

The Contact Lens Rule and the Evolving Contact Lens Marketplace

Panel I: Overview of the Contact Lens Marketplace

BETH FREEBORN: 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 Kodey, who is the Senior Director of Industry Research Services at The Vision Council. Steve will be providing information largely from the consumer side of the market. And next, we have Wally Lovejoy of 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 KODEY: Thanks, Beth. As she mentioned I work for The Vision Council, and we're basically a non-profit 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 VisionWatch 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 1.3 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 vision 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 contact lens 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 sales 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 VisionWatch, 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 wearing 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 in 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 up 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 about 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 VisionWatch, 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 lenses 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 lenses 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 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 relies 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 contact lens 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 lens 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 VisionWatch is that consumers unfortunately, some of them don't abide by the recommended replacement frequency. You have about 10% of all daily lens wearers, and 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, from 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 82% 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 KODEY: 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 Council, from Jobson, from AOA, and Essilor's 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, of those optometrist are 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 here 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, MyEyeDr, 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 I 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 the Eyeglasses I 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 the number of other retail locations with optometrists 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 optometrists 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 eye exam or even primary eye care eye exams by ophthalmologists 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 until 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 also 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 franchisor. 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 franchisor. 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 eye care 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 contact 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 it would be 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 replenishment 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 The Vision Council 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 offer 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 Council 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 Vision Council studies that a lot of still aren't aware that they even have that coverage. And as a result, The Vision Council 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 parents 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 wearers 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 one 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 dailies-- 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.