will hurt consumers, not help them.

Finally, some have argued that legal, modest restrictions on distribution have somehow undercut Congress's goals in passing the Fairness to Contact Lens Consumers Act. That claim is far off the mark. The FCLCA and the FTC's rule implementing it are good for consumers and CooperVision strongly supports them. But there is no indication in the text of the law or the legislative history that Congress intended to force manufacturers to distribute lenses to anyone who wants to be a distributor. That kind of intrusive regulation is completely unprecedented in federal or state law, with the sole exception of Utah, which coincidentally happens to be the home state of 1-800 Contacts.

The question is whether restrictions on distribution so limit choice that consumers are hurt. The answer to that is clearly no. In response to the claim by 1-800 Contacts that these restrictions harm consumers, the FTC conducted an exhaustive study of contact lens distribution. It expressly rejected this argument in a study released in February 2005. The FTC found that the evidence does "not support the conclusion that these restrictions on distribution harm competition and consumers."[1]

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[1] *The Strength of Competition in the Sale of Rx Contact Lenses: An FTC Study,* Federal Trade Commission, February 2005*, available at* http://www.ftc.gov/opa/2005/02/contactlens.htm (the "FTC Study").

CooperVision's Distribution Practices

A number of claims have been made about CooperVision's distribution practices, particularly the claim that one popular family of CooperVision's lenses, Proclear, is sold only to doctors. The suggestion is that consumers have nowhere to go after they get a prescription for Proclear and, consequently, the prescribing optometrist or ophthalmologist can jack up the price. This is supposed to be a "loophole" in the FCLCA.

This claim bears no relationship to the facts. Proclear is sold to over 30 retail chains, including Wal-Mart, Sears, Costco and many others, which make up over 10,000 retail outlets. These retail chains are shown in the Attachment to my testimony. These chains are convenient to consumers, offer low prices, and have the ability to drive hard bargains with manufacturers.

In response to complaints from 1-800 Contacts, the FTC looked specifically at Proclear Compatibles, the CooperVision contact lens that 1-800 Contacts has repeatedly identified as a "limited distribution lens." The FTC report found that CooperVision or its authorized distributors sell Proclear Compatibles to retailers ranging from independent eye care professionals, to optical chains, to wholesale clubs, and to mass merchandisers.[2] An FTC sample found these lenses were available to consumers in 86 percent of offline outlets sampled and 88 percent of pure online outlets sampled.[3] Most importantly, the FTC found that whatever modest restrictions are placed on the distribution of these lenses do not harm competition or consumers. The FTC found that the data "do not support an inference that the manufacturer's limited distribution strategy affects the pricing of Proclear Compatibles."[4]

It is true that CooperVision has historically been hesitant to sell Proclear lenses to Internet suppliers and to retail outlets that have no relationship with prescribers. Proclear has a special FDA approval for late-day dryness, which is a medical condition that requires identification by qualified eye care professional when the prescription is written, and we are very anxious to preserve the reputation of these lenses for high quality. Internet suppliers present potential concerns since they may have no optician on staff for any consultation and there has been a record of some Internet companies failing to actively review prescriptions. In addition, we have had an unfortunate experience of counterfeit sales of Proclear by at least one major Internet supplier, 1-800 Contacts. I am not saying that 1-800 Contacts knew these lenses were counterfeit, but these sales endangered patients' eye health and had the potential to harm drastically the reputation of both Proclear and CooperVision itself. We have recently reviewed our policy of selling Proclear to Internet suppliers and are considering providing these lenses to approved Internet suppliers, provided that certain conditions can be met, including assurances of quality and service. For example, we have made an offer to 1-800 Contacts to begin selling Proclear lenses to them in the near future and we are currently in negotiations over a contract.

Patient Safety

It is essential that contact lens manufacturers, like manufacturers in other industries, retain the ability to choose reputable distributors that have ethical, efficient, and safe business practices. This allows manufacturers to protect and promote quality and insure the reputation of their products. It is important to remember that contact lenses are medical devices regulated by the Food and Drug Administration, and manufacturers must monitor sales and take action if a patient safety issue arises. For example, Bausch & Lomb recently recalled a contact lens solution brand due to a risk of fungal infection.

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[2] FTC Report at 16.
[3] FTC Report at 26.
[4] FTC Report at 14.

And recently in France, CooperVision and Johnson & Johnson worked together with health and legal authorities to stop the sale of counterfeit contact lenses and to trace their source. Therefore, the ability to choose high-quality distributors is critical to preventing patient safety problems and to effectively remedying problems that might arise.

The Problems with H.R. 5762

I understand that this hearing does not specifically focus on H.R. 5762, as introduced by Congressman Terry. However, since that is the only bill addressing contact lens distribution that has been introduced in the House, I would like to discuss briefly some of the problems with this undoubtedly well-intentioned bill.

The fundamental flaw in the bill is its attempt to impose intrusive regulation on distribution decisions that have historically been left to the free market. The antitrust laws bar manufacturers from *colluding* in their choice of distributors. However, neither the federal government nor state governments have *required* manufacturers to sell to anyone who wants to buy their product. For example, there is no law requiring automobile manufacturers to sell their cars to anyone who wants to own a car dealership even though many consumers would like to have a dealership near their home or purchase a car on the Internet. Taking away the right of manufacturers to choose distributors would represent a drastic and harmful change in the legal environment.

Second, H.R. 5762 will undercut competition. The bill requires manufacturers to sell to everyone in several distribution categories and to treat them in a "commercially reasonable" and "nondiscriminatory manner." I cannot stress enough that a law barring "discrimination" in sales is harmful to competition by potentially foreclosing competitive practices that are now followed widely in our industry and many others, including volume discounts, private label arrangements, special promotions, individually negotiated discounts, and so on.

The Robinson-Patman Act already prohibits certain types of price discrimination, but it has a number of defenses and exceptions, including, for example, a meeting competition defense. Most antitrust lawyers and economists will tell you that Congress did no favors for consumers by passing the Robinson-Patman Act, but at least manufacturers can live with it because of the available defenses. H.R. 5762 contains none of these. The result is one the most highly regulatory and intrusive proposals one can imagine. If a manufacturer refuses to sell to anyone in these categories, it is subject to civil penalties. If a manufacturer tries to negotiate a discount with a customer, other retailers can claim "discrimination." If a manufacturer tries to sell a lens under a private label to a discount chain — a common industry practice that lowers prices to consumers — other potential distributors can also claim "discrimination." As I discussed earlier, these practices greatly benefit consumers and competition.

Third, the bill is a recipe for regulatory chaos. Manufacturers are required to sell to every "mail order company, Internet retailer, pharmacy, buying club, department store, or mass merchandise outlet." None of these terms is defined. Wal-Mart is certainly covered by the bill as a "mass merchandise outlet," but it is not clear whether a small convenience store qualifies. Similarly, does a "buying club" that is set up by a few friends qualify for protection under the bill? Does everyone who sets ups an Internet website and wants to sell lenses qualify as an "Internet retailer"? If Congress mandates this intrusive, poorly thought-out regulatory program, confusion and arbitrary enforcement are the inevitable result.

Finally, H.R. 5762 will promote litigation. If a manufacturer turns down a retailer who wants to sell its lenses, the retailer can demand that the FTC enforce these provisions by bringing an action against a manufacturer. The FTC will then have to decide whether to investigate these charges. In states where state law allows a private action based on an alleged violation of FTC standards, a disappointed retailer may file a lawsuit alleging that a manufacturer has failed to sell lenses to it. The courts will then have to police

distribution decisions that have historically been left to manufacturers' business judgment. Ultimately, this confusion and potential litigation could prevent some lenses from being available to consumers.

Conclusion

In conclusion, this bill is bad for consumers and competition by reducing the quality of service, by reducing price competition, and by creating a regulatory nightmare that will promote litigation. It would force the FTC to implement a burdensome and costly regulatory program and to become involved in policing decisions that have historically been left to the free market.

Ultimately, H.R. 5762 represents a solution to a problem that does not exist. It is no surprise that of all the states to have considered similar legislation at 1-800's urging, only Utah—1-800's home state—passed the bill. The FTC has already rejected 1-800's arguments. Former senior FTC officials and economic experts have concluded that the legislation pushed by 1-800 at the federal level would "likely lead to lower quality service and less promotional activity and potentially higher prices."[5] And the House already rejected 1-800's proposed legislation in 2005 when it was included in a Senate Appropriations measure. We urge the House to do the same this year.

Thank you for holding this important hearing and allowing CooperVision to participate.

[5] Froeb & Zywicki Analysis at 3.

Attachment. Retail Chains Selling Proclear

Chain	Number of Outlets
Cohens Optical	68
Eye Masters	67
EyeMart Express	65
GVS	42
Lenscrafters	823
National Vision Inc	400
Novamed	100
Pearle Vision Centers	802
Site for Sore Eyes	21
Sterling Optical	105
Vision Source LP	1500
Wal-Mart	2246
ABC	110
Cole	Duplicate as Sears
Costco	345
Doctors Optical Center	125
Doctors Vision Center	80
ECCA	320
Empire Vision	89
Eye Glass World	60
For Eyes	120
Nationwide	55
Nephew's Group	12
Sears	880
OECC	50
BJ's Optical	143
Group Health	9
Henry Ford Optimeyes	20
Kaiser	110
Moresi/Blum	35
Sam's Club	475
Shopko	140
Target	240
United Optical	60
US Vision	550

MR. STEARNS. Thank you.

Mr. Schein, Dr. Schein.

DR. SCHEIN. Thank you, Chairman Stearns, Ranking Member Schakowsky, and distinguished committee members for inviting me here to testify on the Contact Lens Consumer Protection Act.

My name is Oliver Schein. I am Professor of Ophthalmology at the Wilmer Eye Institute of John Hopkins University School of Medicine. I am a specialist in corneal diseases, and my research expertise is in public health and blindness prevention.

Contact lenses are the most commonly used medical devices in the United States, and I have spent many years studying complications associated with these contact lenses.

I am here today as a member of the American Academy of Ophthalmology, the largest national membership association of IMDs. IMDs are medical doctors who provide comprehensive medical, surgical, and optical care. More than 90 percent of the 17,000 IMDs in the United States are members of the Academy of Ophthalmology.

The Contact Lens Consumer Protection Act, H.R. 5762, seeks to amend Public Law 108-164, the Fairness to Contact Lens Consumers Act. H.R. 5762 requires contact lens manufacturers to make any contact lens they produce, market, distribute, or sell available to specified alternative channels of distribution, such as mail order companies, Internet retailers, pharmacies, buying clubs, department stores, and mass merchandise outlets.

Under this system, no limited distribution programs could be implemented by any contact lens manufacturer. As part of the Fairness to Contact Lens Consumers Act, the FTC was required to examine consumers' access to contact lens, and the study states, in quotations, "it does not support the hypothesis that sellers are able to limit competition or harm consumers by charging higher prices for limited distribution or private label lenses."

After nearly 2 years of experience with the Contact Lens Rule, the American Academy of Ophthalmology remains concerned that particular provisions in the rule place the eye health of America's more than 30 million contact lens wearers at risk. Of principal concern is the so-called passive verification of contact lens prescriptions. Unfortunately, under the current rule, a contact lens prescription can be dispensed simply because a prescriber fails to communicate with the seller within 8 business hours after a seller has contacted the prescriber for the purpose of verifying a contact lens prescription. This is what we refer to as passive or default contact lens prescription verification. In practical terms, contract lens sellers treat a nonresponse from a prescriber in exactly the same manner as they would a positive response. The contact lens in both instances are dispensed to the consumer. In other words, the prescription is dispensed unless the seller is told otherwise within 8 business hours.

The entire concept of passive or default verification is unprecedented in medical practice. Prescriptions for pharmaceuticals and all other medical devices are positively identified. Contact lenses are medical devices and as such are regulated by the FDA. The Academy believes that in the interest of patient safety contact lens prescriptions should also be positively verified prior to being dispensed to the contact lens wearer.

When a contact lens wearer is required to present a new or current prescription to order contact lenses, it increases the likelihood that the patient will undergo an ophthalmic evaluation by an eye care professional. This in turn increases the likelihood of compliance with appropriate hygiene protocols.

It is critical that all contact lens wearers receive professional eye care on a regular basis, at the very least to reinforce good contact lens hygiene practices and for early detection and prevention of adverse events.

Mr. Chairman, under the current Contact Lens Rule, the potential for serious sight threatening ocular injury occurring as a direct result of passive verification of contact lens prescriptions is significant and real. In fact, the leading cause of consumer product related trauma is in fact the contact lens. The responsible and ethical contact lens practitioner endeavors to optimize the safety and comfort of his or her patients by first evaluating the patient, fitting the lenses, and then managing the patient's contact lens wear. Accordingly, ongoing periodic evaluations after the initial prescription are very important to the patient's overall eye health. However, because patients can obtain replacement lenses so easily from online providers, they often neglect follow-up examination.

One of my colleagues recently reported that a 45-year-old patient had his contact lenses dispensed by a contact lens seller for 3 years without an eye examination. The patient presented in August 2005 with a severe bacterial corneal ulcer requiring a 3-day hospitalization. Nine months later the corneal scars still exists with diminished visual acuity to 20/30.

As recently as last week I treated a college student in Baltimore with a severe contact lens related keratitis. She obtains her contact lenses from Internet sources and has not had regular eye care in several years. When I investigated her contact lens hygiene practices, I learned that she has used the same small bottle of cleaning solution for more than 3 years. Whenever it approaches being empty, she simply refills it from a larger bottle. The same bacteria that we harvested from her cornea were grown from that small bottle.

These sorts of stories are familiar to corneal specialists across the United States. The implication is not that Internet purchase causes such infections, it is that Internet purchase reduces the likelihood of periodic examinations and review of a sound contact lens practice.

Since the Contact Lens Rule went into effect in August of 2004, dispensers have compiled a long history of verification abuses that consistently place sales before patient safety.

Extended wear lenses are regulated as Class III devices, which is the most highly regulated FDA medical device category. Passive or default verification of contact lens prescriptions undermines the status of contact

lenses as FDA regulated devices and in essence denigrates the need for a prescription at all. Passive verification is a flaw in the FCLCA that the American Academy of Ophthalmology believes lowers the bar for patient safety and opens the door for prescription verification failures that can ultimately result in patient harm. Unless the seller has a copy of the prescription or it has been positively verified by the doctor, any other verification system seems at odds with the FDA's medically-based decision to regulate contact lenses as medical devices. The Academy of Ophthalmology remains hopeful that Congress will put the ocular health of America's contact lens wearers first by reexamining this practice and occurrence of passive or default contact lens prescription verification, and then opting to eliminate them altogether. Thank you.

[The prepared statement of Dr. Schein follows:]

PREPARED STATEMENT OF DR. OLIVER D. SCHEIN, M.D., M.P.H., BURTON E. GROSSMAN PROFESSOR OF OPHTHALMOLOGY, JOHNS HOPKINS UNIVERSITY, ON BEHALF OF THE AMERICAN ACADEMY OF OPHTHALMOLOGY

Thank you, Chairman Stearns, ranking member Schakowsky, and distinguished committee members for inviting me here to testify on the Contact Lens Consumer Protection Act.

I am Dr. Oliver Schein. I am a Professor of Ophthalmology at the Wilmer Eye Institute of Johns Hopkins University School of Medicine. I am a specialist in corneal diseases, and my research expertise is in public health and blindness prevention. Contact lenses are the most commonly used medical devices in the United States, and I have spent many years studying complications associated with contact lenses. I am here today as a member of the American Academy of Ophthalmology, the largest national membership association of Eye M.D.s. Eye M.D.s are medical doctors who provide comprehensive medical, surgical, and optical eye care. More than 90 percent of the 17,000 practicing Eye M.D.s in the United States are members of the Academy

The *Contact Lens Consumer Protection Act (H.R. 5762),* seeks to amend Public Law 108-164, the Fairness to Contact Lens Consumers Act (FCLCA). H.R. 5762 requires contact lens manufacturers to make any contact lens they produce, market, distribute, or sell available to specified alternative channels of distribution such as mail order companies, Internet retailers, pharmacies, buying clubs, department stores, and mass merchandise outlets. Under this system, no limited distribution programs could be implemented by any contact lens manufacturer.

As part of the Fairness to Contact Lens Consumers Act (FCLCA), the Federal Trade Commission was required to undertake a study[1] to examine the strength of competition in the sale of prescription contact lenses.

The study included these issues:

1. Incidence of exclusive relationships between prescribers or sellers and manufacturers and the impact (if any) of such relationships and competition
2. Difference between online and offline sellers of contact lenses, including price, access, and availability
3. Incidence of, as well as the effect on consumers and competition of contact lens prescriptions that specified brand name or custom labeled lenses

[1] The Strength of Competition in the Sale of Rx Contact Lenses: An FTC Study, February 2005

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

In February of 2005, the Federal Trade Commission submitted the results of that study to Congress and concluded:
"Our examination of these issues – exclusive relationships, private label lenses, and limited distribution lenses – suggests that such relationships are not prevalent in the market for contact lenses and are unlikely to limit competition and harm consumers.

Exclusive relationships are rare; private label lenses, while more common, still represent a small portion of all sales of soft contact lenses; and limited distribution policies are not widely used. Moreover, our inquiry showed that a common, limited distribution lens, or its private label equivalent, was available from the overwhelming majority of outlets sampled.

Given that the FCLCA permits sellers to fill prescriptions with equivalent national brand or private label lenses, consumers have a number of channels through which to obtain such lenses. In addition, these relationships may be an efficient way for manufacturers to provide beneficial incentives to their lens distributors, which in turn may lead to increased competition among various brands of lenses.

In sum, the theory and the evidence examined do not support the conclusion that these distribution practices harm competition and consumers by allowing prescribers to lock in their patients to supracompetitively priced lenses".

In light of these findings, the American Academy of Ophthalmology wonders why there would be any need for *H.R.5762*.

The Fairness to Contact Lens Consumers Act was signed into law on December 6, 2003 and took effect on February 4, 2004. The Federal Trade Commission issued its Contact Lens Rule to implement the Act on June 29, 2004 and the Rule became effective on August 2, 2004. After nearly two years of experience with the Contact Lens Rule, the American Academy of Ophthalmology remains concerned that this rule places the eye health of America's contact lens wearers at risk.

Of principal concern is the so-called "passive verification" of contact lens prescriptions. Mr. Chairman, the entire concept of "passive" or "default" prescription verification is unprecedented in medicine. Prescriptions for pharmaceuticals and all other medical devices are positively verified. Contact lenses are medical devices and as such, are regulated by the FDA. The Academy believes that in the interest of patient safety, contact lens prescriptions should also be positively verified prior to being dispensed to the contact lens wearer.

Unfortunately, under the current the rule, a contact lens prescription can be dispensed simply because a "prescriber fails to communicate with the seller within eight business hours" after a seller has contacted the prescriber for the purpose of verifying a contact lens prescription. In practical terms, contact lens sellers treat a non-response from a prescriber in exactly the same manner as they would a positive response; the contact lenses in both instances are dispensed to the consumer. In other words, the prescription is dispensed unless the seller is told otherwise.

Prescriptions for pharmaceuticals and all other medical devices are positively verified and are not dispensed until the prescription is determined to be valid by the dispenser and in many if not all instances, the DEA or Medical License number of the prescribing physician is determined to be legitimate. Mr. Chairman, under the current Contact Lens Rule, the potential for serious sight threatening ocular injury occurring as a direct result of the passive verification of contact lens prescriptions is significant and real.

The potential for injury is real because we know that the leading cause of consumer product-related ocular trauma is from contact lenses[2].

There is little doubt that the passive or default verification of contact lens prescriptions increases the likelihood that expired or inaccurate prescriptions will ultimately be dispensed to consumers. This likelihood is increased when some contact lens sellers make it difficult, if not impossible, to be contacted by prescribers who are trying to inform the seller that the prescription in question is not valid or inaccurate and therefore should not be dispensed. The inability of dispensers to be contacted by prescribers is a clear violation of the FCLCA and FTC, to date, has issued several warning letters to dispensers requesting that they provide prescribers with a reasonable opportunity to communicate with them regarding prescription verification requests.

Mr. Chairman, what concerns me as an ophthalmologist is the possibility that countless contact lens prescriptions that are expired, are being dispensed by sellers as a result of "passive" or "default" verification.

The responsible and ethical contact lens practitioner endeavors to optimize the safety and comfort of his or her patients by first evaluating the patient, fitting the lenses and then managing the patient's contact lens wear. Accordingly, ongoing periodic evaluations after the initial prescription are very important to the patient's overall eye health. However, because patients can obtain replacement lenses so easily from online providers, they often neglect follow-up exams.

Unlike glasses, with contact lenses there is a greater opportunity to endanger your eye health. Poorly fit contact lenses, along with poor maintenance and hygiene leave patients susceptible to corneal inflammation, bacterial, and other infections that can ultimately be sight threatening.

It is not uncommon for an eye care professional to see patients that have not maintained periodic follow up evaluations. Such patients typically present with an assortment of chronic corneal conditions that could easily have been prevented or ameliorated by regularly scheduled evaluations by an eye care professional.

There is consensus in eye care practice that there is a direct correlation between non-compliance and poor hygiene practices and contact lens related adverse events. Moreover, it is understood that 50 percent of all contact lens wearers, to some degree, are non-compliant with the hygiene instructions that they DO receive so it should come as no surprise that up to 80 percent of contact lens complications can be traced to poor patient compliance with recommended lens care guidelines[3]. Mr. Chairman, these statistics underscore the importance of regularly scheduled evaluations for contact lens wearers and why the dispensing of expired contact lens prescriptions by way of passive verification undermines patient safety.

When a contact lens wearer is required to present a new or current prescription to order contact lenses, it increases the likelihood that the patient will undergo an ophthalmic evaluation by an eye care professional. This, in turn allows for the early detection of contact lens-associated adverse events. It also provides the opportunity to evaluate and improve the patient's compliance with optimal hygiene protocols. It is important that all contact lens wearers receive professional eye care on a regular basis, at the very least, to reinforce good contact lens hygiene practices.

One of my colleagues recently reported that a 45 year-old patient had his contact lenses dispensed by a contact lens seller for *three years* without an eye exam. The patient presented in August of 2005 with a severe bacterial corneal ulcer, requiring a three day hospitalization. Nine months later, the corneal scar still exists with diminished visual acuity to 20/30. As recently as last week, I treated a college student in Baltimore with a severe contact lens-related keratitis. She obtains her contact lenses from internet sources

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[2] Consumer Product-Related Ocular Trauma, Claude L. Cowan Jr., MD, et al, Washington, DC

[3] Clinical Survey of Lens Care in Contact Lens Patients, Susan Stenson, MD, et al

and has not had regular care in several years. When I investigated her contact lens hygiene practices, I learned that she has used the same small bottle of cleaning solution for more than 3 years. Whenever, it approached being empty, she refilled it from a larger bottle. The same bacteria growing in her cornea was cultured from that small bottle. These sorts of stories are familiar to corneal specialists across the United States. The implication is not that internet purchase causes such infections. It is that internet purchase reduces the likelihood of periodic examinations and review of sound contact lens practice.

Extended wear lenses, are regulated as class-three medical devices, which is the most highly regulated FDA medical device category. Passive or default verification of contact lens prescriptions undermines the status of contact lenses as FDA regulated devices and in essence, denigrates the need for a prescription at all. Passive verification is a flaw in the FCLCA that the American Academy of Ophthalmology believes lowers the bar for patient safety and opens the door for prescription verification failures that can ultimately result in patient harm. Unless the seller has a copy of the prescription or it has been positively verified by the doctor, any other verification system seems at odds with FDA's medically based decision to regulate contact lenses as medical devices.

In conclusion, the ocular health of consumers should not be placed at risk by methods used by contact lens sellers that are designed solely to augment the sales and dispensing of contact lenses. Since the Contact Lens Rule went into effect in August 2004, dispensers have compiled a long history of verification abuses that consistently place contact lens sales before patient safety.

The American Academy of Ophthalmology remains hopeful that Congress will put the ocular health of America's contact lens wearers first by re-examining the practice and occurrence of passive or default contact lens prescription verifications and then opting to eliminate them altogether.

Oliver D. Schein, M.D.,M.P.H.
Burton E. Grossman Professor of Ophthalmology Johns Hopkins University
American Academy of Ophthalmology

MR. STEARNS. Thank you.

And Dr. Curtis, welcome.

DR. CURTIS. Thank you.

Good morning, Mr. Chairman and Ranking Member Schakowsky and members of the subcommittee.

I am Dr. Wiley Curtis, a member of the American Optometric Association, the AOA, and a private practice optometrist from Arlington, Texas.

On behalf of the 35,000 members of the AOA, America's frontline providers of eye and vision care, I want to thank you for this opportunity to appear at today's hearing.

The AOA was pleased to have played a very positive role in the debate over the contact lens law enacted in 2003, the Fairness to Contact Lens Consumers Act, the FCLCA. The AOA supported the legislation because we felt it tried to balance the patient's ability to get their prescription with the need to assure that only properly verified prescriptions are filled. In fact, then Congressman Richard Burr, the sponsor of the FCLCA, specifically recognized the AOA in remarks on

the floor of the House of Representatives during the final consideration of the FCLCA bill.

Since then, the AOA has taken a leading role in educating its members about full compliance with the FCLCA. Our education materials have been reviewed and even praised by the FTC. The primary concerns of the AOA and its members today are the same ones we referenced before this panel in 2003, only now we have clear evidence that those concerns have materialized in a tangible form.

We do not want to see any interference with the ability of patients to get their prescriptions and purchase their lenses wherever they choose. We do want to make certain, however, as the FCLCA envisioned, that lenses being sold by Internet and mail order sellers are being sold upon verification with a valid prescription. The contained outbreak this year of fungal keratitis among some contact lens wearers underscores the fact that contact lenses are indeed prescription medical devices and can cause serious injury when improperly fitted, worn, or cared for.

Just last year, after reviewing cases in which consumers were harmed by the improper use of decorative noncorrective lenses that were widely available online or at flea markets, Congress took decisive action to safeguard public health. The passage of the Boozman-Barton-Waxman bill, now Public Law 109-96, provides for the regulation of all contact lenses as a medical device by the Food and Drug Administration and requires that such lenses only be sold pursuant to a doctor's examination and prescription, just like corrective contact lenses.

Optometrists remain particularly proud of this leadership role played by our colleague and your colleague, Dr. John Boozman, in making this a priority issue on Capitol Hill and helping to get it to the President's desk.

It is the very real potential for harm when contact lenses are worn improperly that makes the prescription verification safeguards the most important part of the FCLCA. With this in mind, I will offer my own experiences and the AOA's recommendation for strengthening the law.

First, though, I know that there has been discussion of so-called doctor-only lenses. Senator Bennett and Congressman Terry have introduced legislation seeking to make changes to the FCLCA to govern how contact lenses may be marketed by their manufacturers. Congressman Terry, a long time friend of our profession, has informed my Nebraska colleagues that he would welcome a hearing from optometry on how his bill can be improved. We are most appreciative of that and of his leadership in health care policy issues. With regard to the competition issues, I will expect to look to the FTC today to provide any relevant updates to their findings.

I would like now to return to the issue of prescription verification. Simply stated, we believe that the time has come for some common sense and pro-patient updates to the prescription verification safeguards included in the FCLCA. Here is why. We are seeing contact lens orders being filled by sellers without any verification of the prescription by the prescribing optometrist. We are seeing contact lens prescriptions being refilled well beyond the time period that the prescription in question is valid. We are seeing sellers use mechanisms like automated calling systems to verify prescriptions which impose needless burdens on the doctors who want to communicate important patient information to the seller.

Some of my own experiences are very relevant to this discussion. Over the course of this year I have tracked 18 contact lens orders placed with 1-800 Contacts. I am saddened to report that the first 17 orders were all filled by the company without any verification contact with my office, in an apparent violation of the FCLCA: No contact through the telephone, no contact through the fax machine, and no contact through e-mail. A subsequent order, the 18th, did generate a live automated telephone call request for a patient's prescription to be verified. Nevertheless, since then, I am aware of additional cases in which patients received contact lenses through my office and my office was not contacted for a verification request.

I hope we can all agree that these results fall well short of what this committee intended when it crafted prescription verification safeguards for patients in the FCLCA. That is why the AOA is encouraging Congress to examine the practices used by sellers and take the following corrective actions: Allow eye care providers the opportunity to receive verification requests from sellers through e-mails and faxes rather than automated telephone calls; ensure that all patient health considerations raised by an eye care provider are addressed by the seller before a contact lens order is filled; to increase the fines that could be imposed by the FTC on an unscrupulous contact lens sellers that would violate the law and endanger patients.

These proposals are contained in legislation being crafted by Representative Ed Whitfield, the Chairman of the Oversight and Investigation Subcommittee. Optometry--and I am pleased to report ophthalmology--both support Congressman Whitfield's bill and his efforts to ensure that patients come first.

Thank you for this opportunity to present this testimony.

[The prepared statement of Dr. Curtis follows:]

PREPARED STATEMENT OF DR. WILEY CURTIS, O.D., MEMBER, AMERICAN OPTOMETRIC ASSOCIATION

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Summary of Testimony Presented by Dr. Wiley Curtis, American Optometric Association
Energy and Commerce Subcommittee on Commerce, Trade and Consumer Protection
September 15, 2006

The American Optometric Association (AOA) played a positive role in the debate over the contact lens law enacted in 2003, the Fairness to Contact Lens Consumers Act (FCLCA). The AOA supported the legislation because it sought to balance the patient's ability to get his or her prescription with the need to assure that only properly verified prescriptions are filled.

The primary concerns of the AOA and its members today are the same ones we referenced before this panel in 2003, only now we have clear evidence that those concerns have materialized in tangible form. The AOA does not want to see any interference with the ability of patients to get their prescriptions and purchase their lenses wherever they choose. We do want to make certain however, as the FCLCA envisioned, that lenses being sold by Internet and mail order sellers are being sold upon verification that a valid prescription exists.

In spite of advances in safety and convenience, contact lenses are a medical device and must always be treated as such. The outbreak this year of fungal keratitis among some contact lens wearers underscores the fact that contact lenses are indeed prescription medical devices that can cause serious injury when improperly fitted, worn or cared for. The passage in 2005 of the "Boozman-Barton-Waxman" bill, now Public Law 109-96, provides for the regulation of all cosmetic contact lenses as medical devices by the Food and Drug Administration, and requires that such lenses only be sold pursuant to a doctor's examination and prescription, just like corrective contact lenses.

In spite of patient safeguards included in the FCLCA, optometrists are reporting serious violations of the law by Internet and mail order sellers:

- Contact lens orders being filled without verification of a prescription.
- Contact lens prescriptions being overfilled, beyond the time period the prescription in question is valid.
- Attempting to limit prescriber-seller communications on patient health concerns, including through the use of automated calling systems.

The time has come for some common-sense and pro-patient updates to the prescription verification safeguards included in the FCLCA. The AOA supports:

- Allowing eye care providers the opportunity to receive verification requests from sellers through e-mails or faxes, rather than automated telephone calls.
- Ensuring that all patient health considerations raised by an eye care provider are addressed by the seller before a contact lens order is filled.
- Increasing penalties to be imposed on unscrupulous contact lens sellers that violate the law and endanger patients.

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Good morning Mr. Chairman, Ranking Member Schakowsky and members of the subcommittee. I am Dr. Wiley Curtis, a member of the American Optometric Association (AOA) and a private practice optometrist serving patients in Arlington, Texas and surrounding communities.

On behalf of the 35,000 members of the AOA, America's frontline providers of eye and vision care, I want to thank you for the opportunity to appear at today's hearing. It is

a pleasure to have a chance to report to you on the contact lens prescription verification practices of the online and mail order contact lens sales industry, and the concerns I have regarding their impact on the visual health and well-being of my patients and the patients of my colleagues in communities across the country.

The AOA was pleased to be very actively involved and to have played a very positive role in the debate over the contact lens law enacted in 2003, the Fairness to Contact Lens Consumers Act (FCLCA). The AOA supported the legislation because we felt it tried to balance the patient's ability to get his or her prescription with the need to assure that only properly verified prescriptions are filled.

In fact, then-Congressman Richard Burr, once a member of the Energy and Commerce Committee and the sponsor of the FCLCA, specifically recognized the AOA and his own optometrist, my good friend Dr. Michael Burke, in remarks on the floor of the House of Representatives during final consideration of the FCLCA bill:

> *"I appreciate the support of the American Optometric Association, especially my optometrist in Winston Salem, North Carolina, Dr. Burke, who read through these drafts. He helped us as we put the bill together. He improved the legislation and put us where we are today."*

Three years ago, the President of my association appeared before this panel and affirmed our position that the AOA supports a consumer's right to receive his or her contact lens prescription and have it verified to a third party. Since then, the AOA has taken a leading role in educating its members about full compliance with the FCLCA.

Our widely disseminated education materials have been reviewed, and even praised, by the Federal Trade Commission (FTC). That's why, Mr. Chairman, it is not a coincidence that the FTC "test shops" have found optometrists in compliance with the law, even as they have identified serious compliance issues among contact lens sellers.

The primary concerns of the AOA and its members today are the same ones we referenced before this panel in 2003, only now we have clear evidence that those concerns have materialized in tangible form. We do not want to see any interference with the ability of patients to get their prescriptions and purchase their lenses wherever they choose. We do want to make certain however, as the FCLCA envisioned, that lenses being sold by Internet and mail order sellers are being sold upon verification that a valid prescription exists.

It is important to remember that in spite of advances in safety and convenience – many of which my profession has played a role in – contact lenses are medical devices and must always be treated as such.

The outbreak this year of fungal keratitis among some contact lens wearers underscores the fact that contact lenses are indeed prescription medical devices that can cause serious injury when improperly fitted, worn or cared for. The AOA was a leader in responding to this health situation, providing detailed and reliable information directly to our own members, consumers, Federal and state government officials, manufacturers and sellers, including 1-800 CONTACTS.

Just last year, after reviewing cases in which consumers were harmed by the improper use of decorative, non-corrective contact lenses that were widely available online or at flea markets, Congress took decisive action. The passage of the "Boozman-Barton-Waxman" bill, now Public Law 109-96, provides for the regulation of all cosmetic contact lenses as medical devices by the Food and Drug Administration and requires that such lenses only be sold pursuant to a doctor's examination and prescription, just like corrective contact lenses.

Optometrists remain particularly proud of the leadership role played by our colleague and your colleague, Dr. John Boozman of Arkansas, in making this the priority issue it needed to be for legislation to be enacted and signed into law by the President.

It is the very real potential for harm when contact lenses are worn improperly that makes the prescription verification safeguards the most important element of the FCLCA.

We had, and continue to have, reservations about the verification process in the law, and I will offer my own experiences with it and suggestions for improvements to it later in my testimony.

First though, I know that there has been much discussion of so-called "doctor only" lenses. I am aware that Senator Bennett and Congressman Terry have introduced legislation seeking to make changes to the FCLCA to govern how contact lenses may be marketed by their manufacturers. The FTC, under a directive included in the FCLCA, prepared and delivered a report to Congress last year on contact lens marketplace competition. With regard to so-called "doctor only lenses," the FTC stated:

> **"Our examination of these issues – exclusive relationships, private label lenses, and limited distribution lenses – suggests that such relationships are not prevalent in the market for contact lenses and are unlikely to limit competition and harm consumers. Exclusive relationships are rare; private label lenses while more common, still represent a small portion of all sales of soft contact lenses; and limited distribution policies are not widely used. Moreover, our inquiry showed that a common, limited distribution lens or its private label equivalent, was available from an overwhelming majority of outlets sampled. Given that the FCLCA permits sellers to fill prescriptions with equivalent national brand or private label lenses, consumers have a number of channels through which to obtain such lenses. In addition, these relationships may be an efficient way for manufacturers to provide beneficial incentives to their lens distributors, which in turn may lead to increased competition among various brands of lenses. In sum, the theory and the evidence examined do not support the conclusion that these distribution practices harm competition and consumers by allowing prescribers to lock in their patients to supracompetitively priced lenses."**
>
> ***The Strength of Competition in the Sale of Rx Contact Lenses: An FTC Study February 2005, Page 33***

I will expect to look to the FTC to provide any relevant updates to this finding.

I would like now to return to the issue of prescription verification. Mr. Chairman, this is an area of the FCLCA that is breaking down and, as a result, patients are needlessly placed at risk. Over the last year, the AOA has received hundreds of FCLCA violation complaints about sellers, has evaluated them and, when necessary and appropriate, forwarded them to the FTC. The FTC has also received many direct complaints from doctors.

However, it's not only optometrists and ophthalmologists who are concerned about violations of the FCLCA:

- Last October, after evaluating FCLCA complaints, the FTC issued a warning letter to 1-800 CONTACTS, the nation's largest Internet seller. The FTC's warning cited a "substantial number of complaints" and urged the company to "review the Contact Lens Rule and revise its practices as necessary to ensure that they comply with its requirements."
- In a press release issued last November, 1-800 CONTACTS charged that a competing online seller, Coastal Contacts, was engaged in activities "inconsistent with the prescription verification requirements of the FCLCA and…practices that misled consumers."
- In late June of this year, the FTC issued a series of 18 warning letters to sellers of cosmetic contact lenses for failure to comply with the FCLCA based on statements made on the sellers' Web sites.
- More recently, in August, the FTC imposed formal sanctions on Walsh Optical, an Internet contact lens seller.

In light of this and new complaints about deficient verification practices, the AOA is urging a crackdown on unscrupulous contact lens sellers. In addition, we believe the time has come for some common-sense and pro-patient updates to the prescription verification safeguards included in the FCLCA. Here's why:

1. We are seeing contact lens orders being filled by sellers without any verification of the prescription by the prescribing optometrist.
2. We are seeing contact lens prescriptions being overfilled, well beyond the time period the prescription in question is valid.
3. We are seeing sellers use mechanisms like automated calling systems to verify prescriptions, which impose needless burdens on doctors who want to communicate important patient information to the seller.

Some of my own experiences are very relevant to this discussion. Over the course of this year, I have tracked 18 contact lens orders placed with 1-800 CONTACTS. I am saddened to report that the first 17 orders were all filled by the company without any verification contact with my office, in apparent violation of the FCLCA.

No contact through the telephone.

No contact through the fax machine.

No contact through an e-mail.

A subsequent order – the 18th – did generate a combination live / automated telephone call request for a patient's prescription to be verified.

Since then I am aware of additional cases in which my patients received contact lenses though my office was not contacted with a verification request.

These are not the results this committee intended when it crafted what were supposed to be prescription verification safeguards for patients in the FCLCA. I can't imagine that anyone on this committee envisioned automated telephone calls would be the primary mechanism used by a seller to verify a prescription. I can't imagine that anyone on this committee envisioned that a seller would undermine the law's intention of encouraging patient-focused prescriber-dispenser communications. Unfortunately, that's what's happening.

That's why the AOA is encouraging Congress to examine the practices used by sellers and to take the following corrective actions:

1. Allow eye care providers the opportunity to choose to receive verification requests from sellers through e-mails and faxes, rather than automated telephone calls. This would help facilitate the type of patient-focused communication that occurs between doctors and pharmacists.
2. Ensure that all patient health considerations raised by an eye care provider are addressed by the seller before a contact lens order is filled.
3. To increase the fines that could be imposed by the FTC on unscrupulous contact lens sellers that would violate the law and endanger patients.

These proposals are embodied in legislation we expect to be introduced in Congress in the near future. Optometry and, I am pleased to report, ophthalmology, are in agreement about these proposals and about the need for patients to come first.

Again, Mr. Chairman, let me emphasize that the AOA supported passage of the FCLCA in 2003 and continues to support it now. Our concern – then as now – is that the Internet and mail order contact lens sales industry must provide doctors with basic patient information, in an appropriate manner, so we may respond efficiently, and require that prescriptions be positively verified by the doctor before lenses are sold. This is the balanced and reasonable approach to the competition and health concerns that Congress intended and consumers now expect.

Thank you for the opportunity to present this testimony. We hope you find our input useful and that we can work with you and the members of the subcommittee to move forward with legislation to strengthen prescription verification safeguards and crack down on the unscrupulous sellers who place profits ahead of patients.

MR. STEARNS. I thank you. And I will be glad to allow the Ranking Member, Ms. Schakowsky, a few words here for a second.

MS. SCHAKOWSKY. I just want to thank the witnesses very much for their testimony.

As you heard Mr. Gonzalez say, some of us do have obligations at home. I am going to leave now and catch a flight, but I am glad that I stayed this morning to hear from all of you and look forward, through my office, to be in contact with each of you. Thank you.

MR. STEARNS. I will start with my questions.

Dr. Curtis, you heard Mr. Coon say that they spent 8 hours and 32 minutes calling your office, 192 phone calls. They talked to Gail, Lori, Liz, and someone else. Is your objection that they are automated calls? Because in your opening statement you mention that there was a little bit of a complaint about these automated calls. So it seems to me that 1-800 Contacts is calling you, and they are not getting the response they need. How do you answer Mr. Coon's comment that he has called 192 phone calls over 8 hours and 32 minutes?

DR. CURTIS. Sir, I have an automated phone system in my office also, and I have had it for 5 years. When you call my office, the automated system answers and says thank you for calling the office of Vision Source Arlington, and it starts into a menu that gives direction to the patient to contact the appointment desk.

MR. STEARNS. Can you get ahold of an operator and talk with anybody?

DR. CURTIS. Yes, you can, by--you are instructed to press a button to get ahold of whoever you wanted to, and at the end you are instructed to press 0 to talk to an operator. So I think that it goes through a timely--and his machine is talking to my machine and nobody is talking to a human being.

MR. STEARNS. Mr. Coon, is that true, it is basically two automated machines talking to each other? I mean, in your complaint here, I just want to give you a chance for the two of you to verify right here in a public forum about your complaints against each another.

MR. COON. Yeah. Again, it is unfortunate that we are in this situation where we are competitors that, you know--we need to cooperate with each other, and the patient gets stuck in the middle.

I want to be cautious not to say I think that Dr. Curtis simply falsely represented that he thinks that is the case. I think he actually believes that is true or he wouldn't have put it in his written testimony. However, the facts don't seem to support the allegation. And I would very much welcome any data or any evidence that Dr. Curtis has to the contrary. It is not uncommon for our competitors, the eye doctors, to make unsubstantiated claims. They did it in the litigation with the 32 States--

MR. STEARNS. Let me just interrupt you. Are your two machines talking to each other, yes or no?

MR. COON. No, sir, they are not.

MR. STEARNS. So Dr. Curtis, how is 1-800 Contacts supposed to fulfill their requirement if they can't talk--

MR. COON. Sir, if I could, we use a live agent to make the phone call. We don't hand off to an automated system until after a live person picks up at their office, which is why we know the names of the people we spoke with.

MR. STEARNS. So the question is, can he fulfill his responsibility if he spends all of this amount of time--he can't spend all this amount of time with one doctor. Don't you think he has a legitimate complaint here, that he can't seem to get through to notify you according to the procedures here?

DR. CURTIS. I would have to say that I see it completely on the other side in the fact that I think I have a complaint that his automated system is unable to get ahold of me.

I think he mentioned that there was 192 calls to my office.

MR. COON. Yes, sir.

DR. CURTIS. And I do know that there have been times that the operator has gotten through. And there have been times that a live person gets on the line, asks us to identify, is this the office of Dr. Wiley Curtis, and when we say yes, then they start the automated phone system, which we do follow. But I don't think it happens every single time.

MR. STEARNS. Dr. Schein, both you and Dr. Curtis seem to talk about ocular health and it is a national problem, and I think one of you, Dr. Curtis, somebody mentioned unscrupulous vendors and so forth. In the case you are talking about--I guess it was an after market provider, a refill that disinfection occurred. Dr. Schein, what vendor was it from? How did it occur? Was it from Wal-Mart, was it from 1-800 Contacts? Who was the person that--who did they buy their refill contacts from that created this disease that you talked about?

DR. SCHEIN. I don't know the name. I didn't ask the name--

MR. STEARNS. But the point is that you go on about this ocular health and all these problems, but you have got to be specific because we can't take what you are saying with credibility unless there are specifics behind it and you can say this is how it occurred on this date with this vendor. Because surely the patient would tell you who the vendor is. Because if you just, as a blanket, say there is an ocular health problem, that gives everybody a scare. But we would like to know specifically who is at fault.

DR. SCHEIN. Right.

MR. STEARNS. If you don't want to say anything, but I am just telling you that you lose your credibility. In my case, if I don't hear specifically who is at fault--

DR. SCHEIN. I think you are perhaps misinterpreting the context in which a patient is sent to you emergently with a potentially blinding condition. I am their physician. I am not even aware of an opportunity like today, and if I were, I wouldn't impose that on a patient-doctor relationship. The issue is not--

MR. STEARNS. But you could say it is due to people getting refills from after market providers; is that what you are saying today?

DR. SCHEIN. No.

MR. STEARNS. So that could be done by the doctor himself because he prescribed it and the doctor created this problem himself and the patient created it. So it has nothing to do with after market providers is what I am getting at.

DR. SCHEIN. Right. The point I am trying to make is that there is a link between patient compliance and patient visit to an eye care professional. So I am not at all sourcing the disease to a seller.

MR. STEARNS. Okay. Let me ask of the Federal Trade Commission here, should these three major retailers begin marketing under exclusive doctors-only arrangements once the consent decree expires? Do you believe consumers could or might be harmed to the point where Federal action is appropriate and necessary?

MS. OHLHAUSEN. First, just to clarify, what we found is that there weren't actually doctors-only lenses, that wasn't a major part of the market. We looked at limited distribution lenses, which means that the manufacturer makes a decision not to sell it to every seller. But what we found were limited distribution lenses were actually available through eye care practitioners and then other sellers that had a relationship with eye care practitioners, which would include Wal-Mart, Target, Costco, that typically would have a relationship--

MR. STEARNS. Well, my question is; do you think Federal objection is going to be necessary after this consent decree? That is what I need, yes or no.

MS. OHLHAUSEN. We do not believe at this time that it would be necessary. Our examination of limited service--

MR. STEARNS. So your facts show that it is not necessary after this consent decree expires?

MS. OHLHAUSEN. Right.

MR. STEARNS. Is that the 1st of November? What is the date for that consent?

MS. OHLHAUSEN. I believe that is right.

MR. STEARNS. Okay. Let me just--before I ask one more question here, I want to give Mr. Fryling an opportunity. Well, I think my time has expired. We can go around to a second round. I will go to Mr. Gonzalez.

MR. GONZALEZ. I am going to defer to Mr. Terry.

MR. STEARNS. Sure, Mr. Terry, go ahead.

MR. TERRY. I appreciate that, Mr. Gonzalez, and Mr. Chairman.

Before I ask my question, I want to introduce my ophthalmologist, Steve Wolf, who is in the audience. And even though my boyish face may not be maturing, my eyes are right on in the maturation process, and I just got my no-line bifocals from him. And I will state that I bought them in his store, and that was my choice because, first of all, they offer a real quality service, hands on, and also, I am busy and didn't want to drive around and shop around.

But again, that was my choice. But thanks for being here today, Steve.

Now, I have to admit on the issue of the limited distribution or doctor only, which is the impetus of at least starting this discussion, and it has certainly evolved into passive versus active verification, which I also think is a legitimate discussion to if the 1993 Act is, or the 2003 Act, I am sorry, the Burr bill is actually being complied with. But I am just focusing, for my question, on this limited prescription distribution. And I hear the testimony from the FTC and from Mr. Fryling, and that seems to be counterintuitive of what the advertising is.

So reading the advertising, something is just not connected. Either Ocular Science is not being forthright with the doctors when they are saying that we are going to limit this distribution just to you, so you can get around 1-800 or whatever, on-line, but then, the testimony from the FTC today is it is still widely distributed throughout the community, including to the Wal-Marts and the Costcos and all of that.

So I have got to work through who is right here. Is it widely available, or are you complying with what you are telling your doctors, that it is only going to be their office that can sell this in a community. Mr. Fryling, can you help me work through this apparent discrepancy?

MR. FRYLING. I definitely will. I will help with you that. To get a little history of supervision is, during the last 4 or 5 years, we have bought two companies, Biocompatible, which is the Pro Vision ad, and let me quote Mr. Coon here, an ad for Proclear Lens entices the doctor with the headline, "let's see, you will make more money." That ad hasn't run for over 3 years. That ad was a marketing literature for, that was developed by the company that we acquired, Biocompatible. We discontinued that advertisement a long time ago for the same reason that the FTC found.

It wasn't true. You are absolutely right. And the reason it is not true, and this goes back to what the FTC says, and let me quote on their findings, is that they found that the eye care practitioner, I am quoting off of one of the things, "caught taking advantage of the consumer sacrifices future revenue, not only from selling the replacement lenses to such patient, but also from eye examinations which produce almost twice the revenue of the contact lens sale in 2002." Listening to what we have here, you have to understand the facts. On Proclear, currently, it is 3 percent of the market. And I look at it, we have 14,000 accounts with--

MR. TERRY. I am sorry. I only have a minute and 20 left. Well, let me ask it more specifically and then I will let --

MR. FRYLING. Well, the other ad is also, we don't run.

MR. TERRY. Well, what I want to get to is, are these only being marketed to physicians today? If you go into it, I mean, here is The Wall Street article that says that they aren't being sold at Wal-Marts or Costcos, and that is only September 5, so--

MR. FRYLING. Those articles, I mean Proclear, is sold at Wal-Mart. If anyone can get on the Internet right now, type in Wal-Mart, put the vision center, ask for the Proclear lens, you can buy it at Wal-Mart today.

MR. TERRY. Okay. Mr. Coon.

MR. COON. I think it is important that this committee does know the facts and I have with my CooperVision's current distribution policy from December of 2005. I am going to read from it because he says they don't run the ads anymore, but this is what their contract with doctors says. "Proclear, Proclear Toric, Proclear multi focal are authorized for resale only to patients under the direct care of the original purchaser and for the patient's personal use. Trans shipment, sale, or redistribution by you to purchasers other than patients under your direct control would undermine this goal and is strictly prohibited." This contract goes beyond even what the ad promises. This says a doctor can't even fill a prescription written by another doctor. Even if he is authorized to sell Proclear, he would be violating their current contract if he did.

MR. FRYLING. Can I respond to that?

MR. TERRY. Sure.

MR. FRYLING. That contract basically says to the eye care practitioner that they can not resell the product, the Proclear product, to an Internet type source. That contract does not restrict the doctor in any way to sell the lens to anybody, and that contract does not provide any of these restrictions.

MR. TERRY. All right. But my point is in any physician's office, you sell, as the manufacturer, have the right to sell to the physician. But in any community then, pick one out of thin air, you will also have

distributed the same contact lenses to big box manufacturers as well, the same.

MR. FRYLING. Pardon me?

MR. TERRY. The same contacts that you are supplying to the physicians offices, pick any city randomly, we can go to the Wal-marts and Costcos and the Walgreens or whatever and find the same contact lens.

MR. FRYLING. That is correct. And just going back to that agreement, that restriction doesn't restrict us from selling this lens, and we do sell Proclear to all the retail outlets that were listed in my attachment. There are over 10,000 locations. We have mass merchandising, we have all the large locations there. So that product is readily available throughout the market.

MR. TERRY. My time is up, Mr. Chairman, and perhaps we can--

MR. STEARNS. If the gentleman would yield--

MR. TERRY. I will.

MR. STEARNS. Just another minute. I think you have got a very important point here. Mr. Coon has read your document and you are saying that document does not apply.

MR. FRYLING. No. What I am referring to--

MR. STEARNS. Because you are telling your doctors you will have sole right to sell this and it will not be sold to anybody else. But you are just now telling Mr. Terry that you are going to sell them to all the places they market, and I don't understand.

MR. FRYLING. No, no. The document indicates to the practitioner he can not resell that lens, other than directly to a patient. We have the ability also to sell that lens to all of the other outlets as well. So what we are basically saying to the doctor, and this is a matter of product recall as well, is you can't resell it to, let's say, another, to an Internet company or to so some other group that we have basically indicated we do not want to provide that product to.

MR. STEARNS. Well, let me just read, staff has given me, right from your document, from CooperVision, it says "products for sale over the Internet except to your patients whom you fitted and prescribed the lenses, and any reference to the products on any website you have maintained, you have or maintain, must state clearly that such products are available only to such patients. Except to your patients whom you fitted and prescribed is to sell or resell."

MR. FRYLING. Yeah. We are just telling him he can't be a wholesaler. He can sell directly to his patients, but he can't be a wholesaler.

MR. STEARNS. Okay. Mr. Coon, do you want to answer anything to that?

MR. COON. I am just dumbfounded that he is trying to make it sound like it isn't more clear. It says, you will dispense products only to your patients under your direct control. It could not be any more clear. That is how the doctors read it. Everybody knows the policy. More importantly, they gave this list of all these places they sell to. Every single one of them has a doctor on-site. That wasn't the issue when the 32 States sued. The issue is being able to buy from a non doctor, being able to separate purchase from exam. Wal-Mart has doctors on-site. Target has doctors on-site. The AGs didn't have to sue to get companies to sell to Wal-Mart. All the three major manufacturers were already selling to Wal-Mart.

MR. STEARNS. You know, I am not making a judgment call here. I am just trying to understand. And Mr. Fryling, I mean, what I hear Mr. Coon say in his document, what the staff has given me, and what you are saying, I am having a little trouble. I am not saying you are right or wrong. I am just trying to understand. Could a doctor sell to other patients?

MR. FRYLING. Yes, he can sell to other patients. What he cannot be is a wholesaler. That is what that agreement refers to. And Mr. Coon is correct in saying what that document basically says is he can't be a wholesaler that would then resell it to the Internet outlets.

MR. STEARNS. Okay. My time and Mr. Terry's has expired. I appreciate it. Mr. Gonzalez.

MR. GONZALEZ. Thank you very much, Mr. Chairman. I will start off with some general observations. If I have any questions, obviously they would be predicated on my understanding. A general observation is I really believe there is room for all of y'all out there. We really need to accommodate one another. If you ask Congress to fix the problem, you are going to be surprised because your fate and your destiny will be in other people's hands. You really don't want that. And we really need some direction and some guidance. And I think I understand the Chairman's somewhat frustration of trying to get some answers to some very simple questions.

In the life of the Internet, a million years ago, which is about 10 years ago, Steve Case made the observation that the future of the Internet is not dependent on technology, but rather regulation. We are talking about regulation here. Steve Case wasn't talking about the commercial setting that the Internet has created, but that is where we find ourselves today. And we, as Congress, and you, as physicians, doctors, manufacturers, distributors, can't be behind the curve where the population, our constituency, and the consumer is going, and that is recognizing the role of the Internet, because we have had some of this problem previously but not to the degree that the different parties now

feel that their vested interests may be jeopardized, and it is because of the Internet.

But we better catch up, because your patient and your consumer is moving forward. And this is the way they conduct business. Congress even is asking the physicians to plug into the Internet age. We are talking about health information technology. We have bills that are pending now. Commerce probably feels the greatest impact of the Internet. And so the FTC recognizes that. FTC says we don't have a problem that has risen to the level that creates it. But I have my State Attorney General, and I have the greatest respect for the State attorneys general, first of all, because I think they are in the forefront, and what they are saying is, do you have to be sick before you feel better? Does it have to reach that level before we can improve it?

That is really a good point. But Congress should not act unless it really has to act. And we are being asked to act by the different sides. And the question here is this real curious one. No one is really questioning the adequacy of the prescribed product that eventually ends up in the consumer hands, because I heard Dr. Schein say, look, I am not trying to attribute blame for this malady, or whatever it was, or disease, on one particular manufacturer, so it is not the problem with the quality or adequacy of what is ending up in the consumers hands. Now, that's the first question I am going to pose to each of you. Is there any question here, any fear that we should have, that the end product, the end prescribed product that ends up in the consumers hands is something that we should worry about because of some of the practices that are at issue here. That is going to be the first question. And I don't think that it is.

My second observation, and it is a curious one, and I have to be totally blunt and honest with you. And that is what other situations do we have where the gatekeeper, being the optometrist or the ophthalmologist, really determines whether the consumer is going to receive a certain product through a specific channel? And that is really an interesting one and presents some real problems.

And I think distributors should be free to promote whatever product that they distribute in any relationship, making exclusive, giving it the gold standard seal of approval or whatever, I like that. That is being a great entrepreneur, and I don't think we should interfere with that. There is nothing wrong that. And if it doesn't rise to the level where there is some sort of competitiveness that is being infringed and such and there is no safety or health safety concern, then what are we doing here today? And it all comes down to verification.

And can we come up with a system that will allow the marketplace to proceed with something that is essential and that is verification, Mr. Coon, because I think you understand your obligation to make sure it is a

legitimate prescription, it has an expiration date, and there are dangers associated with prescribing something that if it wasn't being supervised by the physician, the optometrist, we would have some serious problems. And yet verification really lies there at the very feet of the prescriber. And I mean, we have got to figure out a way.

So we are talking about legislation. Let's not just do it with automated phone calls. Let's do fax and e-mails. I don't think that there is going to be a problem with that, to be honest with you. So that is my second question. The second question goes, is the best practices relating to verification. How do we get there?

First question to everyone, do we have a problem with the end products adequacy in meeting the patient's needs as a result of Internet sales?

And the second question, of course, comes down to best practices when it comes to verification, because we have had an example here where we have differences of opinion between Mr. Coon and Dr. Curtis in a real-life setting, so we can imagine how this thing gets replicated every day.

So I have used up most of my time with my general observations, but you know my questions and I am going to ask the Chairman to indulge me some additional time on those two questions. And we will just go down the list.

MS. OHLHAUSEN. On your first question, we have not seen a problem with the product. It seems that it is being delivered to people, that it is widely available to them at competitive prices, and we haven't seen health consequences arising from that.

Secondly, the best practices for verification. When the law and the rule were adopted, there was a shake-out period, definitely, and the FTC did receive complaints from both sellers and prescribers about not being able to communicate with each other well. We have found that those complaints have receded. There still may be, from time to time, complaints, but the volume of them has gone down. And we engaged in quite a bit of consumer and business education to help smooth over this transition period.

MR. KLEIN. Mr. Chairman, Representative Gonzalez, number one, on your first question, as part of the attorney general's litigation and settlement with the contact lens industry, one of the pledges we made to them was that we will do our best as attorneys general to investigate and prosecute people who are engaging in violations and failing to verify. And we invited them to send us the complaints, and we pledged that we will investigate and validate those complaints, and if they have valid complaints we will take action. We are not getting those complaints and have not had any actions that were justified.

On your second point, you talked about gatekeeper. And I think the gatekeeper role is something that is being lost in some of this discussion. I am loathe to criticize another enforcement agency. But I think the economists of the FTC doing the study missed a crucial point, and that is that yes, in a competitive market, there are great advantages to consumers to having the ability, having, letting a manufacturer require a vendor to provide full services. This is not, however, a competitive market. We, in fact, have a gatekeeper who says you can only buy this particular product, and I will tell you the brand name, and you can only buy it with written permission from me. And when you have a gatekeeper, such as the optometrist, who tells you what you need, when you need it, and told you the brand, then we do not have a competitive market and we need, then, to create a better balance to restore some power to the consumers. Thank you.

MS. OHLHAUSEN. Could I respond?

MR. STEARNS. Yes.

MS. OHLHAUSEN. I just wanted to mention that we did examine in our report, because we are certainly aware of the possibility that a gatekeeper could perform this kind of function, and we looked at it to see if consumers were locked in to purchasing lenses at a higher price or less availability. And the evidence that we examined, the pricing evidence, the availability evidence, didn't support the idea that competition wasn't a sufficient check on this ability of the gatekeeper.

So it is not that we didn't know that this could be a problem. We examined it, and we just found that the evidence didn't suggest that the gatekeeper was able to reduce competition in this way.

MR. COON. Thank you, sir. If I might go out of order. If I could, would you mind if I responded to the FTC's remarks since she jumped in?

I think no one argues with the FTC's position that offering a retailer a financial incentive or exclusivity to promote a product is fine. Paul Mitchell doesn't sell their shampoo to grocery stores, right? The FTC, in its study, looked at markets like beer, fragrance, apparel, electronics. There is no problem there because you don't get a prescription for shampoo. I mean, if you can't find it at the hair stylist and you are in the grocery store, you just buy a different shampoo. There is a huge difference here that seems to be lost to the FTC. When a manufacturer offers a financial incentive to a doctor to prescribe a product, the FTC sees no difference between a market in which somebody has no prescription and a market in which they do. And it is best evidenced by the fact that Ms. Ohlhausen has represented that even if 100 percent of the market were to go to doctors-only lenses, the FTC would still see no reason for action.

The first issue I want to address to your two questions, health and the best practice, on the health, both the FTC and the attorneys general are actually in agreement on something. They both agreed that better access to and lower prices for contacts will encourage people to replace their lenses more frequently, which benefits their ocular health. We actually have data on that. The average, according to the major manufacturers, is 28 lenses per year. Customers who order from us average 40 lenses per year. So when their lenses are easier to obtain they do, in fact, throw them away more frequently.

On the second point, I think it is an easy answer. What is the best system? I think we all agree here, it is positive verification. But it is positive verification like the drug industry. Both of these doctors, at the end of the table, if they prescribe you a drug, they are not allowed to sell it to you. But if they prescribe you contact lenses they can. And one of the doctors said earlier, that regulation like has been proposed by Congressman Terry is unprecedented in health care. What is unprecedented in health care is doctors selling what they prescribe. And what is unprecedented is manufacturers explicitly in their ads offering doctors money to write prescriptions for them. If we want a positive verification system, it needs to work like drugs. Doctors need to stop selling what they prescribe. And we would strongly support that.

MR. FRYLING. Thank you very much. I would like to give you some facts rather than some emotional comments based on what we have. Proclear, which is one of the products that they refer to as a financial incentive, which I am not sure what you are referring to at that point.

MR. COON. You will make more money.

MR. FRYLING. Okay. Make more money. If that was the case, you would think that the market share of Proclear, with the limited distribution, would be greater in the U.S. than France. France is a market where the ophthalmologist writes the scrip, and it is filled separately, independently by a retailer. Proclear has a much greater market share in France than it does in the U.S., it is around 7 to 8 percent. By the way, in France, with that separation, the cost of the product to the consumer is higher than it is here in the United States. So let's make sure we understand the consequences of some of these things that emotionally we are throwing out.

Number two, Proclear is sold in 14,000 accounts we sell Proclear to. The average sale is about $2,000 of wholesale. The average sale that a practice sells is about $40,000. So that is 5 percent of their practice. If this is motivated for profit or incentive, you would see a greater percentage of Proclear in that market than anywhere else. If you understand the market, I really encourage you, both of you that have your own practice, you will find that the material profit in contact lenses is a

very small amount for the O.D. He wouldn't risk his reputation to create an artificially high price point that would then not only risk his fitting fees, he also has the potential if they buy glasses, they buy everything else. This just doesn't happen.

That is why the FTC hasn't found a difference in a price point between these products. And as I have indicated to you before, we reached that same conclusion when we bought these companies, and that is why we no longer put those kinds of ads. The only thing we do, or we are trying to do with Proclear is that is a unique product that was approved, has a claim for dry eyes, which is one of the main reasons for patients dropping out. And with dry eye, it is very complicated, and we wanted those patients to be followed up with the practitioner. Sometimes if that condition continues, they can use punctal plugs. There are other things that can help with that condition. That is the main focus on trying to keep those, that product, and only that product, with an eye care practitioner. We want to maintain a reputation of our product. All of the other products are sold. We are in discussion with 1-800 right now, and I agree with you 100 percent. I would much rather let the private market decide how we can get distribution into the Internet.

MR. GONZALEZ. I appreciate that, Mr. Fryling. The problem is that the Chairman has given me actually 10 minutes more than I deserved. And I need to hear from the doctors because it still comes down to verification. At the end of the day, we would like our consumers, of course, to be well served. But they are patients and we want them to get to the doctors on a regular basis. And I think that was Dr. Schein's concern. And I would like to hear his, one, about adequacy of the product, but the other thing too is about verification, which obviously dovetails into the regular visits and such.

DR. SCHEIN. To address your first question first, there is nothing fundamentally different about the product based on the origin of sale. And, in fact, risk with contact lenses is associated with how the device is used and cared for. So whether it is worn, for example, overnight, versus daily only or whether it is the contact lens case adequately cleaned and replaced, those kind of things determine risk, not the inherent device itself.

I think that I am in agreement with Mr. Coon, that the aim should be a positive verification system that works for sellers and practitioners. That should be the goal. That should be the purpose of meetings to draft new legislation. I cannot believe that that is an impossible issue. I have not personally devoted my time to this, but with our communications abilities today and the use of the Internet, I cannot believe that that cannot be done.

MR. STEARNS. Dr. Curtis.

DR. CURTIS. To specifically respond to your question about the Internet and verification, in my particular situation, I purchased a phone answering system 5 years ago and it seemed to be a relatively high tech endeavor at the time. And now, using automated phone systems seem to be relatively low tech. And my office does many things regularly on e-mail, including communicate with patients. And I would love to see a verification system where I received an e-mail requesting the contact lens prescription and be able to respond to that in a very timely, it would be very easy for our office to respond to those types of situations very easily and quickly.

MR. GONZALEZ. Thank you very much. And thank you, Mr. Chairman, for your indulgence.

MR. STEARNS. I appreciate any time when you give, ask questions, because I think, like myself, we are just trying to understand this better, and I appreciate also your observation that sometimes be careful what you ask for when you come to these committees. Having seen what turns out to be a pretty good bill, and then it gets amended, and pretty soon no one likes the bill and everybody's trying to stop it after spending so much time trying to pass it.

But I am going to conclude, and I am going to go, Ms. Ohlhausen, just to revisit here. You had indicated that the FTC did not find doctor only or limited distribution lenses are prevalent. But isn't this because of the three major manufacturers, Johnson & Johnson, CIBA Vision, and Bausch & Lomb, are prevented by the consent decree which expires in 6 weeks from entering into exclusive contracts, isn't that the reason why we don't see that?

MS. OHLHAUSEN. That certainly may be a reason why. We made no conclusions.

MR. STEARNS. So you are saying if we didn't have the consent decree, we didn't need this consent decree, is that what you are telling me?

MS. OHLHAUSEN. No. What I am saying is we didn't make any conclusions in the report as to why the incidence of exclusive distribution lenses was at a certain level. We just examined the market as it existed when we did the study.

MR. STEARNS. But, if the consent decree is not extended, what, do you think that these folks behavior will change at all?

MS. OHLHAUSEN. Um --

MR. STEARNS. I mean you must have some opinion. You had a study on it and you are involved with the consent decree. I mean it seems likes at some point--

MS. OHLHAUSEN. Excuse me. The FTC is not involved with the consent decree.

MR. STEARNS. I understand that. But you were involved with the study of it.

MS. OHLHAUSEN. We were involved with the study that Congress directed us to do.

MR. STEARNS. And what is your observation? Do you think the consent decree should extend or not?

MS. OHLHAUSEN. The FTC doesn't have an opinion about extending it except that --

MR. STEARNS. Okay. I appreciate that. That is probably true.

Mr. Klein, what do you think?

MR. KLEIN. We are very much worried about it. We are hoping, as a result of the consent decree, that consumers would see greater price savings; in addition, that the manufacturers would realize how much better off they were by selling these lenses, because if what Mr. Coon said is true, that consumers are replacing their lenses more frequently through cheaper sources, that will result in the manufacturers selling more lenses. The more lenses they sell, the more profit they make.

But, the concern remains paramount about the gatekeeper function. And a rough analogy is, if a city requires a building inspector, health inspector to come to your home, the health inspector comes to your home and says your refrigerator needs to be changed because it doesn't have the latest filter or the antibacterial lining, and so you have to change your refrigerator. And I am writing you a prescription that you have to buy this particular refrigerator and this brand--

MR. STEARNS. I understand. But I am just trying to get this and I am going to go right through the panel. The evidence that you have, your experience of your boss and yourself, who couldn't make it here, that once this consent decree expires 6 weeks from now, do you think these three manufacturers will cut distribution ties with aftercare retailers such as 1-800 Contact? I mean, just give me your straight up or down here.

MR. KLEIN. Yes, because it grows its share of the other companies they have an incentive to do that.

MR. STEARNS. Okay. Mr. Coon, obviously your feeling is yes.

MR. COON. I don't think they want to start doing it again. I think they have moved on, but I don't think they will have a choice.

MR. STEARNS. Do you think there is an economic incentive to do this for them?

MR. COON. It is an incredible shortcut. I mean, if you have got a doctor who sells what they prescribe, you can just offer the doctor money to write a prescription for your product, which is exactly what these ads offer to do.

MR. STEARNS. But, you know, you are being a little idealistic if you think when you said the statement, doctors should stop being able to sell what they prescribe. I mean, the doctors today, they don't prescribe and sell the medicines, but they sure have a lot of incentive to sell some medicines over others. And you and I both know that. And those incentives come in through lots of different ways that doctors are influenced.

And Mr. Klein, you know that too. So in a free market, lots of things happen. Just like here in Congress, how legislation, I mean, this is a free and open society where ideas come up, but lots of things happen between the cup and the lip. So, you know, your feeling is you need this consent decree extended, right?

MR. COON. To be clear, I think if doctors didn't sell what they prescribed, which is why I mentioned that, this market wouldn't need any regulation.

MR. STEARNS. Well, we are not going get to legislation passed between now and the first of November. That is the bottom line. Unless leadership somehow, after this hearing, decides there is a real need. But I have seen the plate here. It is full. And there are a lot more higher priority issues than this issue. So I guess the question is, knowing that this legislation might not pass--this is just a hearing. We haven't even marked up out of my subcommittee. It has got to go to the full committee. It has got to go to the House, it has got to go to the Senate. There has got to be a conference. Would you want a consent decree extended?

MR. COON. There is no question. And to be clear, if the doctors are unwilling to not also sell what they prescribe--

MR. STEARNS. So you are not willing to call for an extension of the consent decree.

MR. COON. We think it absolutely ought to be extended, and we think the current system can work the way it is. The doctor just needs to compete for the sale, which is what this law would do.

MR. STEARNS. Okay. Mr. Fryling, what is your feeling about the consent degree?

MR. FRYLING. Well, I do think you should ask the other manufacturers or follow up.

MR. STEARNS. Well, I am just asking for your point.

MR. FRYLING. We have had discussions, and we have agreed that we would provide lenses to 1-800 regardless. We are not under the consent decree at this point.

MR. STEARNS. That is right.

MR. FRYLING. What the FTC did was not under that.

MR. STEARNS. So we don't have Johnson & Johnson, CIBA Vision, or Bausch & Lomb so we can ask them. But Dr. Schein, what do you think.

DR. SCHEIN. I have no opinion.

MR. STEARNS. Okay. That is fine. Dr. Curtis.

DR. CURTIS. I would be shocked if any contact lens company changed the way they were doing business.

MR. STEARNS. So with or without the consent decree, that business will continue as it is, and once it expires, Bausch & Lomb and CIBA Vision and Johnson & Johnson won't change their behavior. They will not go about trying to cut distribution ties with after care retailers such as 1-800 contact. You think that is true.

DR. CURTIS. I am way out of bounds speaking for them, but I can't, as a client of theirs or a customer of theirs, I cannot imagine that they would change the way they are doing business today.

MR. FRYLING. Mr. Chairman, could I just give you a reason why I think that all the manufacturers will continue? There is a real concern in the gray market associated with counterfeit lenses. We want these Internet suppliers to get product that we know is our product and not potential counterfeit lenses, so there is a real desire for us to go forward. And so I would be very surprised, I am not speaking for all the manufacturers, that they would not continue with providing product to the Internet source.

MR. STEARNS. Well, thank you all of for your testimony. I am glad we had the hearing. I will just conclude in touching upon what Mr. Gonzalez has said. Sometimes having these hearings is enough to tell all participants, hey, you had better just be careful what you ask for, as he pointed out, because the Federal legislation, you have 435 members with ideas of their own, and a piece of legislation gets an amendment on the subcommittee and the full committee and the House and sometimes you don't even know what you are going to get.

So it would be well for all of you to somehow work together, as Mr. Gonzalez pointed out, and not have the Federal government step up and do anything here. And perhaps Mr. Coon, this hearing alone will say to these other distributors that, hey, the consent decree is over the first of November, but we better watch how everybody plays this game, because you might not like what happens. So with that, the subcommittee is adjourned.

[Whereupon, at 11:07 a.m., the subcommittee was adjourned.]

STATEMENT SUBMITTED FOR THE RECORD BY CIBA VISION

CIBA Vision, the eye care unit of Novartis and a global leader in the research, development, and manufacturing of contact lenses and lens care products, welcomes the opportunity to submit this statement for the record in the Subcommittee's hearing on the topic "Contact Lens Sales: Is Market Regulation the Prescription?" CIBA Vision is deeply committed to the eye health and safety of contact lens wearers. For this reason, the company supported enactment of the Fairness to Contact Lens Consumers Act ("FCLCA") (Public Law No. 108-164) and was a strong advocate for the "Boozman-Barton-Waxman" plano lens legislation, now Public Law No. 109-96, which mandates that the Food and Drug Administration regulate all contact lenses as medical devices and requires that such lenses be sold only pursuant to an eye care professional's examination and prescription. It is CIBA Vision's abiding concern for eye health and safety that compels the submission of this statement.

CIBA Vision understands that one of the purposes of today's hearing is to examine the need for, and the impact on consumers and the marketplace of H.R. 5762, the proposed Contact Lens Consumer Protection Act. This legislation would require contact lens manufacturers to "make any contact lens the manufacturer produces, markets, distributes, or sells available in a commercially reasonable and nondiscriminatory manner to—(1) prescribers; (2) entities associated with prescribers; and (3) alternative channels of distribution." For the purposes of the proposal, "alternative channels of distribution" mean "any mail order company, Internet retailer, pharmacy, buying club, department store, or mass merchandise outlet, without regard to whether the entity is associated with a prescriber, unless the entity is a competitor…."

As an initial matter, CIBA Vision queries whether there is a need for legislation such as H.R. 5762. The FCLCA (Section 10) directed the Federal Trade Commission ("FTC") to "undertake a study to examine the strength of competition in the sale of prescription contact lenses." The statute specifies that the study must evaluate several issues, including, inter alia: the "incidence of exclusive relationships between prescribers or sellers and contact lens manufacturers and the impact of such relationships on competition"; the "difference between online and offline sellers of contact lenses, including price, access, and availability"; and the "incidence, if any, of contact lens prescriptions that specify brand name or custom labeled contact lenses, the reasons for the incidence, and the effect on consumers and competition." The FTC issued its report, The Strength of Competition in the Sale of Rx Contact Lenses: An FTC Study, in February 2005. After a careful analysis, the FTC concluded:

> Our examination of these issues – exclusive relationships, private label lenses, and limited distribution lenses—suggests that such relationships are not prevalent in the market for contact lenses and are unlikely to limit competition and harm consumers. Exclusive relationships are rare; private label lenses, while more common, still represent a small portion of all sales of soft contact lenses; and limited distribution policies are not widely used. Moreover, our inquiry showed that a common, limited distribution lens, or its private label equivalent, was available from the overwhelming majority of outlets sampled. Given that the FCLCA permits sellers to fill prescriptions with equivalent national brand or private label lenses, consumers have a number of channels through which to obtain such lenses.
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> In sum, the theory and the evidence examined do not support the conclusion that these distribution practices harm competition and consumers by allowing prescribers to lock in their patients to supracompetitive priced lenses. The Strength of Competition in the Sale of Rx Contact Lenses: An FTC Study (February 2005) at 33.

This study, which Congress specifically requested, demonstrates beyond cavil that legislation such as H.R. 5762, which would replace vibrant market competition with government regulation, is wholly unnecessary.

However, in CIBA Vision's view, there is a serious defect in current law which Congress should remedy expeditiously—the "passive" or "default" prescription verification provisions of the FCLCA. CIBA Vision concurs with the conclusions of the American Optometric Association and the American Academy of Ophthalmology that passive verification of contact lens prescriptions is not working in all cases, with all sellers, and as a result, the eye health and safety of patients are at serious risk.

Section 4 of the FCLCA provides that a "seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is—(1) presented to the seller by the patient or prescriber directly or by facsimile; or (2) verified by direct communication." Pursuant to the statute, a "prescription is verified…only if one of the following occurs: (1) The prescriber confirms the prescription is accurate by direct communication with the seller. (2) The prescriber informs the seller that the prescription is inaccurate and provides the accurate prescription. (3) The prescriber fails to communicate with the seller within 8 business hours, or a similar time as defined by the Federal Trade Commission, after receiving from the seller the information described in subsection (c)." Subsection (c) provides that when seeking verification of a contact lens prescription, a seller must provide the prescriber with specific information including the patient's name and address; contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate; quantity of lenses ordered; the date of the patient request; the date and time of the verification request; and the name of the contact person at the seller's company including telephone and facsimile numbers. "Direct communication" includes "communication by telephone, facsimile, or electronic mail."

The FTC implemented the FCLCA through the Contact Lens Rule which was promulgated in July 2004. (16 C.F.R. Part 315). In addition, the FTC has issued two relevant guidances-- FTC Facts for Business—The Contact Lens Rule: A guide for Prescribers and Sellers (October 2004) and Q&A: The Contact Lens Rule and the Eyeglass Rule (October 2004). The FCLCA and the FTC's regulation and guidances all make it clear that a seller may conclude that a prescription is valid if eight hours have elapsed since a verification request was lodged with the prescriber and no response from the prescriber was forthcoming. As a result, a seller may dispense a prescription contact lens without ever having had any confirmation that the request was received or that the prescription is valid, accurate, and not expired. CIBA Vision respectfully submits that such passive or default verification is simply not acceptable.

The law is clear that all contact lenses are regulated as medical devices by the FDA and that they may only be sold pursuant to an eye care professional's examination and a valid prescription. Such regulation is manifestly justified by the fact that contact lenses may cause serious injury if not properly manufactured, distributed, fitted, worn, and cared for. The existence of a valid prescription is an indispensable component of the regulatory schemata to protect the eye health and safety of contact lens wearers. The gravamen of the defect in the FCLCA's passive verification provision is that it grievously denigrates the integrity of the prescription requirement and creates a gaping portal for abusive conduct.

CIBA Vision is aware of numerous instances of conduct designed to subvert or circumvent the verification provisions of the FCLCA. Consider the following:

- Some sellers are ignoring the verification requirement altogether and selling contact lenses without any effort to secure verification from the prescriber.
- Certain sellers make it extremely difficult, if not impossible, to be contacted by the prescriber within the 8-hour window and then, having heard nothing from the prescriber, proceed to sell the lenses.

- Contact lenses are being dispensed by some vendors even though the prescription has expired and is no longer valid.
- Some sellers use automated calling systems to verify prescriptions making it extremely difficult for a prescriber to convey critical information about the patient or the prescription.
- Prescriptions are being overfilled, sometimes with an unlimited supply of product, especially immediately preceding the prescription expiration date.
- Unlike pharmaceuticals, because a contact lens prescription is not surrendered when it is filled, patients are able to order from multiple sellers and limitless supplies of contact lenses.
- Lenses are being ordered using false eye care professionals' names and contact information.
- Patients are listing eye care professionals they have never seen as the source of the prescription and without an active verification requirement, some sellers fill the order.
- Certain sellers have developed recurring "computer problems" which prevent communications from prescribers. Claiming that they received no communication from the prescriber within the 8 hours, the seller fills the order.
- TV commercials, websites, and magazine and newspaper advertisements imply that prescriptions are not necessary and that orders can be filled on some other basis—e.g. taking information from an empty contact lens box.

We believe these abuses, and others, have emerged as a direct result of the passive verification provisions in the FCLCA. There is no limit to the ingenuity of unscrupulous sellers who are intent on ignoring or circumventing the weak default prescription verification process called for by current law. The potential ramifications to consumer eye health and safety must be considered if passive verification remains the statutory standard.

A safer and more effective prescription verification system should contain at least the following elements: (1) providers who write contact lens prescriptions should be permitted to require that verification requests from sellers must be submitted by e-mail or facsimile rather than through automated telephone systems; (2) a requirement that the seller satisfactorily resolve all patient eye health care considerations raised by the prescriber before filling the prescription and selling the contact lens; and (3) increased penalties and fines for violations of the active prescription verification requirements.

As Congress considers legislation affecting the contact lens market, it should eschew efforts to reconfigure the competitive structure of the industry. Instead, it should accede to the compelling demands of consumer eye health and safety by eliminating the passive verification system and mandating a system which requires active verification of contact lens prescriptions.

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