

The Shady Optics behind Politicizing the Contact Lens



By *Jamie Wells, M.D.* — October 17, 2016



Credit: Shutterstock [1]

I was blind, but now I see.

I read an article by [an economics student](#) [2] where the author suggests Johnson & Johnson and new contact lens legislation are teaming up to deprive consumers of choice and the ability to get their contact lenses.

Relax, the free market is safe and optometrists are also not in cahoots with ophthalmologists (nor are they the same).

Let's break it down, as I underscore the importance of not being so readily convinced by everything you read. In 2004, The Fairness to Contact Lens Consumers Act passed. In summary, it insisted prescribers give patients copies of their contact lens prescriptions so they can obtain their lenses from their vendor of choice. Wonderful news. Prices went down as more companies got into the game and consumer's options abounded.

So did abusive online manufacturer practices and misuse of the legislation.

For example, on Friday, September 9, 2016, the Department of Justice Office of Public Affairs released a statement: "[Owner of Major Online Colored Contact Lens Business Pleads Guilty in Largest-Ever Investigation of Counterfeit and Misbranded Contact Lenses in the United States](#) [3]." In this case, owner Dmitriy V. Melnik pled guilty to importing counterfeit and misbranded contact lenses from suppliers in Asia and then selling them over the internet without a prescription to tens of thousands of customers throughout the country.

DOJ goes on to state, "Melnik admitted that some of the contact lenses he sold were tested and

found to be contaminated with potentially hazardous bacteria. The prosecution is the result of an ongoing multiagency effort to combat counterfeit, illegally imported and unapproved contact lenses called Operation Double Vision.”

Operation Double Vision. That’s right, there is already an actual investigative body and task force established. Ask yourself why a multiagency effort like this needs to be employed in the first place? Because abuses are taking place and endangering consumers (consumers is also a term I, as a physician, don’t particularly embrace when speaking of patients with respect to a medical device).

The “new legislation” is merely a modernization, a slight amendment, of the 2004 bill, not some dramatic sweeping law that overturns an individual’s or company’s rights as we know them. I will get to that shortly. Of primary import is understanding a little about the contact lens.

The lens itself is a piece of medical equipment. Otherwise, it would not require a physical examination by a licensed eye care professional as well as a prescription. The implication being that if it is improperly used, it can cause harm. As per the Centers for Disease Control and Prevention, “serious eye infections that can lead to blindness affect up to 1 out of every 500 contact lens users per year.” (1) The biggest links to complications occur with improper cleaning, irregular replacement of lenses and cases. A million doctor and hospital visits happen annually at a cost of \$175 million due to keratitis (aka a painful eye infection routinely caused by improper contact lens usage). (2)

The [CDC performed a population--based survey](#) [4] to guide prevention efforts while a separate online survey of contact lens wearers assessed the prevalence of contact lens hygiene--related risk behaviors - approximately 99% of wearers reported at least one. “Nearly one third of contact lens wearers reported having experienced a previous contact lens--related red or painful eye requiring a doctor's visit. An estimated 40.9 million U.S. adults wear contact lenses, and many could be at risk for serious eye infections because of poor contact lens wear and care behaviors.” (3)

Glasses are traditionally encouraged by eye professionals as the primary corrective device but contacts are an acceptable alternative. They require proper management and care to preserve eye health.

Since some bad apples in the proverbial manufacturing bunch have exploited loopholes in the previous 2004 statute, by selling lenses without a prescription or ones that are expired, they have compromised patient safety. That's why Sen. Bill Cassidy, MD (R-LA) presented in April 2016 the Contact Lens Consumer Health Act to reflect minor adjustments to ensure the health of the public remain protected and of paramount importance.

This bipartisan (it is cosponsored by Rep. Kathy Castor, D-FL-14) amendment in no way prohibits sellers from selling as falsely purported by those politicizing the issue. It facilitates a prescriber’s ability to confirm the accuracy and to correct a patient’s prescription when in error. Importantly, it ends vendors’ capacity to sell lenses without a prescription and commit false advertising.

Faulty and dangerous business practices on behalf of certain merchants include using robocalls

with non-working return phone numbers to alert eye professionals that a customer has ordered lenses. The law, as it stands, requires the prescriber to respond within eight business hours or the prescription will be considered verified and filled. If the practitioner cannot reach the vendor to make a correction, then the patient is put at risk and an erroneous script is dispensed. The new bill addresses this issue.

Dissenters make assertions not even in the bill and invoke a quote from one ophthalmologist about microbial keratitis that is not even in dispute. Many factors drive this infection, not just internet access to contact lenses or lack thereof.

Let's talk about the actual [S.2777 Contact Lens Consumer Health Protection Act of 2016](#) [5]:

- *This bill amends the Fairness to Contact Lens Consumers Act to require contact lens sellers to provide a toll-free telephone number and email address that prescribers can use to ask questions about a seller's prescription verification request.*

FACT: This enables a prescriber to affirm the prescription is safe and correct for their patient.

- *Under current law, a prescription is considered verified if the prescriber fails to communicate with the seller within eight business hours after receiving the seller-provided verification information. The bill requires the prescription to be considered unverified until the seller obtains affirmative confirmation of the accuracy of the prescription from the prescriber in cases where a prescriber communicates a question or concern about the accuracy or verification of the prescription to a seller through the toll-free telephone service or email address before the end of that eight-hour period.*

FACT: I know it seems obvious, but that's why things need to be expressly stated in a law or they get abused. As it stands, if a company makes themselves unreachable, then they can sell, sell, sell at will. This practice does not advocate for the patient. Requiring a working phone number or email to convey corrections when utilizing a practitioner's license is unbelievably reasonable.

- *The bill removes the Federal Trade Commission's authority to adjust the eight-hour period.*

FACT: Optometrists are not medical doctors, but are trained to refract patient's eyes.

Ophthalmologists are medical doctors who specialize in eye care and health. I actually think the 8 hour window is quite onerous for a non-emergent prescription — when glasses are perfectly suitable in the interim — given the daily burdens of a busy ophthalmologist who may be performing surgery from corneal transplant to cataract removal and trauma or treating glaucoma and diabetic retinopathy, for example. But, this time frame is not even under dispute in the new bill.

- *If a prescriber communicates a question or concern about the accuracy of a prescription before the deadline: (1) the seller shall not fill the prescription, and (2) the prescriber shall provide the seller with an accurate prescription.*

FACT: This seems obvious in the 2004 legislation. But, again, when it comes to the law if it is not expressly stated then it can be abused.

- *Sellers must offer prescribers different communication methods that the prescribers may select as their preferred method for verification requests.*

FACT: Self-explanatory.

- *The bill allows a seller to alter a prescription only if: (1) a private label contact lens is included on the prescription and the same contact lens is manufactured by the same company and sold under multiple labels to individual providers; and (2) the seller fills the prescription with a contact lens of exactly the same material, design, and power as manufactured by that company under another label.*

FACT: Ill-fitted contact lenses can do harm. There are medical reasons prescribers must list exact power, design, refraction etc.. If the lenses didn't require a prescription from a licensed professional, then a non-licensed merchant could make these decisions. Common sense?!

- *Sellers must maintain a database of the issuance and expiration dates of each prescription they receive. The bill prohibits advertisements representing that a contact lens prescription may be filled after the prescription expires.*

FACT: Again, to protect the well-being of the patient. Expiration dates exist as ocular disease and settings may occur and change, respectively, with the passage of time. That is why an interval exam is so crucial to maintaining superior eye health and vision preservation. Soliciting people to get lenses after they have expired is unethical, unsafe and simply an untoward business practice.

- *Sellers violating certain prescriber verification requirements are subject to increased penalties of up to \$40,000 per violation. Such requirements apply to all contact lens sales in the United States, notwithstanding where the seller is located. The Centers for Disease Control and Prevention must examine the potentially adverse effects of seller violations on consumers.*

FACT: The bill insists a study be done on the impact of these violations since there is not great data on how filling faulty prescriptions harms people. We know contact lenses can certainly cause blinding eye infections (infectious keratitis). This doesn't mean it is a good idea for sellers to be elusive when prescribers attempt to contact them to object to an incorrect prescription or that they should dispense faulty or expired prescriptions.

In Conclusion...

This modernization of the existing law in no way impedes a patient's ability to order contact lenses from an online vendor. The free market is safe. But, since we are speaking of patients as the "consumers," merely requiring sellers to have a way for prescribers to contact them to correct prescription errors that could do potential harm while maintaining reliable records seems like an obvious and requisite consideration. I can see, literally, how this is controversial for those who want to implement shady practices to sell more lenses to individuals who may not need them.

Yes, those like the American Optometric Association and the American Academy of Ophthalmology who are dedicated to maintaining the ocular health of those millions of American contact lens wearers each and every day agree with this bill. Detractors may say "health-care

cronies,” but I say eye experts who actually know and live this subject matter daily, are pro-patient and desire to end misleading marketing ploys (in the name of their own license no less).

SOURCES:

(1) (2) As per the CDC: Contact lenses are medical devices and are regulated by the U.S. Food and Drug Administration (FDA) through the Federal Food, Drug and Cosmetic Act. Read more about Healthy Contact Lens Wear and Care here: <http://www.cdc.gov/contactlenses/fast-facts.html>

[6]

(3)<http://m.kissrocks.com/rw/Pub/Web/WSBTV/Special%20Contents/Documents/Doc...> [4]

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[1] <http://www.shutterstock.com>

[2] <https://mises.org/blog/health-care-cronies-seek-monopoly-powers-over-contact-lenses?source=acsh.org>

[3] <https://www.justice.gov/opa/pr/owner-major-online-colored-contact-lens-business-pleads-guilty-largest-ever-investigation>

[4]

<http://m.kissrocks.com/rw/Pub/Web/WSBTV/Special%20Contents/Documents/Documents/news.medleydocument.9873>

[5] <https://www.congress.gov/bill/114th-congress/senate-bill/2777>

[6] <http://www.cdc.gov/contactlenses/fast-facts.html>