

Tuesday, April 03, 2018

The Honorable Maureen K. Ohlhausen
Acting Chair
U.S. Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Federal Trade Commission,
Office of the Secretary, 600 Pennsylvania
Avenue, NW, Room CC-5610 (Annex F),
Washington, DC 20580.

From:
Kenneth Daniels, OD FAAO

Federal Trade Commission,
Office of the Secretary, Constitution Center,
400 Seventh Street, SW, Room 5610,
Washington, DC 20024

Dear Acting Chairman Ohlhausen,

I am a proud doctor of optometry providing essential primary eye health and vision care to families, including school-aged children, adults and seniors, in and around my hometown of Hopewell – Lambertville, NJ.

My patients are my neighbors, my friends, and they know, trust and rely on me to provide advanced, personalized and fully accountable care to safeguard their sight and protect their health. Through an eye exam, I not only assure precise and healthy vision but I am able diagnose sight threatening and life-threatening diseases and conditions, including diabetes, glaucoma, cancer, hypertension and stroke. In the panel discussion at the recent workshop, patient health and safety was vividly stressed by Dr. Cockrell, Dr. Lakkis, Dr. Steineman and Peter Menzious and yet it seemed to be over-shadowed by the commercial interests of your other panelists.

On March 7th, I was voluntarily away from my practice and my patients to be in Washington, DC in the hope for a fair bipartisan panel discussing the contact lens rule. I wanted to be part of the discussion to ensure that the perspective of concerned eye doctors and their patients is heard loud and clear, especially in a discussion involving the Internet mass retail industry giants that reject contact lenses as a medical device, stand accused of using anti-competitive sales tactics and causing higher prices, use of automated robo-calling systems to disrupt small health care practices and misinform the public under the guise of lower costs.

Specifically, I want to report to you that non-enforcement of contact lens patient safety laws carries a painful and preventable human cost.

As I sat in the audience and observed the proceedings it became very obvious that the FTC has changed their motto of “consumer protection” to “business protection”. The fact that many of the panelists were or have been sponsored or have been paid consultants to the “businesses” represented at the workshop speaks volumes on the direction that the FTC is supporting business and has forgotten the physician’s motto of “do no harm” for if the FTC allows the online vendors to have their way, much harm will be levied onto the public domain. It was unjust not to have every panelist verbal inform the public of their financial disclosure and corporate affiliations in particular Dr. Churm, Atkinson and Hillard whom have been paid consultants to 800contacts while make deceptive and erroneous comments that would favor their employer.

What are the major issues:

- 1) **Patient wellness and safety:** The monitoring of the contact lens patient is not just to evaluate the contact lens but evaluate the health of the patient as part of their overall healthcare.
- 2) **Lack of Proper verification by the online vendors**
- 3) **Shipping before verification** is a direct breach of the FCLCA act and has been common policy for the majority of online vendors
- 4) **Unnecessary financial issues that would be imposed on ECP and all organizations prescribing contact lenses: contact lens paperwork proposal** that would impose compliance costs of more than \$18,000 on small and mid-sized practices
- 5) **Generic lenses being offered by online vendors** such as Hubble and Sight Supply are not clinically acceptable and places the patient at risks.
- 6) **Online examination and replenishment of contact lenses without a direct patient doctor encounter** is a catastrophe waiting to happen- the FTC should not be favoring policies that jeopardizes a patient's health and vision.
- 7) **Passive verification by online vendors is a circumvention of the approved FCLCA system** asking for update on records without a patient consent.
- 8) **Online Vendors deceptive techniques and fraudulent methods of sales and actions against the public trust.**
- 9) **Online vendors utilize deceptive presentation of elevated costs and then the use of "sales"** to make it appear that they are saving money when in actuality the online vendor offers the same or higher fees than the ECP.

If cost was the only issue, then the data presented by Atkinson from 2005 and a now defunct UPP system was detailed in false pretense and in fact as presented by Dr. Lakkis and with supporting data by industry distributors, the cost of products are very much equal between all vendors including private ECP providers. As such, cost of product is no longer the issue even though online vendors continue this false presentation to the public.

The major issue is not the documentation, even though the proposed rule changes increase paperwork when Washington is actively trying to reduce paperwork. The major issue on hand is "patient safety".

The Paperwork Reduction Act (PRA) was enacted to minimize the paperwork burden for individuals; small businesses; educational and nonprofit institutions; Federal contractors; State, local and tribal governments; and other persons resulting from the collection of information by or for the federal government.

<https://www.epa.gov/laws-regulations/summary-paperwork-reduction-act>

There is no justification for targeting eye doctors—optometrists and ophthalmologists—and our patients with new paperwork and document storage requirements as your misguided Contact Lens Rule proposal would do, while the Commission allows retailers who blatantly violate the law to operate unchecked.

Your agency's own complaint data confirms that doctors comply with the law, a finding that Members of Congress have specifically recognized in Congressional hearings with FTC officials and further affirmed on March 23rd through passage of 2018 government funding legislation (Public Law 115-141) and the following report directive:

Contact Lenses—The [Senate Appropriations] Committee is disappointed in the FTC's decision not to include the proposed patient safety improvements related to the prescription verification process in its draft contact lens rule and instead impose new paperwork requirements on patients and doctors that are unnecessarily burdensome. The Committee directs the FTC to prioritize patient safety and consider enforcement mechanisms under its existing authority or revisions to the draft rule that address sales of excessive quantities of lenses, illegal substitutions, and communication challenges associated with prescription verification, including robo-calls. The Committee further directs the FTC to continue to confer and consult with other Federal agencies, including the Food and Drug Administration, to optimize its enforcement and consumer education activities.

Patient Safety Should Be the First Concern

I start with a few examples of why the annual direct patient- doctor exam is so critical and ask your very one sided panelist if they would take such risks for themselves, their children and grandchildren simply to save a few dollars on contacts.

The annual exam with an OD or OMD is not to simply provide contact lenses – it is an eye health medical assessment of the patient that can ascertain the full health of the patient. At every eye exam, we measure blood pressure, we investigate the general health of the patient, we are able to see asymptomatic disease that could in fact be life threatening.

I would ask Robert Atkinson, Bob Hillard and Alex Barger do you really trust a cell phone to determine if you have a brain tumor or if you have undiagnosed diabetes, thyroid disease, carotid artery disease, cancer... and I could go on. Do they really want to risk their life to an app.

- 1) For example, a patient presented for her annual eye health exam and contact lens check. She had no complaints no symptoms. And yet, on exam by properly elevation her eyelids, which would have not been done using an app, we fully evaluated her contact lens we found a gelatinous inflammation which is called Salmon Patch Lymphoma. If we did not see her or simply lift her eyelid – see would no longer be with us. She was referred and treated successfully by ocular oncology.
- 2) For example, a patient presented for his long overdue contact lens check having gotten lenses for “somewhere” but not through our office. He was fully asymptomatic only to complain about reading concerns (due to age). With proper exam, which could not have been successfully on an app, we identified a lymphoma buried in the upper cul-de-sac of his eye. We immediately sent him for biopsy and then to oncology. He died 6 months later.
- 3) For example, a young man in his late 20”s presented to the office for a eye health exam. He wanted to refill a prescription for contact lenses. He was fully asymptomatic. As part of the full health assessment performed in our office, we found a bitemporal hemianopia. Even though he was measureable to 20/20 on each eye, the finding indicates a pituitary tumor. He did not return for additional care and can be assumed the tumor was advancing.
- 4) For example, a young college girl whom had been non-compliant with proper contact lens replacement and cleaning called her parents and said she was returning home from college for the weekend and “by the way” my eye is a little red. The parent called me as feeling her daughter should be evaluated. It was after hours, but I called the mother to see if her daughter had gotten home – she had just arrived. So I asked them to come over to the office (9:00 pm). In short, she presented with a red eye associated to a central Psuedomonas ulcer. We immediately called Wills Eye and made the arrangements for her to be seen that evening - fore any further delay would have resulted in her losing her cornea and possibly the eye.
- 5) Pt was in for an examine 04-03-2018. Last exam 02-14-2017. Since that time she has ordered lenses from (2) different online vendors. As we reviewed the record – there has been no request for verification and yet the patient has received lenses. Not only is this a violation of the FCLCA but as well, she was found to be diabetic during the exam due to a significant myopic shift and elevated AGE measures. If this continued and if the patient did not present for an examine – her diabetic condition may have gone un-dected fore she does not and has not seen a PCP in several

years. She was referred to a PCP for bloodwork and diabetic work-up. The online vendors not only disregarded the FCLCA but has placed the patient at a significant health risk by potentially avoiding the patient –doctor exam.

Without exhausting the many case examples that I could present, I ask the panel of the FTC if one of these cases was yourself, your son or daughter, spouse or significant other, a grandchild – would you want to take the “cheap” supposedly convenient route of checking eyes through an app and getting lenses from an “unknown source” or would you prefer a direct patient – doctor interaction to truly determine the health of your eyes and the relations to systemic concerns that can change the course of your life.

I have spent my entire career in providing not just eyecare but medical health care. I have worked in all environments of eye care and medicine from having a Walmart lease, working at Harvard as a graduate student, working with the founder of soft contact lenses in the US (Dr. Robert Morrison), doing research and development in medical devices and contact lens for Allergan and then Director of Cornea and Contact lens research academically for the Pennsylvania College of Optometry and now a private practice provider and proudly representing the AOA and the state of New Jersey as president of the New Jersey Society of Optometric Physicians.

With these multiple experiences, I was insulted by the many of the panelists stating that OD/OMD are in collusion. I am insulted that they suggest I fit one brand only to serve my financial interest. I am insulted that after all my years of work and research they would have the audacity to suggest “one lens fit all”. I have encouraged and allowed all patients to be active participants in the decision of the appropriate lenses they feel is best for them under my clinical guidance.

I would ask the FTC and their panel – does one set of breaks or tires work for all cars and if so why wouldn't the FTC tell all car manufacturers that generic breaks and tires are fine. Why won't the FTC enforce car manufacturers to install the cheapest set of parts onto all cars – they would not because they would place everyone at grave risk. In the case of contact lens – you are suggesting placing not only the patient's vision at risk (the primary neurological organ) but you are placing at major health risks to simply save a few dollars now that will extrapolate to billions in healthcare cost in the future.

The FTC allowed a paid advisor to 800contacts, without proper financial disclosure, to take the stage (Dr. Chaum), an individual who may have retina training but has never fit a contact lens, and allow him to completely present false data misrepresenting the Academy of Ophthalmology only to be properly corrected and reprimanded by the AAOphthalmology's Dr. Steineman, a Cornea Trained Surgeon, on the proper recommendations of eyecare and exams which is in agreement to the American Optometric Association and the American Academy of Optometry.

As stated, having experience as lease holder with Walmart, I can tell you from first hand experience, the sale at Walmart is more important than the health care. They intentionally limited the products offered based on their negotiations and agreements with manufacturers. When I had the lease, I literally saw the manager of the optical discard a new diagnostic set of Vistakon lenses and replace them with Bausch & Lomb lenses, limiting my fitting options and being forced to strictly fit B&L lenses.

In my private office, as well as many of my colleagues, I have a separate room with every diagnostic set of lenses made available and every lens design that is made. I do not limit, nor do any of my colleagues, fit a single “brand” based on financial incentives as so wrongly described by Robert Atkinson. 37,000 independent Optometrist and over 20,000 Ophthalmologist are NOT collusionary, yet 800contacts, a single company, has proven their force and collusionary tactics having been sued by the FTC for anti-competitive practices.

I am, as well as my 37,000 other colleagues, are fitting lenses based on the patient interview and expressed needs. We will fit them with various lenses to allow them to experience the materials and vision and allow them to self determine, under our clinical observation for health and physiology, which lenses they would prefer. We will do the appropriate follow-up and after care of the patient to assure them that they are getting the best lens for themselves. In short, the online vendors do not and will not go to this extent to safeguard the patient. Their only concern is if the credit card number is valid.

We make sure that the patient has been fully informed, via a signed informed consent, that they understand the pricing of professional fees, materials, utilization of managed care benefits and available cost reduction rebates. With all of these efforts, the patient is fully informed of the FCLCA and regulations, recommended replacement schedules, education on AE's (adverse reactions), emergency care information and proper lens utilization education.

I am a patient as well, I wish to be fully informed and as such everyone of my patients is treated the same as I wish to be treated. If Bob Hilliard, Robert Atkinson, Linda Sherry, Alex Barger.... wish to worry more about a portal that is not used, unnecessary paperwork, and sub-par care let them go to Simple Contacts and risk their life – but I will not risk the lives and health of my patients - when I consider their well - being as I would a family member.

In our efforts with all patients, they are given the full choice to obtain their materials wherever they wish. Copies of all prescriptions are supplied to the patient. However, if they wish to use the managed care benefits and appreciate substantial rebates or discounts on materials offered through our office, the patient (as FTC would call them a consumer) has that right.

No one is ever forced, as erroneously suggested by some you're your panelist, to purchase materials through a doctor's office – this is in reality a "freedom of choice" for the patient to make their own decision. Our office, as due my 37,000 colleagues, offer services and accept many of the managed care vision plans which offer significant cost reduction to the patient especially in combination to rebates offered by the manufacturers.

In reality, **the cost through the ECP can be significantly less than an online vendor whom misleads the consumer that they can use their plan benefits** - but in actuality – the consumer needs to do all of the work to get a lesser reimbursement. In the ECP office, we do the submissions and ordering seamlessly for the patient with direct to home delivery. As such cost and convenience is greater through the private office - ECP than the online vendor.

Unlike online vendors (i.e 800contacts) whom use illegal passive verification that "request a record update" for the patient without asking the patient to initiate any such communication. Unauthorized solicitation of confidential patient information, even a contact lens prescription, is a violation of patient rights and privacy.

As Dr. Cockrell had discussed, we have no problem working with pharmacies in communicating to assure the patient is properly served. A prescription is electronically sent to the pharmacy (or written) and we can be properly verified by phone call and an audit log. Yet 800contacts only has "one person" Brett Nelson whom is responsible and yet – try to call Brett – good luck. If there really is an Brett Nelson – then he should have presented himself at the FTC workshop and take responsibility. There is a complete breakdown of communications to the level of non existence when we deal with the online vendors. This is unacceptable and disregards the respect to the consumer.

Other companies, such as ContactsDirect.com (a Luxottica Company) have called me with an agent on the phone and verbally threatened me stating “that I had to give him the patient prescription or I would be in violation of the law and legal actions would be taken against me”. I had not verification of whom he was – he had no details on the patient other than their name, would not give me details on their DOB / address / phone. I will not simply give out information to an unknown source over the phone without the permission of the patient.

Many of the online vendors use deceptive sales techniques as increase pricing for single boxes or lenses and then places every item on sale to bring down the price to be more or equal to what our office would have sold it for originally. This is not an untypical retail strategy – for all major retailers use the “Sale” to encourage purchasing. Yet, the FTC should be more concerned about price collusion amongst the online vendors and the unscrupulous practice of “price elevation for a sale” This is “consumer protection” that should be sought by the FTC. I re-state: In fact the FTC has sued 800contacts for such actions of anti-competitive behavior.

All FTC members should introspectively ask themselves, are these vendors, whom financially supported FTC workshop panelist, interested in the primary concern of patient health and safety or are that at the table on the behalf of shareholders. The later is correct. **The FTC needs to focus, as expressed many times, the patient health and safety is at the forefront of this discussion.**

When unaware individuals start to discuss “vending machines for contact lenses” is a total falsehood and are simple grand-standing comments to support their stipend paid by the online vendors such as 800contacts. In Europe, Israel, Saudi Arabia, many the advance Asia countries (Hong Kong, Singapore, Japan..) Australia, New Zealand, the Scandinavian countries all have tight regulations on contact lens sales and more importantly on proper doctor – patient care. I have taught many of the doctors and para-health providers in these countries and understand their desire and passion to care for the well being of the patient. The only passion 800contact, Lens.com, Simple Contact, Hubble and others have to the acquisition of payment for materials.

Optometry is a holistic medical profession working closely with Ophthalmology and all medical – health care providers to assure the well being of our patients. Yes, we all try to make a living, but we will not do so if we are forced to sacrifice the health and lives of our patient’s if the FTC feels that it is more appropriate to support disreputable business models rather than protecting the health of the consumer - the patient.

Examples of FCLCA Violations

In preparation for attending the 03-07-2018 FTC Panel, I have gathered cases from my office and from fellow doctors discussing instances of patient harm, abuse and violations of laws, some of which have been reported to you already but have evaded a meaningful enforcement action. As a quick calculation: there are listed 16 infringements of the FCLCA act that have been reported with no action. If action had been properly taken this would equilibrate to \$256,000 in fines against these vendors. And that is a single practice who is diligent about reporting. If you extrapolate this to the 10's of thousands of practices across the country and the erroneous statement on accuracy of verification by Cindy Williams legal counsel to 800contact - 800contact would owe the FTC and federal government over \$25 million in fines.

Case	Vendor	Issue
1	Visiondirect.com	Order # (SF) Received request by fax 05-04-2016 @ 14:46 (the office is closed on Weds 05-04-2016) The prescription was expired as of 05-21-2015: We responded on 05-05-2016, upon re-opening the office and clearly wrote on the request "DO NOT FILL_ RX has EXPIRED" We also called the patient on 05-05-2016 to inform them that the Rx had expired and that he requires and eye exam.
2	800contacts.com	Order: (EP) Fax request received 02-02-2015 @ 6:37 am The request was for Acuvue Oasys for Astigmatism Rx had expired 04-05-2014. The request was sent back to the 800contacts stating "expired do not fill - pt has been notified" 02-02-2015 @7:07. Upon the return of the patient to the office of 04-11-2016: She stated she received the lenses even though the request was not authorized by our office.
3	800contacts.com	Phone Request Record # on 01-20-2016 @ 1:20 pm est Pt. SC Based on our paper trail, we respond to all phone request via fax form - on the form we clearly stated "Do not fill-expired - pt has been informed" The patient still received lenses even though the request was not authorized by our office.
4	800contacts.com	Passive record update request from 800contacts for record Pt: MC The request was received 07-21-2015 @ 19:00 We called the patient first finding out that she had already received her lenses 2 weeks prior to our office receiving a authorization request. Her last exam was 07-09-2015. The patient had illegally received a shipment without authorization on 07-10-2015. we did not authorize the rx request. 800contacts was notified " PT illegally received lenses 2 weeks prior on 07-10-2016 w/o proper verification: FTC will be notified for FCLCA breach.
5	800contacts.com	Passive record update request from 800contacts for record PT: JH receive request on 03-17-2016 @ 7:10:28 We called the patient first finding out that he had already received his lenses 2 weeks prior to our office receiving a authorization request on 03-16-2016. His last exam was 06-10-2015. The patient had illegally received a shipment without authorization on 03-16-2016 we did not authorize the

		rx request. 800contacts was notified by stating on the response "PT illegally rcd lenses 2 weeks ago w/o proper verification: FTC will be notified for FCLCA breach.
6	Arlington Lens Company	Multiple emails on the same day for record PT MJ The patient has keratoconus and the prescription was never confirmed by an examination of the patient. The medical care of the patient was incomplete and as such the Rx authorization was denied. Multiple request received with a response to each one: 02-29-2016 @ 9:04 03-04-2016 @ 14:54 03-05-2016 @ 12:39
7	800contacts.com	Passive record update request from 800contacts for record PT: SK receive request on 12-10-2015 @ 4:55: 33 We called the patient first finding out that he had already received his lenses 2 weeks prior to our office receiving a authorization request on 12-10-2015. We responded: as expired - DO NOT FILL – absolutely not authorized – patient has been notified. His last exam was 01-09-2014. The patient had illegally received a shipment without authorization - we did not authorize the prescription request. 800contacts was notified by stating on the response "PT illegally received lenses 2 weeks ago w/o proper verification: FTC will be notified for FCLCA breach.
8	800contacts.com	Passive record update request from 800contacts for record PT: BS receive request on 11-24-2015 @ 5:28:35 We responded: as expired - DO NOT FILL – patient has been notified. Pt was told not to accept any orders from 800contacts. We later called the patient back, he had still received the lenses. His last exam was 03-23-2013. The patient had illegally received a shipment without authorization - we did not authorize the prescription request.
9	800contacts.com	Passive record update request from 800contacts for record PT: LM receive request on 03-01-2016 @ 8:58;31 after hours and do not re-open till 03-03-2016 The patient was called to find out that she had already received the lenses 2 weeks prior to us receiving the request. She was informed of the illegal nature of the act by 800contacts. We responded immediately to the request clearly stating "Absolutely do not fill – after hours request – Expired patient has been notified 03-03-2016 @ 1:14 pm
10	Lens.com	Order 133228121 @ 10:40 am Pt MM This was fax request that would have been a distinct overfill and would be illegal. As well the information provided was incorrect and additionally it was an expired Rx. We responded Overfill: Illegal: Incorrect Do not fill: Pt has been notified EXPIRED. We left several messages with the patient.
11	ACLens.com	Pt SWZ present to the office for an exam on 05-07-2016 (LEA). She has been receiving lens orders of incorrect parameters from 800contacts without any form of authorization request. We keep a tight

		record of all phone call and fax request – none have been received since 2011.
12	800contacts	ML (LEA) patient: 03-08-2018 we received a “passive” record update request from 800contacts. We contacted the patient and found out that he had ordered lenses on 03-01-2018 and had already received the lenses 3 days before an authorization request was sent to our office. Order # This is a complete breach of the FCLCA verification requirement.
13	800contacts	AL(LEA) 03-08-2018 we received a “passive” record update request from 800contacts record number We contacted the patient – they had already received the lenses prior to any request for authorization. The patient and 800contacts had been notified by us that the prescription was expired – the last exam was 02-09-2016 and expired 02-08-2017. This is a complete breach of the FCLCA verification and expiration requirement.
14	800contacts	JK (HEA) record number 800contacts requested a copy of the prescription 02-09-2017. Then 800contacts made a robo-call request for the wrong prescription on 02-10-2018. We called the patient and informed them that the request was rejected due to the request for the wrong prescription. On 03-10-2018 a passive request was received once again for the wrong prescription the information was returned to 800contacts and the patient informed. As far as we know, the patient has already received the lenses.
15	800contacts	From Dr. Levinson: A passive record request was sent to him dated 03-12-2018 @ 6:45 am. He called the patient, the patient had already received the contact lenses several days prior to the request for verification. This is a complete breach of the FCLCA verification and expiration requirement.
16	Multiple vendors	LAW (HEA) Pt was in for an examine 04-03-2018. Last exam 02-14-2017. Since that time she has ordered lenses from (2) different online vendors. As we reviewed the record – there has been no request for verification and yet the patient has received lenses. Not only is this a violation of the FCLCA but as well, was found to be diabetic during the exam. If this continued and if the patient did not present for an examine – her diabetic condition may have gone undetected for she does not and has not seen a PCP in several years. The online vendors not only disregarded the FCLCA but has placed the patient at a significant health risk by potentially avoiding the patient –doctor exam.

In all of these cases, and many since, the online vendors have unlawfully supplied contact lenses to the patient with full disregard to the guidelines set-forth by the FTC and the federal FCLCA act.

It is not the fact of supplying contact lenses, but the fact that supplying lenses when not authorized by the prescribing physician endangers the well - being and safety of the patient and is a clear violation of the present regulations set-forth by the FTC and the federal FCLCA act.

It is not just the potential risks of corneal and related health complications but the fact the individual is prompted and encouraged by these online vendors to “avoid” proper eye-care which in fact is an essential part of their medical care by over-supplying lenses beyond the 1 year expiration.

It is critical that the FTC not look at this issue as an issue of documentation but how online vendors are intentionally trying to circumvent the healthcare system in their favor and risking the patient health and safety which in turn will lead to an increase in billions of dollars associated with un-diagnosed disease.

In many cases, the optometrist and ophthalmologist is the primary medical provider for the patient. In many cases, as I saw today in my office, several of my patients, children included – had no primary care physician and yet they were seeking my services. During these exams, I (as well as all of my colleagues) have the potential to identify medical conditions that could change the person's life.

If it were up to the SimpleContacts, Opternative, 800contacts, Hubble and others, the avoidance of the direct – patient doctor encounter can only lead to catastrophic outcomes when oculo-systemic conditions are missed when a person (consumer) utilizes services that mislead them to a “false” examination of the eye via a “online refraction” or a photograph acting to substitute for an actual in depth examine of the ocular health.

The FTC should be very aware that the online vendors place the patient at direct risks by the encouragement to avoid eye-care. In everyday practice (patient –doctor direct care) I identify various eye diseases and their relations to systemic medical concerns.

For example, we measured the blood pressure on a gentleman I saw today – it was 134/ 103. This indicates a severe and poorly controlled hypertension which can lead to stroke or heart attack. He was immediately referred back to his primary physician for continued care. Eye care by a doctor of optometry or ophthalmology is more than contact lens care - it is medical care that can save lives.

Two weeks ago, a young girl presented with a viral keratconjunctivitis. This was successfully treated – but additional history tells us her father has a significant history of uvetic eye disease which could have familial relations to his daughter such as the potential of JRA (Juvenile Rheumatoid Arthritis). We have fully discussed this with the parent and are now following her closely and will engage her pediatrician.

Would you, an FTC member, risk your own vision and medical health with a cut-rate – online vendor who cares more about your credit card than your health to allow them to perform a “so-called exam” which would potentially miss significant eye disease or related systemic disease.

FTC members must think about themselves and their own family members and their well – being. They must simply ask - “would you put yourself and your family at risk of missing significant medical concern(s) that could have been easily found during an eye exam” just to satisfy the proposed “simplicity” of online vendors offering “online eye exams” (refractions only) to supply contact lenses (never seen on the eye) and avoid of proper health care.

It is doctors like me on the front-lines of health care in communities across America who are being targeted by a misguided proposed rule that, if imposed, that would devastate small practices and further embolden online companies by putting their own profits ahead of my patients and their safety all in the interest of profit and market control.

I ask you not to attack or penalize doctors like me, the ones whom serve patients with honesty, compassion and with a firm commitment to their health and, at all times, adhere to the letter and spirit of the law.

There is no justification for targeting eye doctors—optometrists and ophthalmologists—and our patients with new paperwork and document storage requirements as your misguided Contact Lens Rule proposal would do, while the Commission allows retailers who blatantly violate the law to operate unchecked.

Your agency's own complaint data confirms that doctors comply with the law, a finding that Members of Congress have specifically recognized in Congressional hearings with FTC officials and further affirmed on March 23rd through passage of 2018 government funding legislation (Public Law 115-141) and the following report directive:

Contact Lenses—The [Senate Appropriations] Committee is disappointed in the FTC's decision not to include the proposed patient safety improvements related to the prescription verification process in its draft contact lens rule and instead impose new paperwork requirements on patients and doctors that are unnecessarily burdensome. The Committee directs the FTC to prioritize patient safety and consider enforcement mechanisms under its existing authority or revisions to the draft rule that address sales of excessive quantities of lenses, illegal substitutions, and communication challenges associated with prescription verification, including robo-calls. The Committee further directs the FTC to continue to confer and consult with other Federal agencies, including the Food and Drug Administration, to optimize its enforcement and consumer education activities.

There are many voices purportedly paying consultants to voice unfounded claims about why you should continue with the proposed rule. I urge you to listen to the nation's eye doctors and other public health experts in recognizing contact lenses as a medical device and by joining with the Food and Drug Administration (FDA) and the Centers for Disease Control (CDC) in making quality care and patient health and safety a priority in Washington, DC.

Why would the FTC support these companies and their misguided methods?

Why would the FTC support companies that make false claims to the public and recognize business entities that have been found guilty of false claims by the FDA, have been sued by the FTC and are presently in litigation, intentionally lie to the public and consumer about “discontinuation” of products, or make false statements that the ECP has vested interest in the products, when vendors house products to avoid manufacturer tracking, sell products close or at expiration and illegally divert lenses (products) from other markets – all of which are unethical and potentially illegal.

Why would FTC endorse illegal activities in ocular telehealth to be merged with online contact lens vendors such as Opternative and 800contacts and Opternative and Sight Supply.

Why would the FTC endorse companies whom circumvent the process of proper contact lens fitting and essential eye health to allow companies such as Hubble and Sight Supply sale “generic contact lenses” using materials that are over 30 years old and manufactured without proper GMP in Taiwan.

- 1) August 8, 2016: **FTC Sues 1-800 Contacts, Charging that It Harms Competition in Online Search Advertising Auctions and Restricts Truthful Advertising to Consumers**
<https://www.ftc.gov/news-events/press-releases/2016/08/ftc-sues-1-800-contacts-charging-it-harms-competition-online>
- 2) October 30, 2017: **Administrative Law Judge Upholds FTC’s Complaint that 1-800 Contacts Unlawfully Harmed Competition in Online Search Advertising Auctions, Restricting the Availability of Truthful Advertising to Consumers**: <https://www.ftc.gov/news-events/press-releases/2017/10/administrative-law-judge-upholds-ftcs-complaint-1-800-contacts>
- 3) **February 12, 2018 Alcon files suits against Lens.com, Allied Vision, National Lens: Alcon announced that it filed trademark infringement lawsuits** in the Eastern District of New York against Lens.com, Allied Vision Group and National Lens LLC on Jan. 19.
- 4) **Warning Letter: Opternative Inc 10/30/17** The United States Food and Drug Administration (FDA) has learned that your firm is marketing the On-Line Opternative Eye Examination Mobile Medical App device in the United States without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act). Under section 201(h) of the Act, 21 U.S.C. § 321(h), this product is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. FDA Opternative in violation of federal law; AOA complaint validated: <https://www.aoa.org/news/advocacy/fda-warning-to-opternative-march-18>
<https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm600029.htm>

“FDA has reviewed your website and determined that the On-Line Opternative Eye Examination Mobile Medical App device is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g),” it states. “The On-Line Opternative Eye Examination Mobile Medical App Device is also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency, 21 C.F.R. 807.81(b).”

The letter asks that Opternative “immediately cease activities that result in the misbranding or adulteration of the On-Line Opternative Eye Examination Mobile Medical App device, such as the commercial distribution of the device through your online website.”

<https://mhealthintelligence.com/news/fda-letter-challenges-opternatives-ocular-telehealth-platform>

- 5) **Fraudulent advertising information on 800contacts website misleading the public on “discontinued lenses” which were never discontinued by the manufacturer (Coopervision):** On October 15, 2004, Coopervision (the manufacturer’s of the Proclear lens) caught 800Contacts **distributing counterfeit lenses in Europe which were being filtered back to the US.**



- 6) **False consumer claims risks the eye health of the patient: Refraction only without a full health assessment will miss glaucoma, cataracts, diabetes.... This is consider a false advertisement of an “exam”. A refraction without an exam is illegal disregarding the minimum exam standards set-forth by the State Boards of Optometry and State Boards of Optometry and as recommend by the American Optometric Association and Academy of Optometry and Ophthalmology.**

I also note that they will perform “refractions” on 18-55. Without going into great detail- simply look at HEDIS scores and the requirements for diabetic eyecare over the age of 40, as well as the epidemiology for high blood pressure, auto immune disease, cardio-vascular disease, cancer... occurring in all of these age groups and all having ocular –systemic manifestations.



These are my thoughts being presented to the FTC to re-consider their proposed actions to the FTC Contact Lens Rule. The FTC should abide by the opinion of over 70 members of Congress, as seen in a letter sent to The Honorable Maureen K. Ohlhausen on July 24th, 2017 to work with Optometry and Ophthalmology in protecting the health and safety of the patient.

In summary, as stated by Dr. David A. Cockrell, OD, Diplomate American Board of Optometry and a past president of the American Optometric Association: **“whatever action the FTC takes that [it] would keep uppermost in its mind that patient health care is also part of your charge. It is not just commerce, and [do] not take an action that might in any way jeopardize the patient health [or] an action that is going to increase the burden on small business.”**

And by Peter Menziuso of JNJ Vision Care "Three things are critical to ensuring a healthy eye health community – both now and in the future," **“First, is continuing to promote the importance of the doctor-patient relationship and regular, comprehensive eye exams. Next, is making sure patients receive the exact contact lenses as prescribed, regardless of where they choose to purchase. And lastly, we believe that contact lens wearers deserve care consistent with the high standard of care they receive in their eye doctor's office”.**

As you make your decisions - I re-state to you: **Would you, an FTC member, risk your own vision, the health or the health of your spouse, significant other, son or daughter or grandchildren and their medical health with a deceptive - cut-rate – online lens vendor rather than receiving quality care with your doctor in a face to face encounter with someone whom listens and can understand your needs and concerns while giving the patient learned clinical advice and guidance.**

Kenneth Daniels, OD FAAO

Diplomate American Board of Optometry

Private Practice: Hopewell Lambertville Eye Associates (New Jersey)

President of the New Jersey Society of Optometric Physicians (2017-2018)

Assistant Clinical Professor: Pennsylvania College of Optometry: Center for International Studies

Former Director of Cornea and Contact Lens Research Pennsylvania College of Optometry

Former Contact Lens Development Research Associate: Cornea and Contact Lens Research Unit:

University of New South Wales, Sydney Australia.

Former Manager of Contact Lens Research and Development: Allergan Pharmaceuticals