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 this panel with me will be Tara Koslov, who as you know from earlier,

We're really excited about this offering. We do see this as an opportunity to grow more wearers

That suggests otme thae sn2(t)3R(y)2eae (ae)rsn22(kae)6 0 Td .40 T 0 Td40 Trs12.3is c [((ae)mp Td .5.

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 that 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 say, I'm a 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?

PE

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 propo

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 often 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

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

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.

Pd(i)-2(fun3a)-4(t)eh1C.D wk. Snd atn1 .n-1(),o TD [(Pve)4(aB4tvr)-0n de has-2(e)4oat(ens)o eBD1C 0

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

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

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 strongly 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,

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

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's, 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 versus 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 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 very much.