FTC Workshop: The Contact Lens Rule and the Evolving Contact Lens Marketplace
March 7, 2018
Segment 1
Transcript

ALYSSA BERNSTEIN: Good morning. My name's Alyssa Bernstein. And I'm an attorney in the Bureau of Consumer Protection Federal Trade Commission. On behalf of my colleagues, I'm very excited to welcome you all to the Contact Lens workshop. We're excited to explore the contact lens marketplace with you today. Before we get to the main event, I need to review a few administrative details, so I hope you've had your coffee already,

Please silence any mobile phones and devices. If you need to use them during the workshop, please be respectful of the speakers and your fellow audience members. Be aware if you leave the Constitution Center building for any reason during the workshop, you're going to have to go through security again. Keep this in mind and plan ahead, especially if you're participating on a panel so that we can do our best to remain on schedule.

The restrooms are just outside the auditorium. The plaza east cafeteria is located inside the building. So you can use it without going through security. The cafeteria is the place to go if you like coffee or tea without having to leave the building. It's open till 11 AM, and then we'll reopen at 11:30, and remain open till 3:00 PM. There's no food or drink other than water permitted in the auditorium.

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Be advised this event may be photographed, and it is being webcast, and recorded. By participating, you are agreeing that your image and anything you say or submit may be posted indefinitely at FTC.gov or one of the commission's publicly available social media sites.

Welcome to those watching via the webcast. We'll make the webcast and all of the workshop materials available online to create a lasting record for everyone who is interested in these issues. For those of you on Twitter, we'll be tweeting today's workshop at #ContactLensFTC. If you'd like to ask a question via Twitter, please tweet your question using that hashtag.

We'll also be accepting questions via paper cards. They look like this, for those who are here in the audience. You may have picked up some of these cards already at check in. Workshop staff will also walk around and distribute these cards during each session. And then we'll collect the

cards, and bring them up to the moderators. Due to time constraints, we will not be able to address all questions during the workshop itself, including those we receive via Twitter, but workshop staff will certainly review all of the questions.

If you'd like to submit a formal written comment about issues that we discussed at the workshop, we welcome online submissions at the FTC's website through April 6. If you need anything during the conference today, please feel free to ask FTC staff who are wearing the official workshop badges, including the paralegals who greeted you at the registration desk.

Lastly, I want to thank our panelists for taking part in today's workshop. We're grateful for your time. Aside from the people you'll see on stage today, the program would not be possible without the great work of Crystal Peters and Bruce Jennings, the honors paralegals that have been helping you throughout the day, the assistance of our college interns, Jennifer Thompson and Breanna Thomas. Also providing invaluable support are Nathan [INAUDIBLE], from our Division of Consumer and Business Education, Nicole Jones from Office of Public Affairs, and Bonnie McGregor from our Division of Advertising Practices.

Now it's my honor to introduce our acting director of the Bureau of Consumer Protection, Tom Pahl, to get opening remarks. He oversees the commission's attorneys, investigators, and administrative personnel working to protect consumers from unfair and deceptive practices in the marketplace. Tom first joined the agency in 1990, and spent more than two decades serving in various positions, including as an attorney advisor for former FTC commissioners, Orson Swindle and Mary Azcuenaga, and as assistant director in the division of Financial practices and advertising practices.

In his position as Assistant Director of Advertising Practices, Tom oversaw the commission's work on the contact lens rule, so he's definitely not a stranger to many of the issues we'll be discussing today. Welcome, Tom.

TOM PAHL: Well, thank you, Alyssa, and good morning, everyone. I'm Tom Pahl, the acting director of the FTC's Bureau of Consumer protection. Welcome to the FTC workshop on the contact lens rule and the evolving contact lens marketplace. It's great to see so many people here getting together on a topic that affects so many Americans. In fact, more than 41 million Americans, more than 16% of the United States population, wear contact lenses, and that number is growing.

In 2002, just prior to the creation of the contact lens rule, about 13% of Americans wore contacts-- 5 million fewer than today. And that growth may be accelerating. According to one industry tracker, the vision counsel, who will be one of our panelists today, 1.3 million more Americans are wearing contacts now than 12 months ago. Contact lenses are also a major purchase for many consumers, with many spending hundreds of dollars a year on lenses.

Besides the benefits that consumers quite literally see, contact lenses are a big business. US sales revenue surpassed $5 billion last year, up from less than $2 billion in 2002. The variety of lenses and of places to buy them is far more diverse than it once was. Consumers can now choose from

online sellers, big box stores, wholesale clubs, retail chains, and of course, from independent eye doctors.

We at the FTC liked to think that the contact lens rule has contributed to the growth and diversity of the contact lens rule marketplace. The rule has been in place since 2004, but it's worth reviewing its history in the statute that provides the framework for the rule. I'm particularly well-suited, as Alyssa had mentioned, to discuss the industry because I was one of the FTC staff members who worked on promulgating the original rule in 2004.

Often, what people think of as requirements imposed by the FTC through the contact lens rule are actually requirements spelled out in the statute. Specifically, the Fairness to Contact Lens Consumers Act, or FCLCA, which went into effect in 2004. At the time of the act's passage, about two thirds of the states already had statutes requiring some form of prescription release to consumers.

Yet despite these laws, Congress determined that many consumers were still not getting copies of their prescriptions, and were having a tough time obtaining lenses from third party sellers due to prescription verification obstacles. Problems with prescription release and verification hampered competition, and limited the ability of consumers to comparison shop. Congress also had concerns that some sellers were selling lenses without requiring a valid prescription.

The act was intended to remedy these concerns. Foremost is what's known as the automatic prescription release requirement, which mandates the prescribers give consumers a free copy of their prescription at the end of a contact lens fitting, even if the consumer doesn't ask for it. They act further provides that consumers can take prescription to any seller to be filled. Because it's not always possible for consumers to present an actual copy-- perhaps the consumer lost the prescription or wasn't given it-- the act also requires the prescribers verify prescriptions.

In the act Congress, opted for a framework that includes three possible methods of obtaining verification. A prescription is considered verified if first, the eye doctor confirms the accuracy of the prescription. Second, the eye doctor corrects inaccuracies in the prescription. Or third, the doctor fails to respond to the verification request within eight business hours. This third method is commonly known as passive verification.

In constructing the verification framework this way, the idea was that prescribers can prevent consumers from using an invalid prescription, and there are sound medical reasons for doing so. But prescribers also would not be able to block third parties from selling to consumers simply by ignoring a third party's verification request. The act also makes it illegal to sell lenses without either verifying the prescription, or obtaining a copy of the consumer's prescription. It also prohibits Sellers from altering a prescription or switching to prescribed brand.

The heart of the act is automatic prescription release, and passive verification. We can, and will talk today about whether these are working as intended. But to substantially alter these requirements would require legislative action. It's not something the commission has the authority to do by rulemaking.

Today, our focus is primarily on the contact lens rule, which the commission issued in 2004 to implement the act. The rule tracks a statute very closely with the same requirements the prescribers release and verify prescriptions, and don't charge extra for doing so. The rule also contains some additional provisions, such as a record keeping requirement for sellers, a definition as to what constitutes eight business hours, and a requirement that during the eight hour period, a seller has to provide an opportunity for the prescriber to communicate with them.

Which brings us to the current rule review. In September 2015, as part of our periodic regulatory review process, the commission sought public comment on the contact lens rule. How it was functioning, whether it was still needed, its benefits and its burdens. In response, the FTC received 660 comments. Virtually all of them agreed that there is a continuing need for the rule, and that it benefits consumers and competition.

At the same time, many commenters also recommended the commission make modifications to the rule. Some felt that sellers and consumers were abusing the passive verification system to avoid seeing their eye doctor, and were getting lenses without a valid prescription. Other commenters said the verification request, robocalls in particular, were a burden on doctors. Yet other commentators said that even after more than a decade, many prescribers were still not releasing prescriptions. Some released them, but only if patients requested them. Others never released them at all, instead steering patients into doctor owned optical shops for their contact lens purchases.

After viewing all the comments, surveys, and other information that was submitted, the commission decided in November 2016 that there was need for improved compliance with the rule's automatic prescription release requirement, as well there's a need to create a mechanism for monitoring and enforcing the rule. To accomplish this, the commission proposed to amend the rule to require that prescribers obtain a side acknowledgment form from patients, confirming that they had received prescribers. Prescribers would have to hold onto these signed receipt for three years.

The commission believes these changes would lead to increased prescription release, which in turn would improve compliance with the rule. Increased prescription release would enhance patient flexibility and choice, reduce costs for patients, sellers and prescribers, and reduce consumer harm from verification errors. The commission believe that these benefits exceeded the burden of one minute per patient that it had estimated it would take to obtain a signed receipt, and save into the patient's file.

In response to this proposed amendment, we received over 4,000 comments, including more than 800 from eye doctors alone. While many commenters supported the proposed amendment, the comments raised many issues the commission decided deserved additional attention and examination. The optical marketplace is evolving in many ways with new developments in telehealth, patient portals, online and subscription delivery models, as well as developments in the types of lenses that people wear. As just one example, less than 8% of consumers use daily disposable lenses in 2005. Nearly 30% use them in 2017. And as many as 50% are projected to use them by 2021.

In light of the changes to the market, and the comments we received, the commission has decided to hold the workshop that we are going to have today. We've assembled a great group of panelists that include optometrists and ophthalmologists. Online sellers, brick and mortar retailers, academics, consumer advocates, economists, and of course, one or two lawyers, because you can never have a panel in Washington without lawyers.

Today, we'll have six panels. We'll start with a short look at the marketplace. Then move on to discuss health and safety. And then competition. After lunch, we'll resume with a panel examining verification, followed by a panel on facilitating consumer choice. We'll wrap up with a panel looking ahead at developments and disruptions that may be coming down the pike.

By having these discussions today, we hope to educate ourselves about changes in the marketplace that may create opportunities for consumers to obtain contact lenses safely, and at competitive prices. We'll also explore how the contact lens rule can foster competition, maximize consumer benefits, and minimize burdens on prescribers and sellers.

So let me thank our panelists for agreeing to share their knowledge and experience with us. I know some of you have come great distances to join us here today, and we appreciate it very much. And let me also thank everyone who couldn't make it in person, submitted comments in advance, or is joining us via online. We read all comments that we receive, and take them seriously.

Finally, I want to thank the FTC staff from the Bureau of Consumer Protection, the Bureau of Competition, the Bureau of Economics, and the Office of Policy Planning, who have worked so hard and well put this workshop together. The fact that this workshop draws from all the different parts of the FTC, to me, really speaks to the breadth the issues, their complexity, and the importance to the agency. And so I've been thrilled to see that our staff folks have been able to work together to make sure that the expertise of all parts of the agency are brought to bear on the issues that we're going to discuss today.

So with that, I'm going to turn the podium over to Beth Freeborn and the first panel to get us started. Thank you everyone, and have a great day.

BETH FREEBORN: All right. So prior to discussing some of the issues that are currently facing the contact lens market, this panel is going to provide a general overview of the current market, and discuss how things have changed since the contact lens rule was enacted in 2004. I want to begin by introducing and thanking our two great panelists who have both done quite a bit of work to prepare information for this panel.

First, we will have Steve Cody, who is the Senior Director of Industry Research Services at division counsel. Steve will be providing information largely from the consumer side of the market. And next, we have Wally Lovejoy Lovejoy Eye Care Consulting. Wally has had numerous jobs in the eye care industry, and brings a wealth of knowledge to this panel. So gentlemen, thank you very much for being part of this panel, and let's start with Steve.

STEVE CODY: Thanks, Beth. As she mentioned I worked for the division counsel, and we're basically a nonprofit organization that serves as the global voice for eyewear and eye care. We have a large variety of member companies, from small family owned businesses to large corporate companies. And we generally try to provide them with information that helps them run their companies better, more efficiently. Whether that's research, training, industry, networking events. Moreover, with access to eyewear trends, the latest advances in technology, and advice from experts in the industry. We also serve the public who are looking for more information about eye glasses, sunglasses, eyewear, and eye care.

And a big part of our research portfolio is our vision watch consumer survey program. It's a continuous study that interviews over 10,000 American adults per month, asks them all sorts of questions about eyewear, and eye care, including quite a bit about contact lenses. So I'm just going to give you guys kind of an overview of the data that we have there, and the trends that we're seeing, not just in 2017, but comparisons to 10, 13, 15 years ago, as the data permits.

Kind of talk about a trend here. Thomas mentioned a few of the statistics about there's 41.4 million US adults wearing contact lenses in the US. That represents about 16.4% of the population. Is also about 3.9 million juveniles under the age of 18 wearing contact lenses. Up as well. The or million user increase last year is just part of the growth that we're seeing for contact lenses. In fact, over the past 13 years, we've seen an increase of about 10.1 million users using contacts, at least some of the time. That's growing faster than any other type of vision correction method or modality in the United States.

About 40% of those users just wear contacts exclusively, no other types of eyewear. The other 60% are wearing them with glasses or over-the-counter readers, things of that nature in conjunction. Really, about 25% of adults 18 to 34 wear contact lenses. That's almost half of the population wearing lenses. And that's up 52% over the past 13 years. But in terms of relative increases, there's been over a 100% increase in the people over the age of 45 wearing contact lenses since 2013 thanks to the introduction of a lot more multifocal presbyopic contact lens solutions that have been introduced into the marketplace.

But we've seen growth among people from higher income households, people from the Northeast region of the country, people who have insurance and manage vision care coverage, MVC-- you'll hear that term a lot today. And those numbers are growing.

For the most part, a majority of wearers-- 19.7 million-- wear lenses all day, but not while sleeping. That's up 41% over the past 13 years. You have about 11 million users wearing contact lenses all day, including while sleeping. That's also up significantly. But the biggest increase is in occasional users just wearing them for a specific functions. That's up by about 67% over the past 13 years. And there's about 7.3 million of those users usually working with eye glasses or reading glasses, and over the age of 45.

As Thomas mentioned, there's a variety of places where consumers can get their contact lenses. Just to give you a perspective, the industry generated about $40.4 billion in total sales last year. That's only up by a tenth of a percent from the previous year. But contact lens were up 4.5% over

the past year. Up 7.5% over the past two years. And really, growth kind of spread amongst the different distribution channels. Independent ECPs. Wally will kind of talk about that later.

The small independently owned practices by optometrists, opticians, ophthalmologists with three or less locations. Generated almost $2 billion in sales thanks to a customer that's more medically oriented, generally older, from a higher income household, with insurance leading the market there. But also losing share-- we'll see in a minute-- to some of those other channels.

Mass merchants, conventional chains, big box retailers also selling a good number of contact lenses, growing by about 3.7% to 4.2% over the past year. And then you have the online channel. Kind of more commodity, fashion oriented customer, younger, from a higher income household. Already buying things online. They almost sold about $800 million worth of contact lenses last year, only growing by about 5%, which is the smallest amount of growth that we've seen from that channel recently. And we'll kind of talk about the long term trend there in a second.

Wally will talk about the landscape for the retail community there. We've seen an increase of about 10% in number of independents selling contacts over the past 10 years that's a corresponding to a 34% increase in revenue for the independent ECP selling contact lenses.

And generally, through vision watch, the great thing about consumer studies-- you can ask them all sorts of questions about behavior. And generally, for the 38 million US adults that wear contact lenses exclusively or in conjunction with eyeglasses, they choose to wear contact lenses for three reasons. First is cosmetic. They feel they look better in contact lenses. Second is convenience. It's easier than taking on and off eyeglasses.

The third is generally also related to convenience, but the fact that many consumers, generally younger, male, people who are outside a lot, participating in sporting activities, they think that eyeglasses won't fit with their active lifestyle. So those are generally the three reasons why people choose to wear contact lenses over eyeglasses.

Now there's about 41.4 million people who do wear contact lenses in the US. There's about 48.8 that were wearing them at some point in the past, but have stopped for various reasons. And again, the reasons why people choose to stop wearing contacts generally come down to one of three things. First one, discomfort. About 44% of all the people that we surveyed stopped wearing contact lenses. Or 41% because of discomfort. About 30% stopped because of convenience, basically. Easier to wear glasses. You hear that, especially from daily contact lens wearers that stop wearing. And finally, dry eyes. About a quarter of the people that stop worrying use that reason in particular.

And the contact lens business has gotten a little bit better at preventing people from walking away from the market with advances in technology and product. When you compare the number of people who've walked away from the market now compared to 10 years ago, there's fewer people leaving the market for discomfort, inconvenience, visual acuity or clarity problems, perceived price concerns, the need for a multifocal or presbyopic solution. You're seeing more people walk away now just because of dry eye issues or because they've had a surgery procedure to fix their vision problems.

This looks at the long term trend lens sales out there. As I mentioned before, there's been about a 32.4% increase in usage over the past 13 years. There's been a 41% increase in the number of transactions that those users use, the purchases of contact lenses on an annual basis, up by 41%.

And the revenue that's brought in by 67% over the past 13 years. And again, distribution by channels vary considerably. Independents losing share here over the past 13 years, but still growing aggregate sales by almost 59% over the past 13 years. The conventional chains growing their sales by about 70%. The mass merchants by almost 80%.

The online retailers growing by about 160% over the past 13 years. That's about 10.7% a year on average. And what we're seeing now is about 85% of those online customers are repeat customers who purchased in the past. And 15% are walkouts who previously bought from a brick and mortar location. And we'll talk a little bit about that in a few seconds here.

Through Vision Watch, we collect pricing information, but it's a little different than what most people would consider as list price or original price. We track the out-of-pocket paid price by the consumer, what's coming out of their pocket to buy the product that they want. So there's a lot of things missing in that equation.

We're missing the rebates from the manufacturer, the retailer. We're missing a lot of packaging and bundling discounts that occur. Managed care influence, people using tax deferred plans, or discount plans. We're not catching that in our data, but we are tracking what people are paying out of their own pocket. And even though it's a little different from what we're seeing from some other pricing sources there, what we're showing is that consumers are paying more out of their own pocket for the contact lens that they're buying.

Particularly, they're spending about $51, $52 per transaction out of their own pocket when buying contact lenses. And on an annual basis, that means they're spending about $121 on just the contact lens that they're buying. And the cost or price per transaction in aggregate up by about 22% over the past 13 years, growing by about 1.7% annually. The entire annual spend up by 31% over the past 13 years, grown by about 2.4% annually.

And there's some differences there based on consumer demographic. Basically, adults over the age of 35 paying more now than they were 13 years ago. And also increasing the amount they pay. Consumers under the age of 35 generally flat. People with insurance benefits also spending more now than they were a few years ago, and some of that might be tied to the benefits, and the allowable benefit for people that have eyeglasses and contact lenses. Sometimes, they're spending money on contact lenses out of their own pocket.

Managed Vision Care does have a huge influence on both the industry as a whole for vision care and optics, but especially for contact lens. We have about 126 million US adults that have some type of vision care or insurance coverage when they go to buy optical products. That's up by 14.5 million from December of 2007 before the recession set in. The people using Managed Vision Care to buy contact lenses is up by 61% over the past 10 years. About a quarter of those folks are using some type of stand alone Managed Vision Care care plan, VSP, IMED, Spectera, so on and so forth. That's up by 5.6% over the past year. It's up by 65% over the past 10 years here.

And again, performance varies based on the channel you're looking at. About 61% of all the contact lens sales involving insurance of some sort happened at an independent ECP. Compare that to the 39% share of the total contact lens sales, and you can see how the independent practitioner depends on insurance a lot for their contact lens business.

About 17% of all MVC sales happened at a chain location, about 15% at a mass merchant location. And really, the growth over the past 15 years has been skewed towards the independents as well. In aggregate, the number of contact lenses that are selling with managed care are up 75%. All the other channels and outlets only up 35% combined in aggregate.

And when you look at the type of consumer that's using Managed Vision Care, it generally lies more on men, adults between the ages of 35 to 54. People from higher income households. And people who are just wearing contact lenses as their only means of vision correction.

We'll take a look at some of the attributes of people wearing contact lenses in the US. About 9.6% are currently wearing some type of rigid or semi-rigid lens. That's up 25% since 2007, thanks to more people from higher income households, people over the age of 45 wearing rigid or semi-rigid lenses. Toric lenses. About one out of every six or so contact lens wearers are using toric lenses. That's actually down a bit from 10 years ago. The multifocal users up by about 30%, again, thanks to that influx of relatively older users over the age of 45.

There's some other attributes. There are about 10.5% of contact lens wearers are only wearing the lens in one eye. About 12.2% percent wear them to enhance or change the color of that. But the biggest change, as Thomas mentioned before, is in modality usage. You have about 29% of the US adult population wearing daily lenses. About 22% wearing weeklies. Almost 40% wearing monthlies. And then finally, just under 10% wearing a long term speciality custom or gas permeable lens.

Since 2007, the number of disposable users up 275%, most of them in the younger age categories. Monthly usage also up over the past 10 years, but not nearly as much. And most of that has come at the expense of weekly, biweekly wearers and fewer custom long term wearers as well.

One of the things that we noticed through Vision Watch is that consumers unfortunately, some of them don't abide by the recommended replacement frequency. You have about 10% of all daily lens wearers in about 12% of all total contact lens wearers not abiding by the prescriber or the manufacturer recommended replacement frequency. Typically, you see younger adults, people from lower income households without insurance, people that are new to the category-- they're more likely to extend the use of lenses beyond the recommended replacement frequency. And fortunately, what we're tracking going back to 2011, there are fewer people now that are disregarding those replacement frequencies and more people abiding by it today.

You look at eye exams out there-- about 114.9 million exams are conducted in the US over the course of 2017. That's flat compared to 2016. There were 34 million contact lens exams over the course of the year. Up by 3.1%, meaning about 80% of the people that wear contacts got an eye exam last year. It was one of the few bright spots for the eye exam industry.

And what we've also found is that about 63% of those exams happened at an independent ECP location. When you compare that to the 39% of lenses bought at an ECP location, you can see there's a pretty high walkout rate. People that take their prescription and go elsewhere with it to make a purchase.

And generally speaking, about 46% of those folks will go to an online retailer, either an online only retailer without a brick and mortar presence, or a reorder site from a brick and mortar site. About 20% will go to a mass merchant brick and mortar location. 16% to a chain. 10% to a wholesale club. 5% to another independent ECP. And one of the things that we've noticed since 2007, the number of people going directly to an online retailer has more than doubled, from 22% of walkouts to 46%.

And they're generally younger, higher income, already buying things online, whether it's food, apparel, other items. And generally speaking, they're also more of a commodity fashion oriented customer. And this is really one of the big driving factors that we're seeing behind the industry there. So that's basically the slides that I had there. I don't know if we're going to do questions now or wait.

BETH FREEBORN: We'll wait.

STEVE CODY: OK. Cool. Sure.

WALLY LOVEJOY: Good morning, and let me introduce myself. As Steve suggested, he has a great deal of statistical data supported by a big organization. The information I'm going to share with you is really, my amalgamation of reading lots of data about the industry from Vision Counsel, from Jobson, from AOA, and [INAUDIBLE] data that are published in trade press.

And I have tried to put together a few slides that will allow me to draw big picture, but I have not put in footnotes. For those lawyers that really like footnotes, if you want my sources, or if you question the data, and would like to offer the FTC better data than what I am going to be summarizing for you here, I know they would welcome it, as would I.

I am an independent contractor. I'm here on behalf of the National Association of Optometrists and Opticians, which means they're paying my expenses to be here. I am not representing them. I think most of what I'm going to be presenting is either objective data or my opinion about how the objective data fits together, but I'm not speaking on behalf of any of the members or the association. This is my interpretation of the information I'll present. And I do think that there is a great deal of information out there from all of the manufacturers, trade associations, and professional associations that hopefully, I have captured accurately here.

One of the things I was asked by Beth to talk about is who's prescribing out there now. And most recent data I've seen is that there are nearly 43,000 US optometrists and 16,700 ophthalmologists, all of whom can prescribe contact lenses. Over 12,000, maybe 12,500-- those optometrist or affiliated with optical retail chains. 11,300 locations. Most of those optometrists do not sell the products that they prescribe, including contact lenses.

And I'm going to make an assumption that just by my look at the Vision Monday report of the top 50 optical retailers, that 12,500 ODs and those 11,300 locations doesn't include optometry led alliances, franchises management service agreements. So that would be brands like Vision Source, my eye doctor, Eye Care Partners, and others. Where the way that the data has been defined is an optometrist who makes the professional judgments at three or fewer locations is an independent. But they typically prescribe and sell product in those groups.

And so I think that those brand names or trade names that I just mentioned are typically included in the 26,000 optometrists that are involved in private practice. So you can query whether semantics makes sense, that it's private, if you're getting a lot of help from a franchise, or a management service agreement. But the independent professional judgments are owned by the OD who owns the practice. And they may pay royalties or management service fees for the help that they get from the nonprofessional side of the business.

There have been changes in the supply of optometrists and in the number of eyewear retail locations over the years. I think it's appropriate, as Mr. Pahl suggested, that more competition has supported that. In 1975-- and this data is from the early eyeglasses one report, that the FTC studied the market before the initial eyeglass prescription release requirement, and the review of some of the advertising restrictions that were in the market at the time, there were about 20,000 active ODs. 85% of them are self-employed. And most of the other optometrists are employed by other ODs.

With the rise of commercial free speech and eyeglass prescription release, the market started to change. At that time, ODs did only about 29 million eye exams, which was 57% of the 51 million that were done that year. And optometrists' involvement in eye exams and primary eye care continues to grow after eyeglasses one rule, and the commercial free speech opening. The number of doctors continued to grow, but the percentage in private practice went down. So that by 1986, only 73% were in private practice.

And by 2003, the number of independent prescribers had grown to 22,500. But a number of other retail locations with that had grown to 16,500. So advertising and some of the other changes that went on as a result of state law changes relating to things like brand names, and commercial or mercantile locations, department store locations began to open up a little bit more. So it became easier for optical retailers like NAOO members to have sublease or franchise relationships.

So while the number of private dispensing optometrists grew, the number of optometrists affiliated with optical retailers grew even faster. And so by 2012, there were 40,000 optometrist's in active practice. And 57% were independent. And independent-- I again go back to my semantic definition-- they were not in affiliation with an optical chain, but rather, selling at the location where they prescribed, also selling eyewear.

And in 2012, optometrists were up to doing 88 million refractive eye exams, not eye health only. And that was out of 104 million. So the percentage of eye exams by optometrists compared to that refractive exam or even primary eye care eye exams by opthamologists continued to drop.

Chain affiliated doctors, doctors who prescribed near a brand optical retailer, has multiple formats. I thought it would be useful for the FTC and this audience to understand what some of those might be. And again, I hope this is a reasonably complete picture, but I welcome feedback, and the FTC is, as I said, taking comments till April 6.

But the most typical is the independent contractor, where an optometrist who owns his or her own practice will practice in co-location with an optical retailer, usually through a sublease or a license agreement. The office is typically equipped by the landlord or the licensor. And most of those agreements sublease or license would specify that the prescriber won't sell eyewear, doesn't profit from the sale of eyewear, and in fact, may face restrictions like Medicare fraud and abuse in being involved in profiting in any way from the sale of that eyewear.

And as I said, it's the most frequently used . Format covers probably 80% of the locations that I mentioned earlier. And often, a sublease or licensee will employ other optometrists and staff to help operate the practice. They may have multiple locations, and as a result, it's a little hard to say that all of these are employers versus employees. I think the number of optometrists who are employed by someone else, whether it's an optometrist or an ophthalmologist, an HMO or the VA, continues to grow. That being an employee as an optometrist seems to be an expanding part of that profession.

Not very many optometrists are directly employed by optical retailers. Maybe 5% to 10% based on my observation. Most states prohibit the corporate practice of optometry. And it depends on the volume and structure of the location, but it's not always an easy model to maintain. So even when optical retailers could legally employ, they often choose not to do so.

And then finally, there are also franchises. And I'm talking now about the optical retail community that we talked about earlier, where the owner could be either a prescriber, or an optician, or retailer, but that's only 5% to 10%. Pearle Vision, for example, is a fairly large franchiser. There other optical retail chains that franchise their business as well.

I am not including in this, as I mentioned earlier, the Vision Source Group, which I think has maybe 3,500 locations, and 5,000 doctors involved. And that is a franchise relationship, but the doctor still has a significantly different kind of relationship with the franchiser. And so it's not included in the optical chain numbers.

Who's doing the prescription of contact lenses? From the data that I saw in 2013, the optometrists were doing 85% of the comprehensive eye exams, and wrote 90% of the prescriptions for corrective eyewear. And 27% of those exams were contact lens exams. I think that the data that was most recently reviewed suggested that the independent eyecare professionals, which would include ophthalmologists-- and I used OMD as the shorthand for ophthalmologist here but I think maybe 5% to 10% of ophthalmologists are osteopaths, not medical doctors, but it's really irrelevant to the scope of practice.

The ODs affiliated with optical retailers did about 28% of the contact lens exams. Maybe it's not surprising, but nearly 9% of contact lens wearers reported they didn't know or got their eye exam

someplace else. And that suggests to me that ophthalmologists are writing under 10% of the contact lens exams.

Steve made the comment that independent doctors sold 37% of lenses, the private ODs. And when you look at how much the chains and the online retailers sold, ophthalmologists are not selling a lot of the product. Perhaps under 4%. I will comment that I don't know that optometrists are losing 100% of the supply of contact lenses that their patients wear.

I think it's fairly typical for the initial exam fitting and evaluation to include the sale of some product, and then the first 30, 60, or 90 days, would go out with the patient, with the prescription. And then the growth in the mass merchants, and clubs, and online sales are more of the replenishments sales. So it's a little hard to tell. But if people are only buying $50 at a time or $52 at a time, that would suggest that they're making more purchases during the year. And Steve may be able to explain that in more detail later.

So product modality. I guess that's the other thing Steve's already flagged for you, but there's a lot of shift going on, both in dollars and patients, as one day wear has been the shining star in growing and continuing to grow. Two week is declining, and people are either going monthly or to the daily wear. And it looks like the specialty lenses and gas perms have been fairly stable. I was a little surprised to see that patient share for gas perms and specialty lenses was higher than their dollar share, but that would suggest that some of these other lenses are just more expensive, I would think.

And vision care insurance-- Steve also flagged this for you-- but the numbers that the division counsel describe about the number of people, the 50 some odd percent of people that make a purchase involving their benefits include a lot of alternatives to pure insurance. It could include a vision plan that's a standalone plan. It could include a health benefit, but it also includes government plans, and FSAs, HSAs, and other spending accounts. And even discount plans, although that's not a significant percentage of the 51% that he mentioned. And surprisingly, there's a lot of people that don't know.

But maybe that shouldn't surprise.

The employers do often vision benefits as an option, and it's growing. For those of you who are not familiar with vision care insurance, monthly benefits for an individual depending on the plan could cost $10 to $20 a month. And as Steve mentioned, about half have vision care coverage. Children have it.

Apparently though, that's not well known by parents. To their credit, the vision counsel has spent time and money trying to figure out how many are using vision benefits and what they know, and how often they're getting eye exams. Since the Affordable Care Act made pediatric vision care an essential health benefit, there's been some data, but it appears from the division counsel studies that a lot of still aren't aware that they even have coverage. And as a result, the Vision Counsel is doing this a couple of times a year-- Steve, is that right?

Every other year, sorry. I wasn't sure if a semi or bi, but every two years, because it's so expensive to find who can remember and talk about what they're under 18-year-old child did with respect to the eye exam. So there's some data out there but it's not nearly as robust as the other data from the consumer panels, because of the difficulty in surveying parents.

But as Steve mentioned, 50% of contact lens buyers do report that they had some benefit. And it might have been a paid benefit, or it might have been a discount, but that's a lot less than in the eyeglass buyer side. The other thing that's interesting is that it's usually an either/or kind of benefit if you're using IMED or VSP. You get $1 allowance for frame and lens, or for contact lens fitting evaluation, and contact lens product. And it could be $100, $150 once a year. And I think it's possible also that the wearers out there-- this is speculation on my part-- eyeglass wearer will alternate, and get contact lenses one year, and eyeglasses the next. But they try to make sure they're using their benefit.

And of course, there could be discounts from a plan that apply to the product purchase beyond what's the covered benefit. That doesn't exist in all plans, and may be restricted in some states, but it would be typical to see a 20% discount on additional product.

And then a couple of slides just to show you the variety in contact lens price. And this is what I have to caveat-- I got a couple of industry sources-- this seems directionally corrected. If people want to go out and shop for contact lenses, they're going to be able to find a real range of prices. And independent ODs, depending on whether you're getting rebates, what's included, whether you're buying an annual supply-- it depends on the product-- but the internet channel, and national retail channel, and club channel will vary depending on the product.

And it also-- I just went to double check this-- but it varies by the day. What's the day rebate. What's the special going on. Are you a first time buyer on that particular channel, you can get an additional rebate. So there are a lot of ways to price shop, but it can be pretty complicated. And you also have to consider, as the buyer, what bundle of services you're buying. What are your return rights, or follow up, and other care included. Are there any warranties, et cetera.

And it's also in daily's-- the similar kind of thing you'll see-- a range of prices subject to some rebates. And even within a channel, you might find significantly different prices, say between one national retailer and another. So the numbers that I've put up here for the FTC to look at are really averages, and it doesn't indicate that every national retailer or every club sale is selling at exactly that price. And my guess is if we went and looked, it would all be different today. But there are certainly a lot of ways that you can look for price on the internet. So that's it. Thank you.

BETH FREEBORN: Thank you, Steve and Wally. And next, we have Rich Cleland and Andrew Stivers, moderating our panel on contact lens health and safety.

RICH CLELAND: We're in good shape.

Good morning.

Contact lenses are regulated medical devices. And it is widely recognized that contact lenses involve some safety risks. And the goal of this panel is to examine some of those risks as they relate to the content lens rule. Before getting into that, I would like to briefly introduce our panel members. And there is additional information in the program material for the bio, so I'm not going to give you everything here.

My name is Richard Cleland. I'm Assistant Director of the Division of Advertising Practices at the Federal Trade Commission. My co-moderator is Andrew Stivers, who is Deputy Director of Consumer Protection in the Bureau of Economics at the FTC. Andrew oversees the provision of economic analysis, and advises to the Commission on all consumer protection matters. Andrew Joined the commission in 2014 after serving as Director of the Consumer Public Health and Statistical Analysis research division at the US Food and Drug Administration Food Center.

Our next panelist is Dr. Jennifer Cope. Is a medical epidemiologist-- and there's going to be more of those, folks. My tongue doesn't always do what my brain says it should. Disease Physician at the Waterborne Disease Prevention branch in the National Center for Emerging and Zoonotic Diseases. She oversees the CDC'S health program, and has published several articles on contact lens wear, behaviors and risk factors associated with infections.

We are also joined by Dr. Malvina Eydelman. And she is a board certified ophthalmologist for over 20 years as an expert medical officer, Senior Medical Advisor, Director at the FDA's division of Opthalmic, Neurological, and Ear, Nose and Throat Devices and Director of the FDA's division of Orthonomic and Ear, Nose and Throat Devices. Dr. Eydelman has played a key role in assuring the safety and effectiveness of medical devices.

Dr. Michelle Tarver is a medical officer of the Food and Drug Administration, and the Center for Disease and Radiological Health. She joined the Food and Drug Administration in 2009, where she works on ensuring that contact lens devices are safe and effective before entering the US marketplace, as well as conducts research that incorporates the patient's voice in the evaluation of such devices.

Also joining us is Dr. Carol Lakkis, who is currently the clinical research fellow at the head of Applied Clinical Services at Johnson and Johnson Vision. She has over 100 publications, has lectured extensively, and is recognized as an international expert in ocular microbiology, and contact lens related infection and inflammation.

Finally, Doctor Edward Chaum is the University of Tennessee Hamilton Eye Institute Inaugural Plough Foundation Professor of Retinal Diseases and Professor of Pediatrics, Anatomy, and Neurobiology, and Biomedical Engineering. Dr. Chaum will become the Margy Ann and J. Donald M. Gass Professor of Ophthamology at the Vanderbilt Eyecare Institute in April of 2018. With that, I'd like to turn the program over to Dr. Jennifer Cope from the CDC. Thank you.

JENNIFER COPE: OK thank you I just want to check can I be heard

Yes?

Great.

So I just want to say thank you to the planners for this invitation to speak here today, and for this opportunity to present a public health perspective to this issue of contact lens health and safety.

First off, I'll just spend a minute or two-- I often start a lot of my presentations this way-- as to why someone here works in the waterborne disease prevention branch at CDC works on contact lens health.

Next slide, please.

So this goes back to our expertise on organisms called free living amoeba, of which one of them is acanthamoeba. And acanthamoeba is the cause of acanthamoeba keratitis, or AK, which is a serious-- fortunately, rare-- but serious cause of keratitis most often associated with contact lens wear. And so it was our expertise in this disease that started our work in contact lens health. And it really goes back to the mid '80s, when our group was called upon to offer advice on increasing numbers of case reports of acanthamoeba keratitis. And that led to our first case control study, looking into risk factors for this condition.

Next slide.

Fast forward about two decades and that brings us to around 2006, when again, we found ourselves in the same position receiving increasing numbers of reports of acanthamoeba keratitis. And this led to another case control study , a large multi-state investigation. And it was during this investigation that a specific multi-purpose solution was identified as the primary risk factor. And this resulted in the recall of the solution.

However, we also documented a lot of other types of behaviors that were putting people at risk for contact lens related infections. And even after this recall, we noted that these infections did not go down to the previous levels. And so that led to subsequent a case control study conducted in 2011, during which we did not find an association with a specific solution, but again, documented a lot of behaviors that might be putting wearers at risk.

And so it was at this point where the group I work with that CDC decided, well, we enjoy investigating disease outbreaks. We wanted to put into practice what we had learned, which was there are a lot of behaviors going on, and probably a lack of awareness as to what these behaviors could be doing to contact lens wearers. And so we really took to heart that second part of CDC's, name which is the Centers for Disease Control and Prevention, and really started to develop our healthy contact lens programs to start to try to prevent these infections, rather than continue investigating outbreaks.

So next slide.

So our healthy contact lens program has a health promotion and education aspect to it, which I'll get into a little bit later. But another aspect of it is just answering some basic questions that we had as a result of the work we had done. One of those questions was, how much keratitis is there.

And while this seems like a straightforward question, there wasn't a straightforward source of data to answer this question.

A lot of the diseases we investigate here at CDC are what we consider nationally notifiable or reportable conditions that have to be reported to a state or local health department. Keratitis is not one of those. And so we have to be a little bit creative in how we try to answer this question. So we ended up using data from the National Ambulatory Care Emergency Department and insurance claims databases. In using this approach, we estimated that there are 930,000 doctor's office and outpatient clinic visits, and 58,000 emergency department visits annually for keratitis and contact lens disorders. And we are also able to estimate that these costs approximately $175 million in direct health care expenditures on an annual basis.

So next slide.

Another basic question we wanted to answer was what epidemiologists are always searching for, which is our denominator. So how many people are at risk for this condition. And so in this case, this is contact lens wearers. And so one basic question we wanted to answer was, how many contact lens wearers are there in the United States? We know there was a lot of market research data on that, but we wanted to put an estimate out in the scientific literature.

And then the second part of that is what are these contact lens wearers doing. What are their behaviors, how prevalent are these behaviors. So that led to our estimate of 41 million adult contact lens wearers. And then the second part of that was surveying about 1,100 wearers, in which we determined about 99%, or almost all of them reported at least one contact lens hygiene risk behavior. And also, part of that survey, nearly one third of them reported having experienced a contact lens related red or painful eye that required them to seek medical attention.

Next slide.

So diving in a little bit deeper to that survey of the 1,100 contact lens wearers, this table is showing the most frequently reported behaviors. So the most frequent reported behavior that could put them at risk was napping in contact lenses. 87% reported that, as well as about half reported sleeping overnight in them. And I point that out because other work in the literature does show that sleeping and napping in contact lenses to be one of the riskiest things that you can you to put yourself at risk for contact lens related infection.

Another common behavior was topping off solutions. So this is when you don't completely dump out the old solution in your case, and you just top it off with some new solution. This was done by over half of the respondents as well. About half reported on replacing their lenses in an interval longer than what was recommended. And then also, a very large percentage reported replacing their case at an interval longer than recommended.

Next slide.

I know there's been data already presented on this, but as part of this survey, we also asked where the wearers were purchasing their lenses. Based on this 2014 data, the majority were

purchasing them in a provider office. 10% we're purchasing them in a retail store without the eye them. And then nearly 21% we're purchasing on the internet.

Next. Slide

And then we did ask this question again in 2016, when we also included adolescents as part of the survey. Numbers don't look terribly different than the 2014 numbers. Again, most are purchasing in the provider office. And then for the internet purchase, you notice that the young adult age group, the 18 to 24-year-old age group, is the one purchasing from the internet most frequently.

Next slide.

So some additional work we did in collaboration with our FDA colleagues was to use a different data source to kind of, again, get at some of these questions we had about how much keratitis, and what types of the behaviors do our wearers have. This time we again collaborated with FDA to use their medical device report database. As you'll probably hear more about from my FDA colleagues, contact lenses are regulated medical devices, and as such, manufacturers are mandated to report any adverse events occurring with those devices.

So in this study, we found just over 1,000 contact lens related medical device reports that contained the term ulcer or keratitis. And not surprisingly, most of them came from manufacturers, and a smaller percentage were reported by the eye care provider or the patient. And 20% of those described a patient who had essential corneal scar, a decrease in visual acuity, or required a corneal transplant following the event. And we reported this data to show just how serious, some of the outcomes are for these events.

Next slide.

As I mentioned, the other aspect over healthy program is a health promotion and education aspect. What we were finding is that just a lot of contact lens wearers were not even aware that some of these things they are doing that they probably just considered harmless shortcuts could actually be putting them at risk for a contact lens complication.

And so on this slide, we just have a couple examples of some graphics that we've created that can be used on social media. You'll see on the far right, we have our contact lenses are like underwear campaign that's been very popular, and has gotten a lot of attention.

Next slide.

One of the hallmarks of our healthy contact lens program is contact lens health week, which has been marked every August, and will be coming up this August for the fifth annual contact lens health week. And that's kind of our major push to get a lot of these messages out through social media, and through our partners. And this is usually the research that I just presented on estimating the burden of keratitis, and reporting on these behaviors. We publish in our CDC's

publication morbidity and mortality weekly report. And so we usually kick off the contact lens health week by putting out whatever our report is that year to garner more attention.

And then next slide.

I'm not sure if we'll be able to get this to work, but this is a video series that we completed last year that featured three patients who had an infection related to their contact lens wear. And they are like video testimonials in which they describe what happened, and kind of the lessons learned from that. So if we can get it a play, it's about two and a half minutes. Great.

[VIDEO PLAYBACK]

RON PARIS: My name is Ron Paris. I'm from Madison, Alabama. I'm a junior at the University of Alabama.

I first noticed that my left eye had a problem when we were about to play LSU, and I was getting ready for game day. And I looked at my roommate, and I said hey, is there something wrong with my eye? He said, no, it looks fine, looks fine. But I was having a lot of pain. And after that, my eye started getting more and more shut every day. And I started feeling more and more pain. You know, I just thought it was another scratch, but I didn't know what it was going to turn into.

About a month later, I went to a doctor's office in Birmingham, and she was like, you have acanthamoeba keratitis. I was like, OK, what is that? She told me that some people experience blindness, very sensitive to light. And that basically, it eats away at your cornea to the part where you can either just go completely blind or you have to have a cornea transplant, or you would lose your eye. And so of course, I'm like, OK, well all those sound bad. I'd rather not have to do that.

I was a terrible contact lens user when I was in elementary school. And I got better when I got to middle school, but it still wasn't very good. So I'd just wash them out in tap water, or lake water, or river water, wherever I was. That was just a normal thing for me. I saw my grandfather had hard contacts, and I saw him do that all the time. So I'm like, all right, no big deal. So it was just another thing. I didn't figure anything could come bad from it. It's just water.

Tap water definitely contributed mostly to the whole thing. That week, I ran out of solution, so I just was using tap water. Just a normal thing for me. Right now, I have a giant scar on the middle of my left eye from infection. I cannot see directly in front of me. I can see peripherals pretty good, but I cannot see directly in front of me very well. If I covered up my right eye right now, I could kind of tell what was going on around me, but I couldn't really say specifically who someone is.

We're hoping that surgery or whatever goes well to get that scar away from me, so I can go back to seeing normal and maybe even wearing contacts again.

If I knew more about washing contacts and what then, I feel like this would have been 100% avoidable.

[END VIDEO PLAYBACK]

JENNIFER COPE: Well, thank you. That's all I have.

RICH CLELAND: Turn it over to you Dr. Eydelman, please.

MALVINA EYDELMAN: It's OK.

Good morning, and thank you for the invitation. As you heard, I work for the Food and Drug Administration. And I would like to take a few minutes to share with you what we do at the FDA to assure US regulation for safe use of contact lenses.

I would like to start out by acknowledging the staff members on this slide who have put together this presentation. Most of them are here in the audience, and hopefully, will be available throughout the meeting should any of you have questions.

This as the official definition of a medical device. Medical device is intended to diagnose, cure, or mitigate, treat, or prevent a disease or condition, or intended to affect the structure or function of the body, and does not achieve intended use through chemical action on metabolism. I would like to point out that unlike drugs, there are no generic medical devices.

All of the devices are classified into three classes. Class 1 being the simple design, the lowest risk. And most of these are exempt from pre-market submissions. Class 2 are more complex with moderate risk. And most of these require pre-market notification to demonstrate substantial equivalence before they are allowed to be marketed. Class 3 are the most complex, highest risk, and these require PMA or pre-market approval to demonstrate reasonable assurance of safety and effectiveness before these devices reach the US market.

FDA regulates all contact lenses. Lenses are classified as either class 2 or class 3. All daily wear lenses, soft, and rigid, gas permeable are class 2. And all of the extended wear lenses are class 3. I would like to emphasize the point that in addition to the refractive error corrections, there are contact lenses that cleared or approved for other indications, specifically to promote corneal healing, bandage contact lenses. For the temporary reduction of myopia, or orso-k. To enhance or alter the appearance of the eye, decorative contact lenses.

Again, these are indications which are currently available in the US. But I would like to emphasize that currently, we are seeing an explosion of other indications that they are being studied, and developed by the manufacturers in the US.

Per our colleagues from CDC, there are approximately 45 million Americans who are wearing contact lenses. 35% wear daily disposable. Over 90% of adult contact wearers use soft contact lenses. Now the next two bullets weren't emphasized sufficiently so far. So I'd like to bring to everybody's attention that about 11 million wearers are between ages 12 and 24. Thus, teens and young adults-- there's a significant public health impact in that population from contact lenses.

The risks from the use of contact lenses are many, and have been addressed by a number of speakers. Some of these, not all, are listed on the slide. These include microbial keratitis, allergies affecting the eye, GPC, corneal abrasion, contact lens induced acute red eye, corneal infiltrates, dry eye, and neovascularization.

In a study that looked at all of the emergency room medical records reports from the National Electronic Injury Surveillance Database, it was found that contact lenses accounted for most medical device adverse events compared to all other devices. I bring this fact to emphasize the impact of public health that contact lenses have. Subsequently, FDA has worked very diligently to put a number of safeguards to assure the safety of contact lenses.

We spend significant resources reviewing pre-market submissions. My division has been involved in standards, both on the national and international level for a number of decades. We have guidance, post-market surveillance, such as MedWatch, PAS, and 522 studies. We have conducted our own research. And we have spent a significant amount of resources on outreach.

All contact lens pre-market submissions undergo thorough review by the team in my division. We make sure that we review the materials and chemistry, manufacturing, sterility, shelf life, biocompatibility, performance testing, non-clinical, and clinical performance testing. Recommendations for these are described in our guidance and the recognized standards.

The chemistry review of contact lenses is quite unique. Properties unique to each contact lens product that may affect performance are summarized on the slide. These are material composition, physical properties, surface characteristics, packaging solution composition, material and manufacturing residuals, interaction with care product solutions, and lens design.

Evidence supports marketing clearance or approval for each new lens material that reaches the US market. We assess the following-- adverse reactions, slit-lamp exams, symptoms, problems, complaints, keratometry changes, visual acuity, average wear times, discontinued lens replacement, contact lens performance, and lens surface characteristics.

We communicate many of these in our contact lens labeling. The following couple of slides summarize the information in our contact lens labeling that is similar to the prescription elements. Specifically, manufacturer's brand name. This really refers to the entire device, inclusive of the material name, manufacturing process, packaging solution, and other factors which may impact the unique attributes to the lens material. Distinguishing attributes can result in differences among materials in contact lens fitting, performance, and ultimately, in ocular health.

Base curve affect the alignment of the lens to the topography of the central cornea. Important to point out that same base curves for different brands may not be clinically equivalent. Diameter affects the lens centration. And once again, same diameter for different brands may not be clinically equivalent. Dioptic power affects strength of the correction. Improper power may result in reduced visual acuity, eyestrain, and headaches.

Currently, there is no regulatory pathway for marketing of generic contact lenses. The current clinical care paradigm does not support substitution of contact lens brands without clinical evaluation. Additional research in education is needed regarding critical design and material properties to support clinical equivalency between brands.

As I mentioned, we at the FDA have worked for a number of decades in creating and recognizing consensus standards. This slide is a summary of those standards, which have been recognized by the FDA. These include both US and international.

Additionally, we have two current FDA guidances which describe our interpretation of a policy over regulatory issues, and they talk about labeling, manufacturing, and clinical studies that we would like to see in the submissions.

Post-market, we have a number of ways to collect information to report adverse events, including related infections. The slide contains the link to the FDA MedWatch and the FDA website specific to report the problem with contact lenses. Additionally, when needed, we have conducted 522 studies, which has a mandated post-market surveillance study.

Given the impact on the US Public Health, we have taken unprecedented measures and conducted quite extensive research in-house. As a result of our research over the last 10 years, we have categorized the numerous silicon hydrogel lenses to address concerns was dimensional stability and toxicity. We evaluated the efficacy of care product solutions in the presence of lenses i.e. real world evidence, real world testing. And we developed acanthamoeba test methodology. The references on the slide summarize some of our articles. Most of these in the ion contact lenses, and the last one was published just a couple of weeks ago.

To ensure the safety and the transparency of our work, we have held a number of public meetings over the last decade. Most of these are summarized on the slide. As you can see, we have had advisory panel meetings and a workshop to address different aspects of safety of contact lenses.

We have a separate team dedicated to outreach for contact lenses. We have published consumer focused articles, which were distributed to over 75,000 subscribers. We have very popular websites, two of which are dedicated to contact lenses at FDA. One is to all contact lenses, and one to decorative contact lenses. We're very fortunate to partner with CDC and working on their website as well.

We have conducted Medscape commentaries and interviews. Have put together and a number of videos, including public service videos, which inform the proper way to wear lenses, and recommended getting an eye exam and a valid prescription.

And we have done something very unique for FDA. We have launched a Twitter campaign regarding decorative contact lenses. And as my CDC colleague has mentioned, we also participate in the contact lens health week, and have launched a Google AdWords campaign.

As you can see, we take safety very seriously, and have dedicated a significant number of resources to assure that the Americans who wear contact lenses remain healthy. Should you have any further questions, I suggest you contact Dr. Angelo Green, who is in the audience. Angelo, if you can wave, he's the acting branch chief overseeing contact lenses at the FDA. Thank you very much.

RICH CLELAND: Thank you. Dr. Lakkis, go ahead.

CAROL LAKKIS: Good morning, everyone. My name is Dr. Carol Lakkis, and I'm representing Johnson and Johnson Vision Care Incorporated. As the head of applied clinical sciences within the contact lens research and development group, I'm responsible for leading exploratory research to support new product development.

In my role at Johnson and Johnson Vision, I bring decades of experience as both an ocular microbiologist, and optometrist, and have spent more than 20 years conducting research on contact lens related infection and inflammation, disinfection and discomfort, and the therapeutic management of ocular disease. In short, I've dedicated my career and my work at Johnson and Johnson Vision to improving patients' overall eye health and the contact lens wearing experience.

Today, I'm pleased to be here to offer my perspective on why it's vital that our vision care regulatory framework continues to preserve the eye doctor-patient relationship to achieve two important goals. First and foremost, to minimize health related risks and complications associated with contact lens wear. And secondly, to bring new and innovative contact lens technologies for physicians and patients.

Over the past three decades, as the contact lens landscape has grown, eye doctors continue to play a critical role, not only in promoting eye health, but also in working with individual patients to find the most appropriate contact lenses to meet their unique and evolving needs.

Ensuring patient access to an eye doctor for a contact lens fitting and evaluation is critical, because contact lenses are applied directly onto the ocular surface, and these complex lens materials interact with the environment, including the patient's cornea, tear film, and eyelids. In clinical practice, I would regularly explain to my patients that finding the appropriate lenses for their eyes doesn't just provide them with overall comfort and enhance their lens wearing experience, but more importantly, it can minimize the negative impact on their eye health, not just over the next year, but over the next 50 years.

That's why wearing any type of contact lens not prescribed by an eye doctor could lead to a variety of complications from mild discomfort to severe adverse events like inflammation and infection. Current research suggests that inflammation and infection are on a continuous spectrum.

So while an issue like inflammation may not sound like a critical health condition, it's important to address as quickly as possible so that it doesn't develop into something more serious, or cause any permanent damage to the eye. In fact, because clinical complications can arise prior to the

onset of symptoms, a regular comprehensive exam with an eye doctor is critical to minimizing risks and impacts on eye health, and reducing unnecessary costs to our health care system.

While we know the value of regular patient visits to their eye doctor, one of the most significant challenges that we face stems from the fact that contact lenses have become widely used, and as technology has evolved, doctors and scientists like myself have focused on ways to minimize risks associated with wearing lenses. And we've had great success.

However, these successes also make it easy to underestimate the importance of consistently going to the doctor for a comprehensive eye exam, even when a patient's current contact lens seem to be working, and their eyes seem to be healthy enough to continue to wear their lenses. Furthermore, a patient's eyes are a window to their overall health, and need ongoing care to keep avoidable health risks low.

Importantly, the challenge of reducing contact lens adverse events isn't unique to the US. We have some notable advantages in how our current regulatory system balances access and choice with patient eye health and safety. In fact, when looking at adverse events globally, the research suggests there are higher risks in markets where patients don't need prescriptions for contact lenses or in those markets that don't require a comprehensive eye exam with an eye care professional.

For example, in many Asian countries, patients don't need prescriptions for contact lenses, and as a result, higher infection rates are reported. In addition, contact lenses can be the leading cause of corneal infections in unregulated markets, such as in Taiwan, which is not always the case in studies from regulated markets such as the US and Australia, where ocular surface trauma and diseases are common causes of infection.

It's extremely important to balance source of supply with an eye doctor's guidance and supervision to make sure lenses have fitted correctly, and maintain biocompatibility with the patient's eyes.

So in closing, at Johnson and Johnson Vision, we take our role as a leader in eye health seriously. It provides us with a platform to advocate for better standards of care for all patients. As part of this commitment, we support the eye doctor-patient relationship, and continued patient access to innovative lenses, which best addressed that evolving eye health needs.

I'd like to thank the commission for this opportunity to share my comments here today. And I'm happy to address any questions during the panel discussion. Thank you.

RICH CLELAND: Thank you. Dr. Chaum.

EDWARD CHAUM: Thank you. I'd like to bring just a slightly different perspective to the conversation this morning. I think you've heard some really important data about the potential risks of contact lens wear if they're not managed properly, and proper hygiene isn't used in their daily care. I think it's very clear, and I certainly agree that all patients who wear contact lenses

should have an appropriate fitting by an eye care professional. I don't think there's any there's any question about that.

But a lot of the health issues around the availability of contact lenses for consumers has focused on the need for an annual eye exam that, in some way, it's critical, as Dr. Lakkis says, feels it's critical for there to be an annual eye examination for the patient, for the patient's health. And the America Optometric Association has a preferred practice pattern, and they recommend an annual eye examination. And I certainly respect the perspective of that Academy. And obviously, its members are going to follow the recommendations of their professional association.

I'm an ophthalmologist, a physician, and surgeon. And my professional academy, the American Academy of Ophthamology has a different recommendation. And I think it's important for the FTC and consumers to understand that there's a difference of opinion about what is required to maintain proper eye health.

So my academy issues what's called a preferred practice pattern. It's their recommendations of how we should manage patients. And the Academy's preferred practice pattern for patients between the ages of 18 and 40 is that those patients need a periodic eye examination to maintain good health. And that examination should occur anywhere between five and 10 years. That's the recommendation of AAO, not mine. That's the recommendation of the AAO.

Patients under the age of 40 should have a good complete examination every five to 10 years. Patients above the age of 40 and less than 55 should have an examination every two to four years. So I think there's a legitimate difference of opinion between the professional societies as to what is required in terms of a periodic exam to maintain good health.

Now clearly, the risk of developing conditions like keratitis in contact lens wearers is known. Dr. Cope has presented a good example of that. It's not an infrequent occurrence. You've seen the numbers there. But Dr. Cope's data also shows that the vast majority of those patients are cured within one visit of the physician. She's published that data.

And it's not clear, actually, that seeing a physician or an optometrist on an annual basis has any impact at all on the incidence or prevalence of keratitis. There's actually no data in the published peer reviewed literature that shows any beneficial relationship between a normal eye examination and the incidence of keratitis.

As a matter of fact, there's one page paper in the literature that actually addresses that association. It was published by Morgan in 2006. And it showed that for case controlled patients who had an episode of keratitis, the patients who had documented a normal healthy eye exam within six months of developing that keratitis were at a two-fold increased risk of developing keratitis. In other words, the normal eye examination documentation was associated with a higher risk in that case control study.

So there's something about the exam per se, that puts that patient at risk. Maybe that patient's behavior changed. But it's clear from the publications across the world for the last 25 years that the risk factors associated with the development of keratitis and contact lens wear are behavioral

and hygiene related risk factors. It is sleeping in your lenses. It is napping in your lenses. It's not changing the solutions.

And we've seen this dramatic decrease in the incidence of keratitis over the last few years that you've heard about in parallel with the onset of the adoption of daily wear lenses. And it's that change in technology that's making contact lens wear safer for patients and reducing the risk of keratitis.

And so really, in terms of sort of helping the FTC decide how should patients get their lenses, who should provide them, the data clearly shows that open access through channels of large retailers online really has no impact at all on the incidence of keratitis, and complications. It's all about the patient's behavior.

And again, Dr. Cope showed some data earlier this morning that show that the incidence of keratitis in patients was unchanged. Two thirds of those patients had a close relationship with their prescriber, and had gotten their lenses from their prescriber. And one third of them had gotten them online. There is no relationship between documenting a normal exam in an asymptomatic patient and the risk of keratitis.

So I don't think there's any question that we all want to provide good health care. The question is how do we provide that in a way that is convenient for the patient, that meets their personal needs, and meets their financial needs, that addresses appropriate management of health care risk, and provides an open forum for patients to participate. And for the physicians to help them wear their contact lenses safely. Thank you.

RICH CLELAND: Thank you.

I would like to start up actually kicking off a couple of things that you said, Dr. Eydelman, and talk a little bit first about the interchangeability of lenses, and the characteristic of lenses that suggest that they may not be interchangeable. And you had a couple of slides here in your presentation about what's unique about contact lenses as well as some labeling-- a slide relating to labeling-- where you mentioned base curve diameter and dioptic power. I wonder if you could comment on what the relationship is between these elements, and the risk to the eye.

The material may be different. How does that relate to safety?

MALVINA EYDELMAN: And I was hoping-- I don't know if there's a way to project the slides back, but I was trying to go back and highlight the specific aspects of prescriptions.

No, I have it. Just the notes so the audience can see it again. Basically, my groups spent a bit of time to try to be very objective, and clearly stated what are factual.

First of all, what we put in the labeling-- only factual information, as you can imagine. We spend a lot of time reviewing the submissions, and then communicate that information in the labeling. And the point we wanted to make-- and I'm going to just essentially accentuate the same-- that the manufacturer's brand name refers to the entire device. And distinguishing attributes within

that manufacturer's brand name can result in differences among materials and contact lens fitting, which will have impact on performance and ocular health.

RICH CLELAND: Right. And I'm trying to distinguish between what part of that relates to comfort, and what part of that relates to safety.

MALVINA EYDELMAN: So sometimes, comfort has to do with fitting. And if it doesn't fit right, first you're uncomfortable. And then at some point, you start getting irritation and subsequent inflammation. And I would like Dr. Tarver to pipe in.

MICHELLE TARVER: So the factors that Eydelman already described in her slide about the different materials-- there are other aspects, such as the stiffness of the material, how the lens's edge, and how it interacts with the ocular surface that potentially could put the patient at a higher risk of infections. And so some of those factors are not the same, even though it may be the same material, or the same base curve, or the same diameter. They may not fit exactly the same from patient to patient, or within the same patient.

RICH CLELAND: And there is no way to determine that without an actual fitting? I mean, we got 41 million contact lens wearers. Obviously, some of those could wear any type of lens, or most types of lenses that are popular.

MALVINA EYDELMAN: And so unfortunately, at the current time, the same diameter of different brands is not identical. The same base curve, the same number, if it's a different brand, doesn't mean the same thing. So ultimately, you still need to fit in or the prescribe the appropriate contact lens.

EDWARD CHAUM: There may be a movement towards a more generic fit. There was a publication in Contact Lens Spectrum last year by Engel that showed that if you look at lenses that are available by brands, they're really becoming commodities. There's one diameter for most brands, and one or two base curves. And Engel's paper showed that 90% of patients had a good and comfortable fit with just selecting one of those base curves, and 98% of those patients were comfortably fit if you checked both.

So the changes in the way the lenses are made, the thinness, the nature of the wear with the lenses is becoming, at least according to this author, much less dependent upon the specific fit, and much more of a generic type of fit.

CAROL LAKKIS: I was just going to add that while there are many different features to lenses that can impact the way that they fit, what we do know and from the research data is that if, for example, a lens is tightly fitting on the eye, then the risk of having an inflammatory or infectious event increases. And sometimes, those things can't be detected just at the fitting visit. It requires evaluation after the lens has been worn for some time, and that is necessary during follow up visits, and examinations at different times of the day. So there are specific ways that different properties of the lenses can actually impact fit that have a distinct impact on comfort comfort, but also on actual eye health.

MALVINA EYDELMAN: To come back to your point, [INAUDIBLE] would be wonderful if one day the base curve would mean exactly the same thing for all brands. Unfortunately, we're not there today.

RICH CLELAND: I have one more follow up question on this topic, and then we'll move on. But in your slide presentation, you had the statement that additional research in education is needed regarding critical design and material properties to support clinical equivalency between lens brands. Given the current regulatory and market structure, is there actually incentive out there to conduct that type of research?

MALVINA EYDELMAN: So maybe this workshop will be the incentive. But in the current regulatory paradigm, that's not needed in order to get new product on the market, new contact lens approved and sold in the United States. But there are many other impetus and perhaps, again, this workshop will be such.

RICH CLELAND: Thank you. Andrew.

ANDREW STILAND: Thanks. I want to spend a little bit of time focusing on the role of the examination itself. And Dr. Chaum talked a little bit about the fact that there doesn't seem to be any data linking eye health to examinations. And I want to unpack that a little bit. I think there's been some discussion of maybe a distinction between an initial visit, and ongoing visit.

But I want to give folks an opportunity to talk-- is there additional data that might be out there that would link these things. And the thing that we always want to see with data is what's the mechanism by which we would think there would be a link. And also examine the empirical data for that mechanism. So I would open this to any of the panel members to talk a little bit about what the mechanism for reducing risk factors associated with contact lens used by the examination, either initial examination, or ongoing examinations.

EDWARD CHAUM: A correction. My point wasn't that any examination was not indicated or required. It's really about how often do you need to reassess the patient. So obviously, every patient deserves and needs an appropriate eye examination, and an inappropriate contact lens fitting. It's very clear that an initial fitting is important. And it's the unregulated use of contact lenses people, who don't get fit over the counter at a flea market or wherever who have significant complications we hear a lot about.

The issue then really becomes what is effective management for that patient, and how often does that patient need to be seen. I would assert that patients who wear contact lenses, when they have difficulty with those lenses, they become uncomfortable. Their wear time goes down. Maybe they get a little bit of redness. They become symptomatic from the use of those contact lenses. And we heard, actually, today about how patients drop out of contact lens wear because they develop these issues.

And I think it's part of our education as eye care physicians to inform those patients that if you have a problem, if you're having difficulty with your lenses, if you're having difficulty with you your wear time, then you should come back for an examination. It's not about keeping the patient

away from the eye care professional. It's about trying to find a balance between what is an appropriate periodic re-evaluation of a patient who is asymptomatic, who doesn't have clinical symptoms, who has good vision.

We used to think that every patient needed a general medical examination every year. I'm incentivized by my health care plan to go see my internal physician every year. My health care costs are less if I do that. But it's very clear from the Cochrane collective publications and from other sources that an annual examination and annual physical examination for someone like me, who is asymptomatic, has no benefit to the patient. It adds health care costs to the system, it has no benefit. And the US Preventive Health Care Task Force, which is an independent agency that assesses health care utilization, came out in 2012, 2013, and recommended against routine annual physical examinations for people like me.

Same thing happened with glaucoma. In 2015, the task force said, patients don't need to be screened for glaucoma on a yearly basis. I think that's a terrible idea for certain patients-- for patients who are at risk. But the routine screening of patients to look for glaucoma was determined by the preventive task force as having no value in preventing disease, and improving health care.

ANDREW STILAND: Dr. Lakkis, seems like you want to respond to that.

CAROL LAKKIS: Yes, I'd first like to make a comment that there are a number of things that can occur when you wearing contact lenses that do not actually first start with symptoms. So one thing that we often see as a complication in contact lens wear is asymptomatic infiltrates.

So sometimes, the first time that these are discovered is actually during an eye exam where you may see a scar. And a scar in the cornea, depending on its location, may impact vision. But more importantly, as I mentioned previously, something like that indicates an inflammatory process is occurring.

Now when inflammation gets bad, then yes, you might notice symptoms. And like we saw in the video from Jennifer Cope, the footballer who noticed that his eye was getting more and more uncomfortable. But a lot of these early changes to the tear frilm, changes to the corneal integrity, looking under the eyelid, and looking for early signs of inflammation in that area as well, these things can occur without symptoms. And as a practitioner, you have a better chance of success intervening earlier if you're able to actually do that rather than waiting until things actually progressed. And in the field of inflammation, what we understand, particularly with CIEs, is once you've had your first corneal inflammatory event, your chance of having another is then increased by 50% for the following year.

So there is a definite need to have a comprehensive evaluation of every wearer for health and safety purposes. But then also, as an opportunity for re-education. So we also heard a lot this morning about the opportunities for modifying behavior, and there is lots of research, and lots of evidence that shows that when you do actually receive education, your behaviors can change. But it's not a long lasting and permanent thing. It requires a lot of periodic re-education to keep

the actual information from patients relevant, and focused on their specific needs, and their lifestyles, and their scenarios . Themselves

RICH CLELAND: Thank you.

Apparently, that's a really that's a very popular view.

CAROL LAKKIS: Yes, clearly. Thank you, everyone.

ANDREW STILAND: One brief clarification question for Dr. Chaum. Does the American Academy of Ophthalmologists have a specific recommendation for the frequency of visits for contact lens wearers in particular?

EDWARD CHAUM: Not that I have seen. Not in their perfect practice plan.

ANDREW STILAND: Thanks. So the final question I want to address sort of in this area of examinations in particular is, there was mention of other countries that have different practices. Is there specific data that relates to the frequency of visits in some of the other areas that have different rules, versus how the US practices?

EDWARD CHAUM: I think the data is actually pretty informative. So outside of the United States, although it is recommended that patients have periodic exams, depending on the country, every two or three years, for all intents and purposes, contact lenses are more of a commodity. You can buy contact lenses in any vending machine in any train station in Europe.

And yet, if you look at excluding the Asian data, if you look at the data of the incidence and prevalence of keratitis in regulated areas like Australia and in Europe, what you see is that the incidence and prevalence of keratitis is exactly the same as it is here in the United States. The risk factors are behavioral, modifiable risk factors that relate to duration of use, hygiene-- sleeping with lens and so forth-- the exact same risk factors. So in countries in which FDA regulations do not exist, and they are less regulated, the incidence is the same.

The one thing that is, I think, important to point out is that things have changed here since the original FCLCA a ruling in 2004. And so the concern at that time, as I go back and read the notes on it, was that we would see an increase in the incidence and prevalence of keratitis associated with contact lens wear if the markets were opened up to online vendors and non-eye care professionals selling contact lenses. That was a very significant concern. And what we've seen since that time is that there's been absolutely no change in the incidence and prevalence of keratitis in this country after the initiation of the contact lens rule.

So I think it's very clear that the vast majority of the risk relates to behavioral use of lenses. And I think the biggest and most important thing that we can do for our patients is to educate them properly, and continue to educate them on how to wear their contact lenses properly.

ANDREW STILAND: Are there any other-- yeah, please.

BETH FREEBORN: I know that there is literature out of France that looked at the different dispensing patterns of contact lenses with opticians, optometrists, ophthalmologists, and found that when the patients did not undergo an eye exam, their risk for microbial keratitis was exponentially higher. So there is data out there about the harms that can happen with contact lens used without the eye exam.

I would want to offer one other statement, which is that a lot of the literature that we're citing are case control studies about the impact of the visit. And what we really need is a prospectively done study, where we are not biased by recall bias of patients who are harmed, recalling when they go to see their doctor. And to do that, we would need a registry or some other mechanism to collect data in an unbiased way on the patient population. That's using contact lenses.

So one of the challenges with a lot of the inferences that are made is that the data doesn't really support a causal inference. So we have to be very careful in interpreting the literature.

RICH CLELAND: I'm going to intervene here just second. We've got about 10 minutes left on this panel, and we still have a couple of questions we want to get out there and discuss. So if the audience could hold their applause in between the speakers, that would save us some time. Thank you.

So we were going to move into actual identification of the risks from use of contact lenses, but I think that's already been covered in a number of the presentations. So we don't have to spend much time on that. I have one question I would like to ask, and probably, I'll start with you Dr. Lakkis, on this question.

When I looked through the research-- and a lot of the research is stuff that articles that you provided to me-- there are a number of studies that focus on microbial-- I got it right-- keratitis. And then there are some other studies, particularly I think the Clay study recently, that look at more than just keratitis. What's your view the appropriate risks that should be looked at in this?

CAROL LAKKIS: So as we've heard about today, fortunately, microbial keratitis rates are fairly low relative to inflammatory event rates. So in microbial keratitis, we're looking at analyzed incidence rates between four and 20 per 10,000. But for inflammatory events, we're seeing rates anywhere between 5% and 25% of contact lens wearers per year. And Dr. Eydelman and Dr. Tarver can comment more than I can.

But for understanding health benefits and risks for eye health in terms of inflammatory and infectious events, we can use corneal inflammatory events as a surrogate for MK, for microbial keratitis. And what we do often see is a lot of the similar risk factors between both. And as I mentioned earlier, inflammation and infection are now, the research tells us, on a continuous spectrum. So what might start off as what appears to be an inflammatory event could actually be a potentially infectious event.

And luckily, for ourselves here in the US, and other countries like Australia, and the UK, the standard of care is that if you say one of these inflammatory events in a contact lens wearer, you

treat it as if it is microbial keratitis, so that you don't take the risk that it will actually progress. So that that's where the data is differing. But the risk factors tend to be very similar for both.

ANDREW STILAND: So I want to ask a fairly specific question in terms of what the role of point of sale might be in determining some of these risk factors. And in particular, is there data? If there isn't data, what the mechanism linking risk with point of sale might be. And then a brief comment about what factors might influence that mechanism, and how that might be changed. And again, open this up to anybody on the panel that might want to comment.

CAROL LAKKIS: I could start. So there's actually some recent evidence that suggests that internet purchase may result in a five times higher risk of infection compared to purchasing through a more traditional channel. But there are other studies that don't show internet purchases being a significant risk factor. So I think we do need more evidence in that area.

Going back to a previous point, more critical, I think, is ensuring that when contact lenses are fitted and prescribed that patients are actually obtaining that actual prescribed and fitted contact lens. That they're obtaining what the eye doctor has determined is the best for their eye health, their eye anatomy, their lifestyle choices, and needs. And so ensuring that that happens, I think, is a factor that plays a role in some of these epidemiology studies.

It's also been suggested in those studies that there could be a lack of relationship with the eye doctor, and knowing when to go back, and see the doctor could be what is underlying that increased risk. So it's not the purchase process itself, but the possible education around that. Further research is needed.

EDWARD CHAUM: Yeah, so there really isn't a lot of data that suggests that there's any relationship between the development in keratitis and the point of purchase. There was a study back in 2004-05 Stapleton's a group in Australia, which has done a lot of work in this area, that suggested that there might be an association. And that study was repeated and was published back in 2016, and showed that there was no association of point of purchase related to that development of keratitis.

The study that Dr. Lakkis is referring to is a recent study by [INAUDIBLE], which is, in my view, a fairly weak study in that the data that suggests that there's a five-fold increased risk of developing keratitis from purchase online. Has to be balanced with the fact that the other findings in that paper were that there was a three and a half fold increased risk if my mother purchased it for me. And there was a three and a half fold increase risk if the young person lived on their own as opposed to having a roommate.

So these sort of weak associations really are, I think, statistical noise, and really don't add to the literature in a meaningful way. We just don't know. But what we do know is that for the many, many, many studies of case controlled keratitis that have been published over the last 25 years, there is no real strong evidence that there's any relationship between point of purchase and the development keratitis.

CAROL LAKKIS: Can I just clarify, I was actually referring to the Stapleton's studies for the five time increased risk. And the more recent Stapleton publication is looking specifically at daily disposables, where point of purchase was not a significant risk factor in reuseable wear as it was.

RICH CLELAND: The reuseable one-- please, you know this better than I do-- I thought the reuseable one with the total was the 2008 study. So it's an older set of data, it's older than 10 years at this point. And the while the 2017 study didn't show a relationship for a specific type of lens-- that's kind of, you don't know what you would do if you had looked at all lenses there at this point.

CAROL LAKKIS: I think it's important to look at the body of evidence overall. We don't look at any one individual study, as Michelle was also saying. You need to actually look at everything-- the information that's coming from all different countries, as well as different types of studies that are conducted, and interpret that overall, rather than just honing in on one particular outcome.

RICH CLELAND: I have one last question, because we're out of time. But I need to at least touch on this for a second. And if somebody has a one minute response, I will take it.

Cosmetic contact lenses. How is that affecting some of these studies? Is the sale of those types of lenses OTC reached such a proportion that they're affecting the results the data that we're seeing at this point?

MICHELLE TARVER: So a lot of the studies have incorporated or collected information about decorative lenses, and we do see a higher risk with decorative lenses. We've seen patterns within our NDR database also with decorative wearers having higher impacts on their vision. The challenge, as I already alluded to, is that we don't have a good denominator, and we don't really know the true incidence rate associated with the different types of devices, because we haven't systematically studied it. And I'll make a plug once again for a registry lenses so that we can have some answers to these questions that we're all trying to understand.

RICH CLELAND: OK, thank you.

All right. We are going to break now. I want to thank all of my panelists for an excellent discussion, and I apologize for all my mispronunciations. But thank you again.

ANDREW STILAND: And we will reconvene at 11:15.

RICH CLELAND: 11:15.