The Contact Lens Rule and the Evolving Contact Lens Marketplace

Panel VI: Looking Ahead: Potential Market Disruptions and Their Impact on Competition, Consumer Protection, and the Contact Lens Rule

MARY ENGLE: Great. OK. Thank you. Good afternoon and welcome to the final panel of the day. I'm glad to see a good number of you have stuck around to the bitter end. My name is Mary Engle and I'm the Associate Director for Advertising Practices here at the FTC. Moderating the panel with me will be Tara Koslov, who as you know from earlier, is the Director of our Office of Policy Planning.

On this panel, we're going to be taking a step back and taking a broader look at the contact lens marketplace, looking at changes in prescribing, selling, and manufacturing technology, developments such as ocular telehealth, and then other regulatory models, including international examples that may offer helpful insights. We're also going to be doing some Blue Sky thinking, similar as was done at the competition panel this morning.

As you recall during his opening remarks this morning, Tom Paul stressed that we are limited in how we can amend the Contact Lens Rule because we really have to hew to the requirements of the FCLCA, the statute. But for this panel, we want to set aside those limitations for a moment and think more broadly about if we lived in a perfect world, what changes we might want to make to the Contact Lens Rule, or the statute, in order to facilitate changes to Contact Lens Rule to better protect consumers and promote competition. Once in a while, Congress does ask the FTC for legislative recommendations. So it's not out of the realm of possibility that that is something that could come along down the road.

Or are there areas-- and I think we've heard some today already-- where additional research is really needed to help better flush out potential changes. So we want to talk a little bit about areas for future research.

We have a terrific panel to help explore these topics. OK. We have Rob Atkinson-- I am not going to-- I'm just going to give a very brief overview, because you do have expanded bios in the materials. But Rob is the president and founder of the Information Technology and Innovation Foundation, a thinktank for science and technology policy. Alex Bargar, Alex is Director of Clinical Services at Simple Contacts, an online ocular telemedicine platform. Bob Hubbard, Bob is an Assistant Attorney General with the New York Attorney General's office where he spent many years working on the disposable contact lens antitrust multidistrict litigation. And Peter Menziuso, Peter is President North America of Johnson Johnson Vision Care, one of the largest manufacturers of contact lenses.

So welcome to the panel and thank you. I hope that most of you were able to hear most of the earlier sessions. I know Bob had to come down from New York in the snow.

BOB HUBBARD: There was some weather.

MARY ENGLE: So one of the first topics that we want to discuss is new business models and what might be coming-- what is happening already, even within the limits of the Contact Lens Rule as it exists, and what we might see coming down the pike. And so we'd like Peter, first, to talk about what J&J is doing with Sightbox.

PETER MENZIUSO: First of all, I want to say thank you. I really appreciate the Commission allowing us to come and sit on the panel. Before I get to the point of Sightbox, I just wanted to take a quick moment to say at Johnson and Johnson everything that we do begins and ends with a focus on patient health. We introduced disposable contact lenses back in 1987. And it's been a mission for us to bring innovative solutions that are going to truly meet unmet needs, that doctors can use to make a difference as they're making a therapeutic choice for their patients. So our promise to live in this space of innovation and think about models that are going to advance care also support the position of a regulatory framework that is really going to protect the health and safety of patients, and at the same time create choice and competition in the marketplace. So really happy for today's discussions.

With the strength that we've had as a global leader in contact lenses with our family brand of Acuvue, we've been able to also start to expand and think about alternative ways to serve consumers. And this is where we came really across, after a long inventory, of a company called Sightbox. Sightbox is a service that is connecting patients with their eye care professional for annual comprehensive eye exams. What's really interesting about it is we are learning that there is a growing need for consumers to gain access to health care, eye health services and products in a convenient way and an affordable way. And this is where Sightbox for us was a very interesting alternative.

Consumers are, again, looking to have options that are really meeting kind of their busy lifestyles, et cetera. What Sightbox is doing is it addresses this consumer need. It also is helping patients know eye health information in a real time mechanism. They're also getting different options for access to contact lenses from an affordability point of view. We also hope that it's going to drive patient retention and at the same time work on category expansion.

So specifically what Sightbox does is it helps online users target an eye care professional to where they want to meet. When that is then determined, Sightbox will actually go out and schedule an appointment with that eye care professional and come back to the patient and say that we've matched your doctor's request with a time. And now we're going to ask that you go see the doctor for that care. The doctor is going to do their annual comprehensive eye exam. They're going to do exactly what they're supposed to be doing clinically through looking at the anatomy, the physiology, the lifestyle of the patient determining what brand is best for them.

And Sightbox is an offering that is agnostic to all brands. Anything that the doctor wants to prescribe, Sightbox can deliver. When the doctor goes through their comprehensive exam, determines what's best for the patient, then a prescription is written. And then Sightbox will continue to fulfill that prescription over the course of the prescription timeline as been advised by the doctor and the patient. Sightbox will also drive the patient to the practice based on the determination of when the next follow up visit should occur to ensure that that patient is staying within a regular routine of eye health and a comprehensive eye exam.

We're really excited about this offering. We do see this as an opportunity to grow more wearers into the category. Because what we do know is patients that are coming into this service most likely have not seen a doctor in a very long time.

MARY ENGLE: Thanks. And how long has Sightbox been in operation now?

PETER MENZIUSO: So Sightbox is a relatively new organization. And we just acquired them in the second half of last year.

MARY ENGLE: OK. So no long-term experience with it yet.

PETER MENZIUSO: No. We're learning. We're learning. We're, again, leaning into this new operating model, keeping the doctor at the center of care, matching where consumers want to be in an innovative way. So it's a great learning opportunity for us.

MARY ENGLE: All right. Thanks. OK, Alex, if you want to talk about how Simple Contacts works?

ALEX BARGAR: I would love to. And first, again, to introduce myself, my name is Alex Bargar. I run clinical operations at an ocular telehealth company called Simple Contacts out of New York. And thank you for giving me the opportunity to speak.

So quite simply, our service is a way for healthy asymptomatic contact lens user, who are happy in their current contact lens prescription, to renew that contact lens prescription online, and easily if they choose to purchase additional contact lenses. And our mission as a company is to make health care simple, to make it affordable, to make it efficient, and to make it patient centered.

And we're a physician run and physician driven company. And our mission doesn't start and end with contact lenses. We have a much broader vision of moving more and more medical care into the cloud to easily, asynchronously, efficiently, and safely deliver care to patients all across the country for a host of medical conditions that could be safely managed with remote monitoring under appropriate clinical supervision.

So what are the benefits of having this service available? A bunch. The first big benefit is a big cost savings. Our online renewal exam costs just $20 compared to frequently an out-of-pocket cost of as much as $150 or $200 in person. It's great for access for rural and under-served communities where we have patients who simply don't even have a local provider or can't do the two or three hour drive.

It's great for prescription portability, which is a huge focus of this panel. Every prescription that's written goes out digitally to the patient and they can take that and they can shop anywhere they'd like.

And lastly, and probably most importantly, it drives better wear schedule compliance among the patients who trust our service and trust our physicians. It's easier access of those contact lenses for them. And instead of wearing those two week and four week lenses for two months or three

months, they're able to replace them on time, easily, affordably when they need to and make sure that they're wearing those lenses exactly as they were prescribed.

I'd love to leave this slide up forever. I don't think I can. But patients love us. We have thousands of reviews on the App Store, 4.8 stars. If you email me, I can send you more.

So let me quickly talk about how it works. First step, the patient provides a medical history in the app or on the website. It's on Android. It's on iOS. You can look it up on the App Store, Simple Contacts.

Next, they record an HD video of their eyes while they're wearing the exact contact lenses that they plan to renew. The doctor reviews this later on in the process. They take a visual acuity test from 10 feet, calibrated to test their vision at 20/20. And that is also reviewed, a video recording of that by the medical doctor who is licensed in their state to treat that patient. And these are all ophthalmologists or optometrists.

And then, as I just said, each medical exam is reviewed by an optometrist or ophthalmologist asynchronously, who decides for that patient based on their medical history and based on all of their clinical findings, whether or not they're appropriate for an online contact lens renewal. And frequently and very importantly to point out, it's quite common for our physicians to refer patients in person for follow up care. They work with tons of optometrists and ophthalmologists across the country to make sure that our patients who aren't appropriate for online renewal can easily and quickly be matched to an appropriate in-person care provider. Thanks.

MARY ENGLE: Thank you.

TARA KOSLOV: Do we know--

MARY ENGLE: I don't know.

TARA KOSLOV: So I'd like to move on to a point that synthesizes some things that we heard earlier in several of the sessions throughout the day. And this relates to the concept of interchangeability or substitutability among lenses. So we heard clearly at the Health and Safety panel, particularly from the experts at our sister agency, as well as from the medical professionals, that currently we are not in a situation where either the science or the regulatory framework supports that kind of interchangeability. But we thought we would open up that discussion a little bit, because when we had the competition panel, we certainly explored the idea that if you're trying to empower consumers to do more comparison shopping at the point when the prescription is being written as opposed to after the prescription has been written, that that concept of substitutability would be an important one to consider.

So we'd like the panel to discuss to what extent the technology currently, or in the future, might support some kind of interchangeability or substitutability, which could include the possibility of generic lenses? What kind of labeling changes might be needed to facilitate that if the science were to get there?

And then one concept that we had batted about when the panel was preparing was could you have a situation where a prescriber could write multiple prescriptions for the same patient? If you had a situation where the prescriber determined that maybe there are a couple of different lenses that actually would work for a given patient, and so you give them both prescriptions and then let them do some comparison shopping to figure out which was what price and other parameters are important to them. So Alex, I think we're going to go to you first.

ALEX BARGAR: Great. Thanks. I can only speak to my experience as the facilitator of hundreds of thousands of online exams at Simple Contacts. But quite simply, although we don't have any evidence that prescriptions themselves are interchangeable safely from a brand standpoint, we do think that with appropriate remote monitoring and under appropriate remote medical supervision within certain guidelines, patients could be offered the opportunity to try new lens brands, report back on symptoms, take follow up tests, and have an easier, quicker way of trying new lenses that are newer on the market that they might not otherwise have access to at their annual in-person exam.

TARA KOSLOV: Peter.

PETER MENZIUSO: So what I'm going to say is, and I think it's a culmination of even what we heard earlier in the morning, lenses are not interchangeable. We absolutely support through a comprehensive eye exam when a doctor is making a determination based on physiology, anatomy, the lifestyle of a patient, there's a brand choice that's made. But what brand choice is much more than material. It's material. And it's also considering things like is there wetting agents involved or not? What are the optical zones that have been designed in the lens structure? What's edge design? What's the modality? So when someone considers this point of interchangeability, it's not something that is easily able to be accomplished and can't be.

ROBERT ATKINSON: Yeah. Thank you. So I can't attest to the technical merits one way or the other on this. But I'm struck by we've heard from a number of the doctors that there's just simply no way to have any interchangeability. Dr. Cockrell said every lens is different. And if that's the case, then I think that has fairly significant implications for going forward because we also heard this morning that there are practices that are sort of J&J practices or Cooper practices.

I doubt that the people who go to the J&J doctor are the ones that only can get the J&J lens. You also see this in terms of the pretty widespread practice of the manufacturers to provide strong incentives to the prescribers to prescribe their lens. If there's really only one right lens for each patient, then that seems to me to be a pretty important conflict of interest which Congress should think about banning, because it suggests that optometrists are prescribing lenses on the basis of finance rather than on the basis of the perfect lens for the right patient.

I always enjoy this quote from Gary Gerber, an OD, who writes in the Review of Cornea and Contact Lenses when the UPP was coming around. And he was praising the UPP because it meant that he didn't have to worry about price discounts from other players. But his quote relative to this was, "If you have a patient with astigmatism and they can wear a UPP lens and a non UPP lens is clinically equivalent, a smart doctor will choose the UPP lens."

That suggests to me that at least many doctors think that there is comparability and that they're making these decisions on the basis of something other than that. And the basis seems to be on the basis of financial incentives.

BOB HUBBARD: Again, no, as an antitrust lawyer who's been in the industry for a long time. It's like we have things like we go to state purchasers and we say how do you do requests for proposals? You don't write it so that only one person can fill it. I mean this industry is the brand specific creates all sorts of difficulties for the purchaser. And it doesn't go away.

And I was thinking the same point that there were practices that focus on them. There are practices that have all of them available. They try on. They ask how it fits, how it feels. I don't know why the consumer isn't the better choice for how does it fit, how does it feel, and able to move forward.

In Europe and other places, they are widely available based on a few parameters. And I'm sure-- and the lenses that we're talking about are sold in Europe, too.

TARA KOSLOV: So a follow up question on that point. So to the extent that the science might not be clear or that we might want to push the science in a particular direction to explore whether there would be technological feasibility, who has the financial incentives to engage in that kind of research? Do we have any expectation that it will happen?

ROBERT ATKINSON: Well, I'd just say no one has the financial incentive here, because it's very clear, if I'm a manufacturer, I'm in a terrible position because I cannot sell my product directly to a consumer. So I'm 100% dependent on this middleman. And that is a terrible position if you're a company to not be able to have a direct relationship with your user. So you are trying to do everything possible to have that middleman sell your product.

And the idea that the manufacturers would want to support research for generics or for even more interchangeability, they have no incentive to do that. I would argue the providers have no incentives to do that as long as you still have these rebate and other kinds of incentive programs that these companies have where certain practices, if you up your sales of a certain brand, you get more money from the manufacturer. I don't see why prescribers would have any incentive to do this. So I just don't know anybody who has any incentive in the system to move to interchangeability interoperability.

BOB HUBBARD: Yeah, no. I think that this probably flows from if you can somehow focus a health care regulator on these issues it might work a whole lot better. Because I think that the public policy background for that regulator and other things, I think, would ask the appropriate questions for doing that. I think a lot of the problems in contact lens is that we have historical regulatory systems that haven't been updated. So they still have regulatory systems when you used to grind the glass lens on each and every individual eye, the statutory language is still the same. Maybe some sort of effort to update those or to provide opportunities first for state regulatory systems to diverge from the usual practice and actually mandate that a manufacturer not be specified. And the amount of the description of the product to be purchased is general enough so that it could be satisfied by different brands.

PETER MENZIUSO: And I think that gets back to the point that we know that a brand is not a brand is not a brand for all the attributes that we were just talking about. There's multiple parameters that when a doctor is having that comprehensive eye exam, they're making the determination what is best for that patient based on those multiple attributes that then guides them to a particular choice.

I think the other thing that's very important for me is let's not forget these are Class 2, Class 3 medical devices, so this conversation about direct consumer going around an intermediary, we are in service of the doctor who's in service of the patient. So we do need to make sure we're driving innovations that are meeting unmet needs that are allowing that doctor to make the very best therapeutic choice for their patients that are on an individual, one by one basis.

ROBERT ATKINSON: Well, If that's true, then why do producers have incentives? Because if there really only is one lens that is the perfect lens for a patient, you don't need incentives. They'll just prescribe J&J lenses, because they are the right lens. You don't need incentives. Think of all the money you can save?

PETER MENZIUSO: We want to make sure that we are serving doctors wherever they are practicing. And we want to make sure that patients have access to our products wherever they shop. And that's where you come into programs where you create affordability for patients to ensure they can get the product that a doctor is prescribing. So it is important to be focused in that area as well.

BOB HUBBARD: And I just keep coming back to I'm a consumer. Do I go to doctors? Yes. Do I listen to what they say yes? Do I follow invariably everything they say? No. And I think that that's the purchasers of the contact lens, the consumers who buy contact lens are similarly deserving of respect for making their own decisions about which is best instead of having an incentive driven system for the prescriber.

MARY ENGLE: Peter, following up on your point about a brand is not a brand is not a brand, but you're not actually saying that there's only one brand that's right for each patient, right? I mean in my own experience, I wear a brand and then I might go to my doctor and he may say let's try this different one. And I say, well, that feels good, too, and I go out with that one. So Tara mentioned the possibility of a doctor writing prescription for several different brands possibly. Could the doctor just fit different brands?

PETER MENZIUSO: So again, through the mechanism of a comprehensive eye exam, there is a determination that a doctor is making and then they're letting a patient trial different lenses to see what is best for their acuity, for their comfort. Are they getting the extended wear that they want? So we are not seeing markets where there's a 100% market share to a particular brand. There is brand choice in the market of soft contact lenses.

MARY ENGLE: Yeah. OK. OK. Well we almost touch on this a little bit. So next we want to discuss sort of the balance between state and federal regulation of this area. Obviously, we do have the Contact Lens Rule, but we also have extensive regulation at the state level for the

practice. And the Contact Lens Rule sets a floor for prescription length of at least one year. States could say it could be longer, that the minimum could be longer, sometimes it's two.

How do people feel about the current balance between federal and state regulation here? Do we think it's good as it is, that it ought to shift one way or the other, and which way? Anybody want to take that?

BOB HUBBARD: Well, I want to start here with I've been a state enforcer for 30 years. And in contact lens and in other places, the state has been blamed for a lot of stuff that it hasn't caused. In the disposable contact lens antitrust litigation the defendants all argued that whatever restraints were in place, a limitations on who could sell, the limitations on what a prescription was written, all the restraints that we were challenging as anti-competitive flowed from the regulatory system of the states.

We had 37 motions of summary judgment. We defeated all those. We were blamed from the beginning for causing all of the problems. Certainly, when we started to investigate, that's what we heard from practitioners. And probing through, we found that there was a lot less from the state than there was from how the regulatory system was presented by practitioners and manufacturers and everybody else.

So with that caveat, that foundation, I think that we live in a great federal system and that the laboratories of democracy, all those other things are useful. You heard about Utah's system that responded to the UPP. I thought that that was a harm to consumers that I'm glad that the Utah statute eliminated. There are states like New York who say that a replacement or duplicate contact lens can be sold without a prescription. That's a good thing.

And there are other possibilities within states who focus on these questions, who update their regulatory system, that they can do those things. Probably, I certainly recognize the Byzantine nature that can sometimes result from state systems. And I certainly endorse minimum standards. But I think that particularly in a dynamic country, a lot of innovation happening, there's a lot of benefits to having regulatory systems that are controlled by states that you can move forward on and see whether they work.

MARY ENGLE: Alex, do you want to weigh in about the challenges you face.

ALEX BARGAR: Yeah. I would love to weigh in. And before I share my perspective, I would like to commend Bob's office. Bob and his office have done incredible work to protect consumers and so has the AG of Utah. My hat, the hats I wear, are somewhat unique. We are the only entity that is responsible both for maintaining an extremely large, nationwide telehealth network in addition to administering one of the largest online contact lens retailers.

So my role as the head of legal and regulatory compliance for both of those entities, additionally, in understanding of local rules and regulations around simply the practice of medicine, the practice of optometry, and the practice of ophthalmology, we more often than not, instead of seeing state agencies stepping in to protect consumers and ensure a well-functioning marketplace, we feel like we're jumping through an endless series of hoops, mostly arbitrary

ones, just as a method or mechanism to give sometimes an arbitrary state regulatory agency as a way to rope back control over something that, quite frankly, the FTC and other federal agencies have weighed in on.

A few examples that I'd love to call out in Texas, we weren't able to practice telemedicine at all until recently when Teladoc won a lawsuit against the medical board of Texas, which accused them essentially of protecting licensed physicians in Texas from out-of-state competition, ruling in favor of Teladoc. It took a really long, wound out, legal action to open that market up to everyone across the telehealth world. Specific to ocular telehealth, which is where we operate, we are constantly engaging with local legislators and regulators to explain what we do and comment on proposed regulations and proposed legislation.

One example that is great to bring out, in the state of Indiana, there's a large telehealth legislation that was passed the year prior that basically lets you do almost anything that you'd like through telehealth except for three things. You cannot prescribe abortion inducing medications. You can't prescribe opiates. And, thank god, you cannot prescribe a contact lens. Luckily, the following year they reconvened and they rolled back their restriction on opiates. So I can go online now and I can get my opiates. But a physician who prescribes a contact lens in Indiana for telehealth is still going to have an enforcement action against them.

It's not just Indiana. I know the FTC has weighed in on specific legislative fights already. I hope they continue to do so. But I see the state influence there as a mechanism to prevent the roll out of technology instead of protecting.

Lastly, something as simple as what needs to be on a prescription in a state to be able to fill a contact lens prescription. The disparity in requirements are absurd. If I look at-- I'm just going to pick one random one. And I don't I don't mean to pick on Oklahoma-- but the prescription needs to have the patient's address on it to be a technically valid prescription for us to fill under Oklahoma state law. That's not true anywhere else. And so we get Oklahoma prescriptions and we don't know what the heck to do with them if they don't have an address on them. And I can't think of any reason at all for such disparity to exist nationwide other than to prevent economies of scale that larger, more sophisticated operations are able to achieve.

ROBERT ATKINSON: So I agree with Bob in two senses. One, I do think that one of the big roles states have to play is as an enforcer. And Bob and other AGs have done that. And it's great. We don't want to take that away. The second is the laboratory to democracy issue. There are some states for, who knows what reasons, they have enlightened policy makers and they make pro-competitive pro-consumer laws. Those are the exceptions.

What we see is much more about the Tip O'Neill's aphorism that all politics is local. It is much easier for industries to go to their state legislators, including the optometry industry, and get their way with them because they're local. Oftentimes the competitors are out-of-state. They're local. They know the members. And it's much easier to influence legislatures at a state level for anti-competitive regulations and laws.

Combined with that, I worked for a governor once-- very few states have an FTC. Very few states have an OIRA [Office of Information and Regulatory Affairs]. Very few states have a Council on Economic Advisors. Very few states have that level of sophistication to analyze laws and rules from a pro-competition, pro-consumer perspective. And so it's just easy to capture state legislators. And we've seen that over the last 15 years. That has been the battleground for many of these cases where the industry knows they can go to states and they can oftentimes get their way. And Alex's point now with telehealth, that's the battleground because there are lots of states giving into industry pressure.

So to me that just makes it imperative that we have federal rules here. One that I'll talk about later is a federal telehealth law. I mean when we're desperately in need of a federal telehealth mandate to preempt state laws here because practitioners have gone to states to limit them.

MARY ENGLE: So before we get to telehealth, we're just going to move from looking at the states to looking internationally and whether there are any lessons to be drawn from how other countries do or do not regulate the sale of contact lenses. We heard a little bit about that earlier today. I don't know if anybody wants to comment a bit further. And one issue that we've heard come up is the fact that here in the US that the manufacturer, at least for verification purposes, that the brand is required, the manufacturer is required. Is that a common requirement, do we know around the globe? Or is that something unique to the United States?

PETER MENZIUSO: So I can start with saying that we absolutely believe the best way to drive patient care is through a doctor-patient relationship wherever you are across the globe. And that's insuring that the comprehensive eye exam is occurring and that patient is getting exactly what they need based on anatomy and physiology. We also strive in the markets that we play, we're a global player, that we are adhering to the highest standards of care.

We know in those markets when we're adhering to that that standard of care, there is the best patient outcomes. There's greater patient education. There is greater initial onboarding with contact lenses. There is better engagement through the course of their wear. And fundamentally overall, high health is improved. So we are striving to always make sure that we're meeting that highest standard of care. And that is something that we keep very, very true to what we do, because again it really is about patient health and safety that's managed through the doctor.

BOB HUBBARD: Yeah. But there are not brand specific prescriptions elsewhere in the world, I don't think. People know that I've worked on contact lens, for a long time. I had a German visit me. And she says, oh, no, you can get them from vending machines. And you can choose the one you want. You need four parameters, you can pick the one you want. That the health outcomes appear to be the same.

I am a competition lawyer. And over time, I've realized how little I know about and I should not regulate health. And so I don't I don't try to have my recommendations about what competition or enforcement action to take colored by that. There are regulatory agencies that handle that and otherwise. And I think that that's actually a better way to go.

I think that vision is something that people have a lot of emotion about. And it was striking to me how these themes about the eye health problems have recurred whenever competition activities arise. That was one of the major themes in the disposable contact lens litigation. It was a major theme elsewhere. And they didn't have the formative studies in the past. They still don't have them. And after a while. I think maybe we should decide that you have to put up or stop making those arguments.

PETER MENZIUSO: I think we have to understand that the reality is in markets outside the US-- the US has a terrific regulatory framework-- outside the US there is not an environment to actually capture adverse events. So it is likely that these events are not actually being reported, because they don't have that framework to capture it.

ROBERT ATKINSON: So I would just point out what Sweden did. I don't think anybody in the room could argue that people in Sweden have bad hygiene or they're poor or that the government is controlled by libertarians who don't believe in a heavy handed maternal state. Yet in 2011, the Swedish parliament passed the Swedish Patient Safety Act. It lets anybody freely prescribe contact lenses. It lets a patient self-certify that they have a prescription. And the Swedish National Board of Health and Welfare studied this issue extensively. And they were confident, they actually supported the legislation, they were confident looking at studies around the damage and other problems with that that there were no real reasons not to do this provision.

And we see that-- by the way, at least one study I looked at, although I don't know the date, I have to go back and look at it-- the rate of keratitis in Sweden is lower than in the United States, even though the online purchasing rate appears to be about 75% higher. So and we heard that again this morning that in certain European countries where the rules are less stringent and less protectionist, there don't appear to be adverse health outcomes.

For example, in France the prescription is a guideline. The user is given the choice of what brand to use. In Spain, again the consumer has the brand, has the choice of brand. Italy, Japan, Hong Kong, Netherlands, there's no requirement for a prescription. In Japan, you can buy one in a vending machine, including J&J lenses. I would assume that if there are big problems with this in Europe-- that the Europeans are more regulatory than we are, and they have extremely, extremely competent health authorities-- that they would have looked at this and said no.

TARA KOSLOV: Anyone have any further thoughts on international? So we've touched on telehealth multiple times today and in particular on this panel. But I do want to come back and just delve into telehealth a little bit more and really look at what developments are occurring in ocular telehealth and trying to figure out, over the longer term, how those developments are going to affect the contact lens marketplace, and specifically to focus on whether there are any statutory or regulatory changes that would be needed to better facilitate the use of telehealth in appropriate circumstances. And Alex, I know you've already touched on some of this, so I don't know if you have anything else to add to that. And then I know some of our other panelists have some thoughts there.

ALEX BARGAR: No, I mean what I said about the importance of federal standards still stands on what I said a few minutes ago. The only other thing I'd like to add is that the technologies and

capabilities are improving every single day across the multitude of companies who are investing heavily in researching this type of tech. There's thousands of physicians across the country who are trusting these tools to treat their patients remotely. And I want to emphasize that every single one of these services that we're about to discuss is run and administered by either physicians or optometrists who have the exact same responsibility to their patients-- and they are their patients-- and they have the exact same responsibility to those patients whether they treat them through telehealth or whether they treat them in person or any other modality that might exist.

TARA KOSLOV: So Alex, to pass along two questions that came in through our comment cards. And we had one factual question. Is Simple Contacts FDA approved?

ALEX BARGAR: We are FDA registered, which is the extent of our requirement.

TARA KOSLOV: And then we had a question. To paraphrase, basically, how would you use an online exam to diagnose asymptomatic problems with contact lenses if it's early stage and they might not be as visible during a telehealth exam.

ALEX BARGAR: So I think a really important thing to clarify that I, unfortunately, didn't go into too much detail about how our service works in my little intro. The service has a plethora of clinical requirements that are within the medical history portion that the patient has to meet to be eligible. And additionally, the patient has to receive in-person care as well. So it's not about replacing the in-person visit. It's not about that at all. And every single touch point we have with the patient is carefully crafted to make sure that the patients who are using this service understand the service they've received.

But we, as I said before, send patients very regularly to in-person providers. Whether it be a symptom that surfaced in our questionnaire, whether it be something that the reviewing physician or optometrist found in the video of the patient's eye that they looked at, or whether it be simply that it has been too long since that patient has had an in-person assessment, because to your point, there are conditions that can develop without frequent in-person assessment. And we would never want one of those patients to use our tool.

PETER MENZIUSO: Changing vision, again, we believe incredibly strong in the doctor-patient relationship and the importance of a comprehensive eye exam. When telemedicine can match an in-person comprehensive eye exam, we should absolutely embrace it. That's going to enable us to serve more and more patients. But it must match that in-person comprehensive exam.

ROBERT ATKINSON: Yeah. Just on that specific point, I mean any regulation always balances off costs and benefits. And if a year is good, why not six months? Wouldn't six months be better? And there's a reason why there's a year or the gentleman this morning from Tennessee was saying for them, it's four years. So the notion somehow that if you can do what Alex's company is wanting to do-- which to me sounds like it's going to save a lot of money, wouldn't it be lower cost-- those savings are real. And I think you have to always balance those out.

Second point I think is when we think about innovation, one of the things that struck me listening to the last panel was that only 25% of doctors have some kind of PHR or electronic health

record. That is pretty low when you think about the rest of the universe here. And one of the advantages I think about companies like what Alex is doing or any of the other bigger companies that are more online in the bases is that they are able to collect machine readable data and use that for analytics. And I don't know that you're using it yet for analytics.

But we're in we're in a world right now where increasingly we're going to be using big data analytics, and machine learning, and AI. You see that now with NIH, and what Francis Collins is doing with the 1 million patient initiative. It seems to me that's one of the visions that we should have for this industry is that we're going to aggregate large pools of data for analytics around what's the kind of best practices and what lenses work best for these different things. But I don't think we're going to get there if we don't embrace and allow these other models to come about.

ALEX BARGAR: One other thing I'd like to add to that is that the technology that we're using and that other companies are using as well is personalized. The care that's being provided to these patients is personal to them based on their health history. And one of the things that we've heard is a recurring theme in this panel is that one of the largest, or the largest, risk factor associated with the usage of contact lenses is the behavior around how patients choose to use those lenses.

Our platform allows us to provide targeted education and advice to those patients on a much more frequent basis than that patient could ever receive from just an annual in-person exam. We're able to calibrate that and adjust it on the fly for what that patient needs down to the level of specificity of how frequently that specific patient wears their lenses. So yes, there are some things that they're not getting with the online assessment. There are some things that they're getting that technology enables that they would never be able to get anywhere else, just from a practical standpoint. And I think that's really an incredible development.

TARA KOSLOV: So just to add one additional thought on telehealth in the interest of full disclosure on the FTC's priors. So we have been actively engaged in what we call competition advocacy around the issue of telehealth. We've filed some comments in response to requests from state legislators to comment on particular pending bills. Our general position we do not ever take a position on what is medically appropriate in any specific area. Typically where we come out is we think that it should be up to the individual providers to determine whether the use of telehealth is appropriate within whatever standard of care they are held to.

And to Peter's point, the idea that it should be the same standard of care regardless of whether it's in-person or via telehealth and that the legislation or regulations should be technology neutral, so that it is up to the individual providers to decide. And if they are comfortable providing telehealth services and they think it's within the standard of care, that that should be allowed. And so we do have some advocacy comments that we have filed along those lines. And I think the discussion we just had is fairly consistent with the position that the FTC has been taking.

MARY ENGLE: OK. So turning now to some more blue sky thinking. So beyond the changes that we've already proposed to the Contact Lens Rule, if you had your druthers, are there other changes that we could make? And since we're doing blue sky thinking, we'll accept thoughts on

changes that would actually require changes to the statute as well. Let's see, Alex, do you want to go first since you may be where the rubber hits the road with your business model?

ALEX BARGAR: Yeah. I'd love to. Thank you. So again, my perspective is provided as someone in sort of a unique role of running an online contact lens retail, and facilitating the operations, supporting a nationwide telehealth network. One of the things that we have seen from both sides-- that I'm a little surprised hasn't been discussed more exhaustively-- is some new bad actors in the space who are using verification requests for contact lenses, passive verification, to essentially fit contact lenses without any visit or doctor involvement at all, companies like Hubble and others that are entering. We get dozens of requests from them for lenses that no provider using our services ever fit.

And the reason that I want to emphasize this is because it leads into my suggestion for portability, which I think is really the problem here. The reason that companies like that are able to take advantage at scale of this verification framework is because what we want is a better portability solution. I would love to see an incentivization for independent providers to adopt EHRs instead of a mandate or a stick-based solution. Something like if you are using an FTC approved EHR that meets minimum requirements for prescription portability, you could be on a do not call list. You can't possibly verify a script with an optometrist who is using one of these 20 approved FTC records.

What's the point of it? All we really want is for accurate prescriptions to go to everyone. And we want them to go out quickly. And we want it to go out every single time. And so if we could do something that would actually incentivize a lot of these hardworking ECPs to adopt this tech instead of feel like we're antagonizing them or forcing them into it, I think that would be a win for everyone involved.

ROBERT ATKINSON: So I would build on that idea. Again I'm really struck by the conversation in the last thing about people using faxes. I haven't used to fax in I don't know a long, long time.

BOB HUBBARD: State of New York occasionally does.

ROBERT ATKINSON: Pardon?

BOB HUBBARD: We do occasionally.

ROBERT ATKINSON: I'm sure you do. I haven't faxed Amazon any time lately. And then hearing about just the calls, the faxes, the pieces of paper-- somebody even mentioned carbon copies.

[LAUGHTER]

OK. So I would build on what Alex said which is-- by the way, I don't think this is really-- you don't have to have an EMRs to do this. There are cloud-based prescribing apps. You don't need

an EMR. You just sign up through a cloud-based prescribing app. Your patient can download a thing on their phone. They have it. You have it. Super easy to do. Or could be easy to do.

And I think what I would suggest is at minimum what Alex said, that you don't get any more calls and you're prohibited from calling if you have that, as long as the patient has access to that. I mean that's the key. The key has to be that the patient has automatic access to this without telling the doctor where you're going to file it. You then can choose any provider you want to file your e-prescription. And it has to also be done with what you call an open API, application protocol interface, so that any company-- Walmart or Costco or whoever-- could automatically have their machine interrogate the app machine and say, oh, yeah, this prescription is real.

So you don't even need people in this. It's all sort of machine to machine communication. But I would argue that if you did that, then you would-- by the way, I fully support also the proposed regulation of the three year retention rule. But to me, if you did that you would automatically be exempt from having to have these three year things because those would be stored automatically on the app.

But guess I would even go further in the sense of I feel like we've been fighting this fight for 15 years. There's always some barriers.

BOB HUBBARD: At least 22.

ROBERT ATKINSON: Huh?

BOB HUBBARD: At least 22.

ROBERT ATKINSON: For you 22, for me 15. There's always some new trick. Always some new thing that gets in the way. Put up the signs, or whatever. Don't give them the prescription even though you have to do it by law. I would argue that we should just pass a law that says you cannot prescribe if you're an optometrist unless you give it in an electronic format through one of these open API applications. If you're not willing to do that, don't prescribe. To me, that would open up the market. It would allow people-- the other thing you wouldn't run across these mistakes and this and that. It would all be electronic, machine to machine. To me that's the ultimate easy solution.

BOB HUBBARD: The pie in the sky, the kind of thing that prescriptions are not manufacturer specific.

MARY ENGLE: Says blue sky, not pie in the sky. Look at the slide. See there's no pie, it's just blue.

BOB HUBBARD: Yeah. But the other thing on the prescription release idea, one of the things that I've increasingly worried about is that the process of fitting itself is another means by which to delay the release of the prescription. And it's always struck me that an optometrist will let a patient leave with lenses that are safe and effective, but still not release the prescription because something else needs to be done. You would think that enough work has been done for that

optometrist to have decided that it's safe and effective for that patient. And that if it works for that consumer, that consumer can buy it. So I don't know why fitting is an additional delay of the release of the prescription.

PETER MENZIUSO: We support a regulatory framework that is putting patient health and safety front and center. It's allowing competition to come in with great innovation that's meeting unmet needs and allowing doctors to make their very best therapeutic choice with brands available. So with that, I would even say it's important that preserving the prohibition on brand substitution in the current law act is very, very important.

We feel very strong that keeping the one year expiration to a prescription stay true. We want to see that patients are going back to their eye care professional for that exam to make sure that the health of their eye is front and center.

And at the same time, we want to make sure that competition is coming into the marketplace. We love that there is more innovation, more ways to serve patients, greater access to care under a regulatory framework that's keeping health and safety paramount.

TARA KOSLOV: I wanted to ask a follow up question about the EHR point. So we've heard from many of the providers and the prescribers who have been on our panels today that many, many doctors are giving prescriptions to patients, they want to give the prescriptions to patients. And they're following the law. And then on the other side, we have lots of consumers who have a strong interest in having better access to their prescriptions, enabling technological solutions. Though they are slowly adopting EHR, we certainly have a generation of patients who are increasingly taking advantage of EHRs and are learning the benefits of that technology.

Where is the mismatch here? Why do we have a situation where the market has not really yet enabled these technological solutions that could-- if it is so easy to solve this problem-- why has that not happened yet?

ROBERT ATKINSON: Well, first of all, the EHR is to me-- the idea that you would think EHRs are a solution to me is just don't understand what EHRs are. Nobody-- I mean what the consumer wants. They want open APIs on all these EHRs, they want the labs. They want the hospitals. They want the doctor. They want all of this together in one place. Right now you don't have that because the EHRs are vendor specific. And they're not interoperable. They have closed APIs.

And so it's not surprising to me. I mean I have an EHR with my doctor. And I use it. But I don't get everything I want. I also want it in machine readable form with graphs and all the stuff, which you just can't get.

I think the point that the point here is you don't need EHRs to make this work. You need, essentially, access to the internet, because we've now moved to this world called cloud computing with cloud apps out there. And I guarantee you if you passed a law or a rule that said you cannot prescribe unless you make an electronic health record, you would create a market overnight for some Silicon Valley or New York company to come up with an app that would do

that incredibly easily. And it would automatically port for the companies that have an EHR, it would automatically port their EHRs into this app. It would allow the consumer to have this.

So I think we shouldn't get hung up on the notion that every doctor has to have an EHR, because EHRs frankly aren't all that good and they're not going to get us where we need to go. But I think if we think about much more of a cloud-based world with open APIs, then we can get to what we want to get to. And by the way, not a lot of money. I mean, that's the great thing about the cloud. I mean we at ITIF moved to cloud storage, cut our IT costs by 70%, and an increased accessibility and ease of use by 100%. So these are really easy things that technology companies are building now.

TARA KOSLOV: So the moral of this is I should quit my job, work with my high schooler, and we should develop an app. And we're going to make a killing.

ROBERT ATKINSON: There you go.

TARA KOSLOV: OK. Note to self. Anyone else have any comments on that point?

ALEX BARGAR: I just think it's really important to do this through an incentivization process and not a mandate. I hear completely all the technical issues with implementing an EHR and understand that they're not adequate for a multitude of the things you'd use them for. But I think if we found a way to reward providers who are adopting those so that everyone could see the benefit and no one felt like it was a burden that was being forced on them, that we might realize that there is a way to do it that everyone can agree on. And that doesn't generate nearly as much contention.

PETER MENZIUSO: And I think the last thing I'd say is I think all of this should just be under the premise of how is this going to improve patient health.

ROBERT ATKINSON: Again to point one thing is I see this as a doctor would have a tablet or a laptop or whatever it is. They type in the app. They press the button on the app. Up pops a simple form. They type in the prescription or they have it ported automatically from their EHR. And that's it.

And then I see it automatically on my phone about four seconds later. I have it on my phone. And then I can go on file. So I go to Walmart. I type in whatever the Walmart thing is. It automatically takes the information from my app in the cloud and puts it into their system.

And then to Peter's point about patient help, to me this would be an improvement in patient health because you would have, first of all, more easily accessible prescriptions. And you'd be able to renew your lenses. But you'd also have more accurate prescriptions. You wouldn't have problems with mistakes and all that, unless the doctors were making mistakes. But all these other mistakes along the way, like telephone tag, those would be all eliminated.

TARA KOSLOV: So I don't want to leave anyone in the audience with the wrong impression of where the FTC is on electronic health records. So I just want to assure you there actually are a

few of us who have been deeply involved in looking at the evolution of EHR and interoperability issues and sort of the intersection of competition, consumer protection, privacy all of that. So it is an area sort of adjacent to contact lens inquiry, but there are a few of us who follow those issues. And so we know that it is not as easy as anybody might be making it sound. Although this idea of an app that is not yet cloud-based that is not EHR, we do understand that distinction. And it's something we can think about.

BOB HUBBARD: And when will you have it fixed?

ALEX BARGAR: We'll make it.

TARA KOSLOV: It's not within the FTC's jurisdiction.

ROBERT ATKINSON: I don't think it's-- to me it's a demand issue. It is not a supply, it's not a technology issue. The technology could be built within 30 days. It is not a supply issue. It is a demand issue. That's the issue.

BOB HUBBARD: No. I'm still sort of am amazed at the questions that I get answered from Google that 20 years ago I just knew I would never know the answer to that question. And it takes a while for my brain to adjust to the different world. And I know that there were plenty of things I hated about Facebook when my kids were on it and stuff. And now we have this little family thing and we communicate and it works.

And there are a lot of things that I think these are longer processes than I think we're used to. And they're more fundamental in brain rewiring than I think we're used to. And I'm more tolerant at how slowly this is taking I think than most people.

ROBERT ATKINSON: Do you have a cell phone, Bob?

BOB HUBBARD: I do.

ROBERT ATKINSON: Is it a smartphone?

BOB HUBBARD: It is no longer a smartphone. We went from phone to smartphone to phone again.

ROBERT ATKINSON: All right. I have sympathy for you then.

TARA KOSLOV: So in our last couple of minutes, I want to raise one final question. If we can answer this quickly. Are there any topics that would benefit from additional research? That's something the FTC always likes to tee up. Whether the research by the FTC, whether that be clinical research out in the field, or additional research by other stakeholders besides the FTC, just quickly any other topics that we want to throw out for anyone, including all the PhD students out there who are looking for dissertation topics. Always good to give them--

ROBERT ATKINSON: I think one would be-- the big claim that the industry makes, the providers make, that you can't do any of this because there's going to be adverse health outcomes. I think we need more research on that. There are what, seven states that have the two year requirement, I believe. That's a good natural experiment you can look at. You can look at the evidence in those states and compare them to the states where you have the one year and see whether, controlling for all other variables of income and socioeconomic factors, is there any difference.

You could also look at the difference between independents who can't prescribe-- sorry independents who can prescribe and then chains who can't prescribe, is there any difference in the prescribing behaviors? Is one group prescribing something that's where you can see a statistical difference? That might suggest that it's not just about patient, what's best for the patient, but what's best for the doctor. So those would be the main thing I would think.

BOB HUBBARD: And I think that there's a big regulatory issue that ought to be understood fully. I don't think it's an antitrust enforcer's job to do it. But I think that it's important to understand where these problems arise. And if it's a regulatory system-- I think it's less regulatory systems than most people probably in this room. I think that it gets distorted by those within the industry. And I think that probing that kind of stuff, the competition advocacy with the FDA, where they understand that a brand specific prescription has adverse competitive consequences, I think is all very useful things.

PETER MENZIUSO: And what I would end with is putting the health and safety of a patient first, I think with the regulatory framework that we have today, how we can work to better enforce what's there today.

TARA KOSLOV: Anything to add, Alex?

ALEX BARGAR: Nothing at all.

TARA KOSLOV: Great. Well, we are at time. I would like to thank everybody, especially everyone who stuck it out for the entire day of our program. Extra thanks to our tech folks who managed the webcast, our support staff, and our event staff who manage the space and kept everything running smoothly.

We want to remind everyone, again, that the record will be open for another month. And we really do welcome your additional comments, especially if the things we discuss today raise some new or different points and you want to supplement something you've submitted before, we really are reading all those comments and taking them very seriously. And then finally, please return your lanyards and badges as you are leaving. Thank you all very much.