

# The Contact Lens Rule and the Evolving Contact Lens Marketplace

## Panel IV: Examining the Verification Process

BETH DELANEY: OK. So with that, I want to just point out that we do have someone that will be walking around and collecting questions. That's Courtney and she's sitting over in this corner over here. So she'll get up every once in a while and kind of wander around. Just hold up your card, if you have one. And she'll collect that and bring it over to Rich who will then deliver them to me. And hopefully we'll have some time to answer questions. But, as Alyssa said, if not, we're certainly looking at all of them. And we'll incorporate those issues into the rulemaking record.

So what I'm going to start with is we're going to talk about the verification process. And as you all know, the Fairness to Contact Lens Consumers Act and the Rule set forth the conditions under which contact lenses are sold. More specifically, a seller may sell contact lenses only in accordance with a prescription that is either presented directly to the seller or verified by direct communication.

The direct communication means that a prescription is verified if: the prescriber confirms that the prescription is accurate by getting right back to the seller, the prescriber informs the seller that the prescription is inaccurate and provides the accurate information, or the prescriber fails to communicate with the seller within eight business hours after receiving the verification request. So with that statutory framework in mind, the goal of this afternoon's panel is to examine the verification process from the perspective of the prescriber, the seller, and the consumer. And what we want to do is to explore what's working with verification, what isn't, and we want to use our time today to brainstorm to improve the process to make sure that consumers are getting the contact lenses that have been prescribed for them. We have a great panel here today. I'm looking forward to a very informative and interactive discussion. And Paul's going to introduce our panelists.

PAUL SPELLMAN: Hi. I'm Paul Spellman. And, as you know there are longer bios in the handouts outside. But I'll just give brief bios of the panelists we have with us today in no particular order. Cindy Williams is the general counsel of 1-800 Contacts. As such, she advocates on behalf of contact lens consumers and is responsible for managing legal and legislative affairs for 1-800 which was, as you know, one of the first and still the most prominent telephone and online sellers of contact lenses.

Jennifer Sommer is the director, US Ethics and Compliance at Walmart. For the past eight years she has overseen the optical practice compliance program for all Walmart Vision Centers and Sam's Club Optical stores in 47 states and Puerto Rico. Dr. Tim Steinemann is a professor of Ophthalmology at Case Western Reserve University in Cleveland, Ohio. He also sees patients at the MetroHealth Medical Center Hospital in Cleveland and at University Ophthalmology Associates, an eight-doctor private practice.

David Cockrell is an optometrist who has a practice with his wife, who's also an optometrist, in Stillwater, Oklahoma. Dr. Cockrell is the past president of the AOA and has testified before various state and federal legislatures about contact lenses and eye health. Shaun Schooley is the Vice President of Global Marketing Technology at CooperVision. He's responsible for CooperVision's global marketing initiatives including technology development, e-commerce, and the subsidiary EyeCare Prime, which operates the contact lens subscription LensFerry. And with that, I'll hand it over to Beth.

BETH DELANEY: Great. So to get some background information, we're going to start with an overview of the verification process from the seller's perspective. So Cindy, could you give us an overview of how 1-800 processes verification requests?

CINDY WILLIAMS: Yeah, sure thanks, Beth. I'm glad for the chance to talk about our verification system. It's something that we are very proud of as a company. 1-800 processes close to 3.6 million orders every year. And we take our compliance obligations very seriously. We have made significant investments in developing efficient systems and protocols that allow us to ensure that for every order, we either have the customer's prescription or we properly verify the order.

Today we have current prescriptions on file for about 40% of orders. We would like to process more orders with a prescription. With a prescription, the consumer gets their lenses faster. And they are often on their last pair, which is evidenced by our data showing that 32% of our customers pay for expedited shipping. But prescribers don't always release. We've talked about that in earlier panels. And some consumers may not have their prescription handy when they place an order.

So we need to verify to serve our customers. That's not going to go away. So to handle verifications, we use a system called HIVR, which stands for human initiated voice response. We don't consider this to be an automated system. Every call is initiated by a live customer service agent who confirms that the call was received by the right person, or the right office. So, for example, if we are trying to reach Sears Optical, our live customer service agent confirms that the call is actually answered by Sears Optical.

We use a recorded voice to convey the information because it is likely to be more accurate and be more reliable. The length of our call varies, depending on whether it's answered live or if the information is left on an answering machine. But in both cases, it's just about two minutes. HIVR is the gold standard for CLR compliance certification. It conveys information accurately and in an understandable fashion with minimal burden on prescribers and allows us to document our compliance efficiently.

Our records show that, on average, prescribers are asked to verify just one order a week from 1-800 Contacts. Prescribers are not always cooperative. They often hang up on our calls, rather than taking advantage of the option to hold or have our system call them back later. We would like prescribers to understand that while the call was coming from 1-800, it's their patient who is asking for them to take two minutes to verify their prescription.

We are acting as their patient's agent, just like a pharmacy might call on a patient's behalf. After the call is placed, if the prescriber tells us that the customer is not their patient, or the prescription has expired, we cancel the order every time. We think the current verification system works well for consumers. Our data indicates that the error rate, under the current system, is relatively low. And the contact lens wearers are getting exams on a regular basis within the AOA's own guidelines, which, as we heard earlier today, are more restrictive than what the AAO recommends.

In less than 30 seconds, let me give you some facts. Our survey evidence shows that the majority of contact lens wearers have an exam about once every 12 to 16 months. And that is consistent with the Johnson & Johnson survey that was submitted in the rulemaking.

BETH DELANEY: OK. So this is going to be quick?

CINDY WILLIAMS: Yes.

BETH DELANEY: Because I want to get back to verification and--

CINDY WILLIAMS: OK, absolutely.

BETH DELANEY: Focus on that.

CINDY WILLIAMS: So I won't go into any more. I was just going to talk about exam frequency. But the one other thing I wanted to mention, Beth, is that our data shows that consumers are, we talked about expired prescriptions and buying lenses. Our data shows that about 10% of consumers are able to purchase lenses with an expired script. And importantly, that number does not vary across channels. So about 10% of consumers report buying lenses with an expired prescription regardless of whether they purchase from an independent retailer like a Big Box store, an online provider like 1-800, or their own ECP's office.

BETH DELANEY: OK. So we'll get more into expired prescriptions with Dr. Steinemann. And you'll have a chance to talk more about that but I did want to just get this information from you. So 40% of your orders are made with a copy of the prescription?

CINDY WILLIAMS: Yes.

BETH DELANEY: OK.

CINDY WILLIAMS: It's either on file when the customer orders, Beth. Or it is provided during the ordering process.

BETH DELANEY: OK. And do you have any sense of what percentage of verification requests are corrected by a prescriber?

CINDY WILLIAMS: You know, we didn't track that. I know you asked us. But what we know is that, of the 60% that are going to verification, right, some are corrected. As you said, some are

approved by doctors. And sometimes we get a prescription in from a doctor during that process. And it's fair to say that of those that go to verification, the majority are passively verified. And we're going to try to get you more specifics in our comments.

BETH DELANEY: OK. That's great. So let's turn to Jennifer who also has some interesting information about a different way to verify prescriptions.

JENNIFER SOMMER: Thanks Beth. So I'll be speaking on behalf of our retail locations. We have approximately 2,800 Walmart Vision Centers and 500 Sam's Club Opticals across the country in 47 states. And in 46 of those states, we actually sell the contact lenses. That's about 3,300 locations. We have probably 3,500 to 3,700 doctors who co-locate with us. And as you probably remember from Wally's presentation, there's three different models. The vast majority of our model is actually a sublease or a license agreement with those doctors.

So in response to your question, Beth, about our verification process, we actually have a corporate policy that says that if a customer or a patient comes into the vision center or the optical and wants to purchase contact lenses and they don't have a prescription in hand, then we have a form that our opticians are required to complete. And it has all of the necessary information that would be relevant for that verification process.

Those opticians then will contact the prescriber's office to make sure they have the correct fax number. And they'll actually fax that form over to the prescriber's office. If the prescriber doesn't respond in some form or fashion to say that that prescription is invalid, or it's incorrect, then the opticians will dispense. Now that being said, we did an informal survey across our vision center managers. It was approximately 40 vision center managers in 15 states that responded in relation to this workshop.

And they found that the verification process that we have doesn't serve their patients in the way that they want. So we're really proud of our opticians for taking care of their patients. What they actually do is they'll call the prescriber's office while the patient is there in the vision center and obtain a copy of the prescription. They find that that's more effective. They can ensure that there's an a valid prescription and that they have all of the parameters needed to fill the order.

And so our verification process is actually extremely low for our stores in that we probably verify less than 10% of our prescriptions, just because our opticians are actually calling the prescriber's office. When we probed a little more and said, well, how long does it take to get a copy of the prescription? We're very pleased to hear that it's within 15 to 30 minutes if the doctor's office is open.

And so they can take care of that patient while they're in the vision center in a very short amount of time. And they can either walk away with their order or have it shipped to their home according to their preference.

BETH DELANEY: Can I also interrupt for a second? So, do you get the prescription back by fax?

JENNIFER SOMMER: Correct.

BETH DELANEY: And faxes are still being used?

JENNIFER SOMMER: Yes. I'll give you a little content--

BETH DELANEY: Let me get this on the record that faxes are still being used.

JENNIFER SOMMER: Let me give you some context for that. So it has been just recently that, obviously, our vision centers are in a larger part of our store. We're a mass merchandiser. And it's been recently that we've actually opened it up to where our hourly associates can receive attachments via email. And that didn't have anything to do with the vision center itself. But obviously, we have a number of hourly associates in a typical super center.

And so we didn't want them to receive attachments. That would inhibit the ability to receive a prescription via email. We've also found it's more secure, especially with the prevalence of privacy concerns and data security concerns. And Walmart being a very large corporation, we found that fax is much more efficient. It's the same process that we use in our pharmacies. So we have approximately 5,000 pharmacies across the country. And so we still do use fax, which makes it better for our patients. Because we know that their data is being secured during that transmission.

BETH DELANEY: So then, just to close the loop on Walmart, I know you also sell online. And could you just briefly tell us how that process works? I think it diverges a little bit from your in-store process.

JENNIFER SOMMER: Absolutely. So we have two websites that we operate, one for the Walmart brand and one for the Sam's Club brand that sells contact lenses online. That's a partnership that we have with a third party that actually operates those sites for us. And so their verification process is when the patient doesn't have a prescription that they can upload or text or email back to the company that they will actively call the prescriber's office.

About 80% of the verifications occur. The company is looking into how they can make it easier for patients to get their prescription to the company so that they can lower that verification number. But they've had pretty good success with verifications.

BETH DELANEY: So that would then be active verification, because they're calling and they're actively verifying?

JENNIFER SOMMER: Yes.

BETH DELANEY: OK. So not much passive verification at Walmart.

JENNIFER SOMMER: No, it's actually pretty low.

BETH DELANEY: OK. Great. So what I'm going to do now is just ask both of you kind of a follow up question. So what I'm wondering is, from a business standpoint, does it matter to-- I mean, you've kind of almost answered this. You would like to get the copy of the prescription. That's ideal.

CINDY WILLIAMS: Absolutely.

BETH DELANEY: OK.

CINDY WILLIAMS: We think the consumer gets their lenses faster. And there's more burden involved for both sides.

BETH DELANEY: OK. And so when you get the copy from-- and the same for Walmart?

JENNIFER SOMMER: Absolutely the same.

BETH DELANEY: OK, just to clarify, so with Walmart, if you get a copy of the prescription, then the inquiry ends there? Or do you still contact the doctor?

JENNIFER SOMMER: No, we actually, once we get a copy of the prescription, if it has all the required elements per state law as well as it's valid, we will go ahead and fulfill the order.

BETH DELANEY: OK, great. And that's both in-store and online?

JENNIFER SOMMER: Yes.

BETH DELANEY: OK, great. So do either of you have suggestions on how to incentivize consumers to give the prescription? Because I think we've heard some data that even if patients have-- that there's a certain percentage of patients that have a copy of their prescription that aren't using it.

JENNIFER SOMMER: So I'll speak from a store's perspective. And I think opticians have done a fantastic job of this. You know, they educate the patient on the value of having that prescription in hand. Because the customers already come to the store to purchase their contact lenses. And if they don't have that prescription in hand, they make sure that the patient understands that there's going to be a time period. And that's not convenient for the patient. And we're all about convenience and making sure that the patient has the best experience.

And so as they're going through that education process, what we've found through our informal survey of our vision center managers is that we actually have a number of patients who will call their prescriber ahead of time before they even come to the store so that they can have that prescription faxed in so that it's not inconvenient for them. Now, if we do have to make that phone call, and again, it's usually 15 to 30 minutes by the time we actually get a copy of the prescription, usually we'll invite the customer to either sit and wait or they can shop in the store.

But again, that's an inconvenience for the patient. So we've undertaken that education effort to make sure that they understand they really need to have that prescription in hand.

BETH DELANEY: Cindy, do you have any anything to add with what 1-800 does to incentivize?

CINDY WILLIAMS: Well, absolutely, Beth. We are always trying to get prescriptions from consumers. And during the ordering process alone, we ask them at the beginning to upload their prescription. If they don't have it at the beginning, we ask them again at the end to upload it. And then as soon as their order is processed, within two minutes, they're getting their order confirmation that they got their lenses.

And we're telling them, if you didn't use prescription this time, please give it to us now for your next order. Because it's going to make it faster for you. So we have also run promotions to get prescriptions from consumers. So, for instance, in May of 2016 and May of 2017, we offered consumers a 10% discount on their next order of contact lenses if they would simply send us in their contact lens prescription.

BETH DELANEY: And did that incentivize consumers? Was there a bump with that?

CINDY WILLIAMS: Yeah. We have seen that these promotions and the regular interaction during the ordering process and reminding them that if their prescription is on file, in 10 minutes we can process their order for shipping. They don't have to wait that extra day for the verification process. And that message really resonates with consumers.

BETH DELANEY: OK, great. Paul, I'm going to let you--

PAUL SPELLMAN: Sure. We've heard a little bit about the seller perspective, so if we could switch to the prescriber perspective with verifications. We could start with Dr. Cockrell. What's your view of the verification framework, how the process is working?

DAVID COCKRELL: Thank you very much, Paul. The verification process, as it stands right now, is ineffective and maybe the politest was to say it is it doesn't work. It's a one-way system. In my particular office, and every office, I'd like to recognize all the members of the AOA that are here from across the country. This is such an important issue for us. We want to make sure our voice is heard. We appreciate that.

Every single doctor in this office gets contacted virtually-- I mean in this building, every single day by some seller with a prescription that's expired. Or maybe it's correct or maybe it's incorrect. When we try to recontact that entity that sent it to us, there is no way to recontact that entity. So it's a one-way issue. I heard reference this morning that one of the companies perceives themselves as a pharmacy.

With a pharmacy, if there's any question at all about a medical prescription, when I write that, and these are medical prescriptions as we heard from the FDA and the CDC. When I wrote that medical prescription, if there's any question, I'm able to get a hold of them. I can't get a hold of a

reseller. So, no I don't think the verification process works. I think, along with that, for example, we've got a situation where some retailers, for example, Hubble Contact Lenses tells patients online, get back with them within 48 hours.

Well, the rule says, eight hours, right? So it's intentionally misleading to a provider, or a provider's staff if they don't realize it. So there's a variety of problems with it.

PAUL SPELLMAN: Could I just ask you a little bit about how your office handles verification requests typically? Do you handle it or does the staff handle it? And do you have a preference?

DAVID COCKRELL: In our office, our staff handles it. We have five doctors, 32 staff. And so when that verification request comes in, it goes to our contact lens manager. It comes in by fax often. Sometimes it comes in by a robocall, many of which we can't understand. We actually played one for Chairman Ohlhausen last year that came into my office that you couldn't understand. So sometimes they're just not able to understand.

But at any rate, once we figure out who it is, it goes to our contact lens manager. At that point, we make certain that the information goes back within that eight-hour period of time.

PAUL SPELLMAN: Dr. Steinemann if we could switch to you. How does your office handle such requests? And what's your view?

TIM STEINEMANN: So we receive about 5 to 20 of these requests per week across different sites. Most of these requests come in through fax. Some of them come in through calls. And these are not live calls. These are robocalls. Many of those robocalls are unintelligible or cut off. We have no way of responding or even verifying the information. So I agree with Dr. Cockrell, the verification framework is insufficient. It doesn't work. And it's not properly enforced.

In many instances, prescribers receive verification requests that are expired, incorrect, or for a patient that we have no record of. And, in fact, we studied this. And I'll be glad to share that information.

PAUL SPELLMAN: Yeah, if you could. And I should preface this by saying that you conducted basically an informal survey of your offices.

TIM STEINEMANN: That's correct. I work at MetroHealth Medical Center. I also work at a private office called University Ophthalmology Associates. So we have two very different sites of practice. The MetroHealth site is a community hospital. It is the county hospital of Cleveland. It is a very large busy hospital. We see probably well over 40,000 visits per year. We serve everybody. And so we have a very, very diverse patient population.

We serve many underserved people, modest means. On the private side, it's your typical private office. And we see people who are insured. In any case, we looked at verification requests in both sites. What we found, in the MetroHealth office, we found an error rate anywhere from 50% to 60% at the MetroHealth site. At the University Ophthalmology private site, we found about 25% error rate.

So there's a big difference. But it's way too high. I even polled my colleagues at the Cleveland Clinic Cole Eye Institute. I don't work there. But I polled them. And I asked them to look at their site and look at verification requests there. It's about a 30% error rate there.

PAUL SPELLMAN: If I could just interrupt for a second. When you specify error rate, my understanding is that there you've grouped a number of different things.

TIM STEINEMANN: Correct.

PAUL SPELLMAN: Could you explain what those are?

TIM STEINEMANN: So we found four main sources of error. The biggest problem and the biggest offense are expired prescriptions. How big? At MetroHealth probably 40% are expired. At the private office, probably 20% are expired. At Cole Eye Institute probably 30% are expired. The second biggest are patients that we have no record of. These are not our patients who are claiming that I am their doctor. How big is that? 10% to 15%.

The third problem we see are errors in the-- presumably the errors in the transcription of the prescription. The prescription is not accurate. And then the fourth error that we see are people who are either not approved for contact lens fitting, did not complete the fitting process, or do not have a valid prescription, don't have a prescription and are trying to gain one. Let me give you an example. Here is something that we just received at MetroHealth the other day. This came in on Friday, 3:00 A.M.

This patient is a patient of ours. Her last exam was 2015. We have no record at MetroHealth that this patient was ever fit with contact lenses. I know, by the way, this is the third attempt in three weeks to try to gain contact lenses. There's a contact lens prescription listed here. We blocked it.

PAUL SPELLMAN: Well, now some people would say that by blocking it and by noting these incorrect verification requests that the system is working and that you're stopping these incorrect requests. So what do you think we should take away from these responses?

TIM STEINEMANN: My response to that is see how much time this takes. Does it take one to two minutes? No. It takes probably at least five minutes to do an average request. If there are discrepancies, try 20 or 30 minutes.

BETH DELANEY: OK, well lets--

TIM STEINEMANN: It's a tremendous expense.

BETH DELANEY: Let's talk a little bit about the prescriber preferences for verification requests. Do either of you have a-- what do you think would work better in terms of--

TIM STEINEMANN: Written requests only, no robocalls.

DAVID COCKRELL: On top of that, I think it needs to be a two way street. We need to know that re-- we need to know that whatever it is we sent is received. We need to be able to contact whoever that seller is immediately. We can't even leave a message on most of them, let alone not be able to contact them. So with no verification, and just as these ones that we reject, like Dr. Steinemann was talking about, yesterday, day before yesterday when I was in my office, we had three immediately from three different online resellers for the same patient for two different prescriptions, two of the three.

So the patient is clearly shopping to see who will fill it or will miss it. And we have no idea if they got it filled or not. There's absolutely no-- there's no response from the reseller to let us know, we received your rejection. We did not fill his prescription. If we really want to look after patient health care, I think it's important.

I'd like to correct one other thing that I heard this morning. Since she mentioned it earlier. I took moment over lunch to look at what the American Academy of Ophthalmology actually says in terms of contact lens examination.

BETH DELANEY: I joined you, right?

TIM STEINEMANN: Let me speak to that.

BETH DELANEY: OK, OK. You can, OK, Dr. Steinemann, I want it really quick though. Because we need to move on with verification, too.

TIM STEINEMANN: That was quoted out of context, five to 10 years applies to people who are young, under age 40 and have no risk for eye health problem.

BETH DELANEY: OK.

TIM STEINEMANN: Contact lens--

BETH DELANEY: Guidelines--

TIM STEINEMANN: There is always a risk for eye health.

BETH DELANEY: It's not listed in the guidelines. It is in the AOA guidelines. But contact lens use is not listed as a risk factor, I thought, in the--

TIM STEINEMANN: Please look at the preferred practice patterns of the American Academy of Ophthalmology, annual exam, contact lens exam.

BETH DELANEY: OK.

TIM STEINEMANN: Annual exam for contact lens wearers.

BETH DELANEY: OK. So this is a--

TIM STEINEMANN: Please look at the EyeSmart website, annual exam for contact lens wearers.

BETH DELANEY: Well, this is a factual issue that we can clear up. But I did want to have-- we've a little bit more time before we switch over to Shaun. So I have a question. So taking into account the things that we've heard today so far, in terms of what the risk factors are, which are overwearing your contact lenses, some hygiene issues. If the biggest percentage of problematic verification requests are expired prescriptions, but we also have data that shows that it seems like contact lens consumers are going back fairly frequently, I think from Steve, his data showed that 80% seemed to indicate that they had an exam in the last year.

And if you bump that up to two years, it was 94%. So how do those data points translate into your concern? So, do you know what I'm saying. Like, if people are going back and there is-- maybe somebody is ordering a couple of months at the end of their prescription, is that related to a health risk?

TIM STEINEMANN: Sure.

BETH DELANEY: I mean-- so, yeah.

TIM STEINEMANN: Sure, it's related to a health risk. Why? Because people don't come back. Or they may not know it to come back. And nothing can replace a face-to-face teaching, monitoring, and most importantly supervision. That supervision is stronger and the teaching is stronger through the follow-up contact lens exam. It's not so much the exam, I want to know when the patient comes back, tell me how you take care of your lenses. Are you having any problems?

Now, trust me when I say, I don't fit contact lenses. But I spend a considerable amount of my time taking care of people's contact lens problems.

BETH DELANEY: OK, OK, so let's--

DAVID COCKRELL: Can I address that as well?

BETH DELANEY: Sure, yeah.

DAVID COCKRELL: You know, all of us, every doc in the room sees patients with contact lens problems from minor to serious in patients who come back on time but certainly in patients who don't come back on time. I had a patient within the last month who's been wearing the same daily contact lens for over two years. Now think about that for a second.

BETH DELANEY: Right, I mean, there's--

DAVID COCKRELL: So the reality is there's all these outliers. But as you heard this morning, I've got patients who've also purchased the same sort of contact lenses for four years in a row and

never been seen. So there's multiple problems with it. If we get back to the health problems, there as Dr. Steinemann described. We all see them every day.

BETH DELANEY: Right, and part of what this workshop is about is extracting empirical evidence about what's going on. Because it is horrifying, I'm sure, for you to see a patient that has done these things. But we also want to have some hard data on the numbers of people that are going back to the doctor and the actual risk factors and the actual adverse events, how that translates across the whole population of people wearing contact lenses.

TIM STEINEMANN: You know what you know. And all I can say is, from my experience, I'm a clinician. I am a cornea-trained specialist. This is what I do when I go to work every day as an ophthalmologist. And ophthalmologists, I think, are in a very unique position to see these sometimes, disasters. And that data was presented. You want the data? The data was presented this morning.

BETH DELANEY: OK. So let's--

CINDY WILLIAMS: Can I just respond to the--

BETH DELANEY: Yes, Cindy, jump, yes, yes.

CINDY WILLIAMS: Right. So 1-800 I know that maybe Dr. Steinemann's data was verification calls through fax. But 1-800 does have a 24-hour doctor service line that is toll free that can be used by the doctors at any time if they want to cancel an order. I think it's really important to note here that prescribers have the option to cancel orders placed with an expired prescription by simply responding to those calls. When they do this, we honor it every time.

If they think that buying with an expired prescription presents a serious health risk, then one would expect that they would do that every time for their patients in the best interest of their patient's health.

TIM STEINEMANN: Beth, let me just say one other thing. And that is to change behavior is difficult. And we all talked about in many of these sessions, we've talked about changing behavior. Because they're absolutely right. Why do people get into trouble? It's their behavior, misuse, not a product. This is a medical device and needs to be treated with respect. The patient needs to buy into that. The patient needs to have some skin in the game. We need to be very careful about over-commoditizing this process.

BETH DELANEY: Right. We do need to figure out ways to change behavior. And hopefully we'll get some study evidence. I mean, right now I don't think we have evidence that shows that annual exams are the be-all and end-all yet.

DAVID COCKRELL: It's going to be difficult to get that. But I will tell you that I didn't come to this meeting expecting to be surprised by anything I heard. I was surprised. So for at the last panel that completely disregarded patient health when it came to filling prescriptions and the

attempt to imply that all contact lenses fit the same were that virtually all patients can wear one or two lenses. That's just not true.

BETH DELANEY: OK, well--

DAVID COCKRELL: I want to make one more comment.

BETH DELANEY: I know. What I do want to reiterate is we have a comment process that's open for another month. And we want to hear. We want all these issues that are raised. We want you to go home, write up your rebuttal to it, and send it in. Because we got 4,000 comments. I read all 4,000. I did group the form letters together. But we did look at all of them. So let's switch gears a little bit. And we'll enjoy the next presentation from Shaun. We're going to talk about CooperVision's LensFerry product and how that product works and how prescription verification works.

SHAUN SCHOOLEY: Thanks Beth. So LensFerry is a contact lens reorder system that allows a prescriber, an ECP, to offer their patients a really convenient email, web, and mobile reorder capability. LensFerry works by drawing the data out of the practice management system, or the EHR, and then sinking it over to LensFerry. That allows a patient to be able to access an active and validated Rx for their future purchase. So they don't need to actually go through a verification process when they make a re-purchase through the LensFerry product.

Some of the obvious benefits of that are, this is a vast simplification for the prescriber. And then for it really opens up for the patient an incredibly convenient and simple way for them to be able to access products through the way that they like to purchase today. Right? Through pretty much any channel.

BETH DELANEY: So how does how does LensFerry compete with other retailers? I mean, in terms of price, like if somebody is at the optometrist, they might pull out their phone and price contact lenses right there. How does-- is it just the convenience that makes it?

SHAUN SCHOOLEY: It's really not. And I guess, I sat through this morning as well. And I've heard these comments. And I'm lucky in my job. I get to spend a lot of time out in the field. We work with over 5,000 offices globally in the direct patient space. And I spend a lot of time watching behaviors in the office and what this process is that they go through for verification and for validation.

The things that I see happening are, the commonalities are, that consumers are probably more empowered now than they've ever been, as far as being able to shop and buy. And it is very true, I think if we all stepped away from our desk job here today and thought about how we buy and how we interact, we've all got a computer in our hand essentially at this point. It's a fundamentally different world that we live in today then I think when we looked at from 2004 even.

And because of that, like you're saying, Beth, there's a lot of transparency of price. And because of transparency of price, my experience at least is that doctors are very aggressively setting--

prescribers are very aggressively setting price. And they often are benchmarking it off of the online retailers. Because they know the consumer can open their phone standing there in the office and find the same exact product available for a stated price online.

So LensFerry allows a doctor to set their own price. We don't dictate price through LensFerry. And then the doctor, what we do find, is the doctor is often benchmarking that off of the industry standards that are out there. And there are additional features and capabilities in there for negotiations or other set pricing or price matching or other things like that for specials and that sort of thing. It opens up a convenient way for the patient to be able to access products from their prescriber without having to go through some of the steps that they might have to go through otherwise.

BETH DELANEY: So we're going to hear more about another subscription model later in the day. But so LensFerry, you're kind of acting as an intermediary between the sale of the contacts and the doctor?

SHAUN SCHOOLEY: That's right.

BETH DELANEY: And then are there any particular technology challenges with setting up an interface with the doctors' offices? They have different-- or do you just bring that all to the table?

SHAUN SCHOOLEY: Yeah. It's probably an oversimplification to say we just pull the data across from their practice management systems or EHRs. Somebody had mentioned it earlier there. The catalog, the contact lens product catalog is significant. There are 80,000 plus products. There are nearly 10 million active SKUs at any given point. In our product, some of the technology challenges that we face, and I think that the industry faces, and it's just you've got multiple manufacturers that all carry that many SKUs. Those SKUs need to be understood and be carried at a detailed level to be able to bring across prescriptions carefully.

You've got a dozen different practice management systems, or electronic health records systems, that are out there. Every system works a little bit differently. Fields are used differently. Even doctors use the fields differently. So there's a lot of customization to be able to pull data across correctly. But done correctly, it brings across the right prescription and gives the doctor a comfort level that, when they're selling a product to a patient, they're selling the product they prescribed and not something that's been switched or changed or it's not going to be healthy or the right product for them.

BETH DELANEY: And from the interface, can the patient pull down a copy of their prescription?

SHAUN SCHOOLEY: LensFerry is not-- the business model on LensFerry is a purchase model. It's a commerce model, right? It's meant to sell products and allow for simple access through a mobile device, browser, email. There are products out there in the marketplace that act as electronic health records or carry that sort of thing.

BETH DELANEY: Portal.

SHAUN SCHOOLEY: Or portal kind of capabilities. But that's really not LensFerry's model.

BETH DELANEY: OK, great. Does anybody have anything to add to that before we move on to our free-for-all portion of the panel? OK. You want to start with a--

PAUL SPELLMAN: Sure, well, Dr. Steinemann, you've certainly identified invalid verification requests as a concern. And others have talked, and yourself have talked about how time consuming the process could be. Now keeping in mind that verification is required by the statute. So it's not something that the FTC can just do away with. What suggestions do you have to improve the process?

TIM STEINEMANN: So we would request an expansion of the verification window to promote fewer requests that are passively verified. So expand to two business days.

PAUL SPELLMAN: How about as far as the accuracy of the verification requests, is there anything you can think that would make it easier or more likely that the request would be accurate?

TIM STEINEMANN: As I said, the phone call, recorded messages are sometimes garbled and cut off. We can't-- they're unintelligible sometimes. There's no way to respond. So written requests only. But I'm told that you can't do it through regular email because it's not HIPAA compliant.

BETH DELANEY: I don't want to get into the HIPAA stuff. But I think you could-- there's certain things you could do. If the patient gives permission for the prescription to go with email to them, they can do it. We can-- there's other challenges, I think, with email, whether the verification request gets caught in a spam filter and isn't received.

PAUL SPELLMAN: Also telephone communications is spelled out in the statute as one of the ways. Dr. Cockrell, do you have any thoughts on this?

DAVID COCKRELL: Two thoughts. As I said earlier, I really believe a verification provided in writing where we get a receipt notice that we did, in fact, verify that and get it back to them so I know that we've closed that loop on a two-way system. And then the second thing would be that any other way to close that communication loop, as Dr. Steinemann said, I realize telephone is approved in the statute. But a robocall was not approved in the statute.

And we get a robocall that we can't respond to, that's not communicating. That's a one-way deliverance. And literally it's routine that we can't understand who it is. So, therefore, we can't respond. Therefore, the prescription gets filled, right? That's exactly what happens. So if we have a live person on the phone that we're talking to, we can actually have that two-way conversation, we can resolve it right then.

PAUL SPELLMAN: Cindy, did you have any thoughts in response?

CINDY WILLIAMS: Well, yes, especially related to your suggestion about the eight-hour window. 1-800's data that we presented to the FTC did not support expanding the eight hours to a longer period of time because our data says that when doctors do engage in the verification process, that they do so by calling our doctor service line within two hours of the time that the verification call was placed.

And then our records indicate that we then get back to the doctor in one hour. So that's a three-hour time period to get the entire transaction done so that when doctors engage, they have plenty of time to actually get it corrected or canceled if necessary. Also, I would say, if we can think about, and I know John Graham mentioned that earlier this morning, 1-800 being a pharmacy.

If you think about doctors and the Walgreens for a prescription, for instance. When you're in the doctor's office, your prescription is usually over there electronically at the Walgreens pharmacy before you even leave the doctor's office. So that, I think, also supports the idea that eight hours is plenty of time to be able to determine whether there's a prescription in the patient's file.

BETH DELANEY: So some commenters have said that they struggled to identify the correct patient when they get-- it can be a fax or it can be a phone call. Is there anything that any of you could suggest to-- is there a way to have a unique identifier or--?

TIM STEINEMANN: There needs to be more information, date of birth, address, phone number.

BETH DELANEY: Well, address is part of the Rule. But I think patients move, or maybe they have their lenses shipped to a different address. But that is part of the Rule currently, patient name and address.

PAUL SPELMAN: Date of birth might help.

TIM STEINEMANN: I said that.

DAVID COCKRELL: A date of birth would help. I have four different patients with the same name only divided by the middle initial. And two of those four with the same initial, all of whom wear contact lenses. All of whom buy their lenses elsewhere. And so we often don't know who it is. We have to pick up the phone and call to see, are you the one who just sent this prescription in?

BETH DELANEY: Right. So date of birth might be a unique identifier. I know that a lot of doctor's offices use that. Certainly have to remind me of how old I am every time I go in.

CINDY WILLIAMS: Beth, could I just mention that--

BETH DELANEY: Yes.

CINDY WILLIAMS: That would be challenging for 1-800's business model. Because when patients, or when customers, are actually ordering, we don't request their date of birth. It's not a

required field. So in many instances, we wouldn't have the date of birth to give to give as a unique identifier.

BETH DELANEY: OK. Can I ask, what percentage of the online market do you think you are, if you have that information handy?

CINDY WILLIAMS: About 60%, 65%.

BETH DELANEY: OK. So what I want to do is just move on to another area that we're interested in. So one of the underlying premises of the verification framework is that prescribers would correct erroneous requests and they'll deny invalid ones. And some say that that may not be happening or at least not as often as it should be happening. So I just want to ask the panelists, are there ways that we can motivate or encourage prescribers to pay attention to verification requests?

TIM STEINEMANN: Again, it can't be done quickly. That's been our experience. It doesn't take two or three minutes. Give us extra time.

DAVID COCKRELL: I actually don't think prescribers do not pay attention to verification requests. We all recognize-- first of all, it's our patient. We'd like to see them back. If we don't respond to them, they're not likely to come back. Second, that once that analysis is made, as Dr. Steinemann said, it takes a little bit of time to run through that. Even if you have electronic medical records like we do, it's not an instantaneous one-minute process, and it's done.

We have to make sure we transmitted the correction, the answer correctly, either yes, it's acceptable or no, it's not acceptable. I guess we don't really respond if it's acceptable. If it's not acceptable, we have to make certain that we got that right. So it's a lengthy process to do that.

BETH DELANEY: So I guess that what I'm hearing, though, from some of the comments is that people are very worried that contact lenses are being sold through passive verification. But if a seller, I mean, certainly if somebody notified the seller that the sale was invalid, they would stop within eight hours. So the sense I'm getting from the comments is that there's not enough prescriber feedback on denying the prescriptions. It's just a sense. It's from an anecdotal sense from the--

DAVID COCKRELL: I can tell you from a factual statement, in our office we respond. And we still routinely see patients of ours back three to four years later that have been buying contact lenses every single year online. And we've said no, if we get a verification request. So somehow it's happening.

CINDY WILLIAMS: Beth, can I answer about the motivation of doctors?

BETH DELANEY: Sure.

CINDY WILLIAMS: So I thought a lot about that when you brought it up in our panel discussion. And I think that 1-800 has already worked to encourage prescribers to engage in the

process because we've developed a best in class phone system. And just to address some of the issues with the call, we immediately identify that 1-800 is the person calling. It's easy to understand. We abandoned text-to-speech for all but the parameters.

It takes just two minutes of time and can be shortened down to 1 minute and 45 seconds if the doctors are getting regular calls and they utilize the IVR aspect. We allow the prescribers and their staff to pause, to replay, or to get a callback at a later time. And we did all this without being required to do so, without a rule, without a regulation, without a law being passed. Because we thought that was best for our customers and for the doctors. So at this point we believe that the prescriber should be motivated to listen to the call because it's in the best interest of their patient.

PAUL SPELLMAN: The Rule currently requires that prescribers release a copy of a patient's prescription to a designated third party. This is the actual prescription itself, not just a verification request. If the FTC were to impose a timeframe for responding to such requests, because currently there's no timeframe like the eight-hour verification timeframe, how do you think that that would impact the number of verification requests? I mean, could it possibly reduce the number of verification requests? And do you think it would impact the use of passive verification?

CINDY WILLIAMS: We think, at 1-800 that a timeframe would be very beneficial that it would actually reduce verifications. Our data shows that prescribers only respond to our authorized requests for a copy of the customer's prescription about 46% of the time.

BETH DELANEY: Wait 46?

CINDY WILLIAMS: 46. And that those--

BETH DELANEY: Do you have an-- I'm sorry to keep interrupting. Do you have an idea of when they respond?

CINDY WILLIAMS: Yes, I do.

BETH DELANEY: I'm sorry.

CINDY WILLIAMS: That's my next point. But those that do respond do so on an average within two calendar days. So we recommend that prescribers be required to respond within five business days, which should be sufficient for busy offices or those that are on vacation or closing for emergencies. And we also believe, Beth, that the FTC has enforcement discretion. So if there was a situation where you established five days and there was an emergency and the office was closed for some time that certainly the FTC would be able to use its enforcement discretion to take all those factors into account.

BETH DELANEY: So if you're recommending five business days, the purpose of that request is not that sale.

CINDY WILLIAMS: That's correct.

BETH DELANEY: OK.

CINDY WILLIAMS: It's to have it on file for the next order that the consumer would be coming to actually obtain.

BETH DELANEY: OK. And then if you get a copy of the prescription, you have a copy that has an expiration date on it.

CINDY WILLIAMS: Indeed.

BETH DELANEY: So then you have a record. And then that's an enforceable problem for you if you're selling. You know now that it's expired. It's not a matter of passive verification happening and you don't know. You actually have a copy of the prescription and your foreclosed from selling.

CINDY WILLIAMS: I would be remiss if I didn't say that sometimes the issue date and expiration date are not on the prescription. But certainly when they are on there, you are absolutely correct. We're vested with that knowledge. And a sale past that date would be a violation.

BETH DELANEY: So Dr. Steinemann, do you want to weigh in on--

TIM STEINEMANN: I'd like a follow up to that. Expiration date and total number of lenses allowed.

BETH DELANEY: Yeah. I don't-- that's an interesting point. I mean, I think when you look to the purpose of the Rule, it's to give the patient portability. And it's for sale of lenses with a valid prescription. And I think part of the background for the Rule was that some patients may wear their contact lenses faster. And when you have a risk factor, one of the major risk factors being somebody overwearing them, I think the quantity-- you know, we have to have empirical data. So when we have data that shows how many contacts people are buying, which is not ginormous amounts, and when we have data that shows that people are going back for annual exams, we don't really have the quantity data that people complain about anecdotally. We would like that data. And we're hoping in the next month, if you have it, to give it to us.

DAVID COCKRELL: But we all know, depending upon the type of modality that they're prescribed, what an annual supply is. If you make the decision to leave that number off, then that patient can fill that as many times as they want in that year for multiple years of annual supplies allowing them to go through four, five years. If there's a limit on the number of boxes or depending upon whatever the modality is, then they cannot fill it more than that.

Just like a medical prescription, if we refer to the pharmacy analysis again, there's a limit on the number of times it can be refilled. There's a limit on the number of drops to be used.

BETH DELANEY: There's been quite a bit of discussion in over, since 2003, on that issue, about the intention of the Act and the Rule. And we continue to look at that. But I think when you look back at what the risk factors are, that we have to look at all the empirical data. And when we look at sales data, and when we look at health risks, and we look at when people are going for exams and when we look at the cost of contact lenses and I don't know how much evidence there is that people are stockpiling several years of contact lenses. If that's true, we would like to see it. I mean I know anecdotally it might happen. But I mean I make a fair amount of money as a lawyer and I never purchased a year's prescription. It was something could happen. My vision could get worse.

DAVID COCKRELL: I doubt seriously there's a single doctor in this room that doesn't have that problem I just described. And that's just this room with 70 or 80 doctors in it.

BETH DELANEY: Right. I agree, it might happen. But I guess we'd have to look at the percentage, 41 million contact lens wearers. We have to look at it from an empirical perspective not just anecdotal. But this is data that we want and we're inviting you to provide. But I did want to get back to Dr. Steinemann. Because I think the CLAO, which I know you're part of that organization, I think that they had, in their comment to the NPRM, had said two business days for this proposal would work.

TIM STEINEMANN: Yes.

BETH DELANEY: OK, great.

TIM STEINEMANN: Yes.

PAUL SPELLMAN: Jennifer, did you have any thoughts on that?

JENNIFER SOMMER: Like I stated before we've been pretty successful in getting a copy of the prescription within the same business day when we make that phone call to the doctor's office. So when I polled our vision center managers, they said, we don't believe that the FTC needs to weigh in on this unless there's other purpose. But they've been pretty successful without any type of requirement.

BETH DELANEY: OK. So just from a hypothetical perspective, I mean if each and every prescriber automatically released prescriptions to their patients, would the verification framework still be necessary? So what I want to hear about mostly I guess from retailers is does verification serve a purpose, even if someone were to have a copy? What contingencies would require verification to still be there?

CINDY WILLIAMS: Well, if a person, actually the doctor released and they have their prescription, why would verification be needed under that circumstance?

BETH DELANEY: Right. If you had a perfect world where every patient got a copy of their prescription.

CINDY WILLIAMS: Well, we think that sometimes consumers can misplace a copy of their prescription. Sometimes consumers are going to be ordering, for instance, at work, Beth. And their prescription may be at home. So I think they are definitely going to be circumstances where, even with a perfect release, that we're still going to need the verification system. But certainly it would be required less. But it's still going to be necessary.

BETH DELANEY: And Jennifer, do you want to weigh in on this?

JENNIFER SOMMER: Yeah, absolutely so. I agree with Cindy. I'm a contact lens wearer. And I'm not sure I could tell you where my prescription is right now. My doctor did give it to me though. But I can tell you that we operate pharmacies. And the analogy we like to give is that, if I go to fill my initial prescription at a Walmart and decide maybe I want to go fill it out another competing chain, the pharmacist had the discretion to do a pharmacist to pharmacist transfer.

And so the patient is no longer involved in that process. Right? The patient can say, well, Walmart Pharmacy I need you to transfer it somewhere else. And then the pharmacist per their state requirements can have that transaction occur without the patient involved. And so that is something that, I don't know if the state boards of opticianry would need to weigh in or if the FTC could help us with that.

But that might be helpful is to allow seller to seller, optician to optician to have that connection without having to either go back to the prescriber. If one optician or one seller has a copy of the valid prescription, could they transfer it using the same thought process as what's currently allowed under state pharmacy laws?

BETH DELANEY: And the other thing I wanted to ask you Jennifer was, we had talked previously about possible fraud or forgery with prescriptions. Is that an issue that you think verification would still would help a retailer? If you have concerns or no?

JENNIFER SOMMER: I can tell you if a consumer is desperate enough to forge or falsify a contact lens prescription, they're going to figure out how to do it, even though maybe Walmart or 1-800 Contacts catches it or a prescriber denies it the first time. They're going to be pretty creative on how to get that done. And so I'm not sure that there's a control that can be put into place to mitigate any type of wrongdoing or bad actors.

BETH DELANEY: OK. So I guess what I'd like to just ask, though, as we wrap up the panel, I don't think we have any questions from the audience. I haven't got-- well, Rich, bring them on up. We also, just to ask, in terms of best practices, should the FTC get involved in that? Should we issue some best practices? Put out a comment process and get folks to kind of weigh in on that, would that be helpful?

DAVID COCKRELL: I'd like to comment on that. I'd like to leave a comment from a perspective from a state board member from 20 years. In 20 years' experience on the state board in Oklahoma, we've never had those issues arise. So I don't know. And I did queries. I told you I would, our National Association of Regulatory Boards to see how big of an issue this particular

thing was. It's not, so no I don't think the FTC needs to get involved in that. I don't see a problem that you would need to come in to resolve.

PAUL SPELLMAN: I know that back in 2004 the AOA had actually recommended that the FTC create like a standard verification form. Do you have any thoughts on whether that might be helpful?

DAVID COCKRELL: I think a standard form would be excellent. Because we don't get standard forms, which makes it more time consuming to sort out.

TIM STEINEMANN: I agree.

PAUL SPELLMAN: How about you?

CINDY WILLIAMS: I think when it comes to best practices, we might have agreement with the AOA that I don't know exactly how they'd be enforced. Would they become de facto rule? So in the abstract it'd be difficult to comment on that. And I may lean against it. But I'd be happy to take suggestions that you might have if you opened up the comment period. But I think what's really important to consider is that businesses need the flexibility to comply with the FCLCA in the way that makes sense for their customers and their business model.

BETH DELANEY: So we'll finish up. We'll do the speed round. Everyone can say the one takeaway you want us to take away from the panel. We'll start with Cindy.

CINDY WILLIAMS: I think that the verification is working fine. We've said that in our comments. For the most part, it's really working. We'd like to see more prescriptions in the hands of patients so that they can use that during the ordering process. And we'd like to see that doctors more engaged in the calls where they want to cancel.

BETH DELANEY: Shaun, do you have anything to add to our--

SHAUN SCHOOLEY: Yeah, absolutely. Yeah, I would just say that, I mean, from my seat, technology has come a long way. And there's always open areas for opportunity and particularly in an area like this where there's errors that are introduced because of verbalization of complicated parameters and data points. And yeah, I would think that taking in an open-minded attitude to what the future might hold as far as being able to digitize these things or have them come across in more forms that you're able to react to and react to in a way that you're always accurate. That could be a really positive, positive step forward.

JENNIFER SOMMER: So I would encourage the FTC, if you have the ability, to allow for some sort of process where the sellers can communicate, instead of going back to the prescribers similar to what's happening in pharmacy, that that would be great for the patients. Because they have the ability to actually transfer that prescription. And to the physicians on my left, I believe that would help with a lot of the issues that you have on limits of number of boxes or lenses that would be prescribed.

Because that information could actually transfer with the prescription very similar to when you're transferring your prescription, maybe a chronic condition prescription. You know how many refills are left on that prescription. So I think it helps with that issue as well. And make sure that the patient has adequate supply but still goes back to their eyecare provider for the necessary exams.

BETH DELANEY: All right, Dr. Steinemann?

TIM STEINEMANN: Communication is key, not only two-way communication but communication of choice for the prescriber. And if I can close with a statement crafted by Dr. Jacobs, past president CLAO that the renewal of these prescriptions, and particularly expired prescriptions, which may be in the seller's interest and the consumer's immediate interest, but not in the interest of the consumers long-term eye health or in the public health. This is our major concern.

DAVID COCKRELL: I do have a comment. I would like to see the FTC not move forward with the proposed rule as you've laid it out right now. And the reason for that is, as we looked at the number of complaints the FTC received over the five-year period of time that we requested information from you, and if there really are 40 million contact lens patients a year and if they really do replace their prescriptions every 12 to 14 months, over the five-year period of time, that's any place between 160 million and 200 prescriptions. And on record, that would come out to the number of complaints you received as .000006%.

My point in saying that is, if it was a real problem for patients, you would have an enormous number of complaints. It wouldn't be six zeros to the left of the period mark. And so as I look at that, I've really tried to decide, is this really a big issue for patients? Or is it an issue that retailers want to turn into an issue? I think in this case, it's not a big issue. Or you'd have a lot more complaints and just don't see them.

BETH DELANEY: Yeah. As Paul just said, we're going to tackle that on the next panel. And you're on that panel.

DAVID COCKRELL: Great.

BETH DELANEY: I mean from the FTC's perspective, we feel that the complaints we do get are a tip of the iceberg. And if you don't know that you have a right to your prescription, you certainly don't know that you're supposed to complain to the FTC. So on that happy note, let's give a round of applause for our panelists. Thank you very much.