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November 29, 2018

The Honorable Joseph J. Simons Chairman Federal Trade Commission 600 Pennsylvania Avenue NW Washington, DC 20580-0001

Dear Chairman Simons:

As you know, the Fairness to Contact Lens Consumers Act (FCLCA) became law in 2003. Under the FCLCA, the Federal Trade Commission (FTC) plays an important role in overseeing and enforcing the law's key provisions. The FCLCA requires that contact lens prescribers provide consumers with a copy of their contact lens prescription. Since 2003, eye doctors have dutifully complied with their requirement. Recognizing that the Federal Trade Commission may soon be finalizing its proposed changes to the Contact Lens Rule, I wanted to ensure that the Commission understood that I continue to have concerns with its proposal. After nearly two years of deliberation, the plan continues to threaten to impose an unnecessary and burdensome mandate on tens of thousands of small business health care practices while also failing to consider strategies aimed at improved enforcement of existing patient health and safety provisions of the FCLCA.

In late 2016, the Commission put forward a proposed rule change seeking to add an additional requirement for the approximately 50,000 actively practicing eye doctors who prescribe contact lenses in the United States. This rule change would require these doctors to obtain from each contact lens-wearing patient a signed document indicating that the patient received a copy of their contact lens prescription. The doctors would then be required to maintain each document for at least three years to aid the FTC in case of a future federal investigation. The FTC asserts that the new proposal is needed because it believes that eye doctors are not following the law. However, based on publicly available information, the Commission has only issued a total of 55 warning letters to contact lens prescribers in over a decade. Additionally, 2017 Freedom of Information Act data shows that out of the roughly 200 million prescriptions issued between 2011 and 2016, only 309 complaints regarding prescription release were lodged with the FTC. An analysis by a group of independent health economists shows that the plan would cost roughly \$18,000 per doctor, per year. As an alternate approach, the Commission should consider the posting of signage notifying patients of their rights under the law.

I am further concerned that the proposed rule fails to address improved enforcement of existing FCLCA provisions that are aimed at better protecting patient health and safety by combating illegal sales, including through the filling of expired prescriptions and filling of prescriptions with something other than what was prescribed. While safe and effective when properly used, contact lenses are federally-recognized Class II and Class III medical devices that present a moderate to high risk of illness or injury. A poorly fitting contact lens, for example, can lead to irreversible corneal neovascularization (growth of blood vessels) and result in scarring, infections, blindness, and even removal of the eye due to persistent, uncontrollable pain. That is why improved FTC enforcement of existing FCLCA patient health safeguards are important and why eye doctors (both optometrists and ophthalmologists), the U.S. Food and Drug Administration, the U.S. Centers for Disease Control and Prevention all agree that the key to keeping contact lens wearers safe and healthy is to support the doctor-patient relationship and not allow it to be undermined through illegal sales. With this in mind, it is troubling that even those retailers who have been warned by the FTC for possible violations are able to continue their deceptive business practices without consequence.

As the FTC moves closer to finalizing its proposal, it is important that the Commission know that there continue to be concerns with the proposed rule. The paperwork mandate it proposes represents an unnecessary requirement for patients and a costly regulatory burden for the nation's eye doctors, many of whom operate as small businesses. Additionally, it is disappointing that the plan lacks strategies aimed at better combating illegal sales. I urge the FTC to reconsider this proposal as it could prove detrimental to patients, their eye doctors, and small businesses across America. As an alternate approach, I encourage the FTC to develop strategies aimed at better enforcement of existing patient health and safety provisions of the FCLCA and to consider supporting the posting of signage notifying patients of their rights under the law.

Sincerely,

David P. Roe, M.D.

Member of Congress