To the Federal Trade Commission Re: Proposed Changes to Contact Lens Rule

I am an academic ophthalmologist who has worked at the leading edge of telemedical technology and its adoption as an important, new, and scalable paradigm for health care delivery in this country for over a decade. As a physician, surgeon, and eye health professional, as well as an entrepreneur building telemedical networks, I am keenly aware of the major issues that are currently being addressed by the FTC in its review of the Contact Lens Rule (CLR), balancing the need to enhance commerce and competition, patient access and choice in the marketplace, as well as the need to protect the health of consumers through monitoring of practice as it relates to prescription release by practitioners, access by patients, and verification by vendors.

As an ophthalmologist, I have seen cases of corneal disease and injury from the misuse of contact lenses and from modifiable factors such as sleeping in lenses and improper lens hygiene and care. However, anecdotal cases of contact lens-related complications provided by the medical community have not been viewed as providing empiric data supporting safety concerns related to contact lens commerce to be addressed by the FTC. This appears to be borne out in the medical literature. The literature, while replete with case-controlled studies of contact lens-related keratitis over the past two decades, fails to demonstrate any connection between online commerce and the incidence or prevalence of keratitis. The incidence of this complication has not changed since contact lenses became available to patients online (with a proper prescription provided after fitting) when the CLR went into effect in 2004. Similarly, incidence rates for keratitis do not appear to be different outside the US, where lenses are available over the counter in many countries.

Additional arguments provided by the medical community regarding the need for annual reassessment of the cornea and eye to maintain safe contact lens wear have also not been viewed as providing empiric data supporting safety concerns related to contact lens commerce to be addressed by the FTC. There is disagreement between the professional academies of eye care specialists as to the frequency of recommended eye examinations. The American Optometric Association (AOA), the society of optometrists who provide non-surgical eye care, refractions, and contact lens fitting recommends annual eye exams for all patients. The American Academy of Ophthalmology (AAO), society of physicians and surgeons recommends exams every 5-10 years for patients between the ages of 18 and 40, except for patients with known vision threatening disease like diabetes. In fact, there is no evidence in the literature to suggest that annual eye exams have any impact on "eye health" in contact lens wearers, beyond the personal preference of the practitioner and anecdotal cases as noted above. This concept of the annual physical exam being required or even beneficial for healthy patients is now being discredited in general medicine. An article by Ezekiel Emanuel in the New York Times in January 2015 noted, that in "*2012, the Cochrane Collaboration, an international group of medical researchers who systematically review the world's biomedical research, analyzed 14 randomized controlled trials with over 182,000 people followed for a median of nine years that sought to evaluate the benefits of routine, general health checkups, that is, visits to the physician for general health and not prompted by any particular symptom or complaint. The unequivocal conclusion: the appointments are unlikely to be beneficial*." In response to this lack of evidence, the United States Preventive Services Task Force — an independent group of experts making evidence-based recommendations about the use of preventive services does not recommend routine annual health checkups. The medical literature suggests that the same is true for "annual eye exams" to assure healthy contact lens wear. I have personally worn contact lenses for 45 years. I have never had an "annual eye exam" for contact lens wear. My contact lens fit has not been reevaluated since I was a teenager. I have never had keratitis because of good lens wear habits. I do not need an annual exam to tell me this fact.

Telemedicine, the remote delivery of health care services and physician/patient interactions, has reached a "tipping point" as a health care delivery model. Over the past 3 decades billions of dollars have been spent by Federal and State agencies to build telemedical infrastructure as part of a large investment to improve health and wellness using telecommunications technology. As an emerging technology,

telemedicine is an efficient and cost-effective way to deliver health care services over large geographic regions. The integration of remote data acquisition and patient management into web-based models of health care delivery by physicians is not new.

However, the increasing role of patient portals and patient-controlled management of their own health care information should be an important consideration now and in the future regarding how that information is accessed, recorded, and retained. Proposed rules to document compliance should include provisions to document such compliance within the EHR and evolving portals. Such metadata could include date stamped refractions and contact lens prescriptions, automated scheduling for eye exams required by Rx dates and state statutes, etc. Patient access and use of their PHI prescriptions for the purpose of obtaining lenses from online vendors could trigger electronic acknowledgment forms requiring electronic signatures and storage. Such transactions would be active on the part of the patient (obtaining her own health information for the portal) and reduce the need and burden of passive verification on the part of the both the provider and the vendor. A common pain point for both.

A recent review of the status of patient portal utilization and engagement from 120 peer-reviewed studies addressing five major topics (patient adoption, provider endorsement, health literacy, usability, and utility) [Irizarry et al. J Med Internet Res 2015;17(6):e148] concluded that patients' interest and ability to use patient portals is strongly influenced by personal factors such age, ethnicity, education level, health literacy, health status and role. Health care delivery factors, primarily provider endorsement and patient portal usability also contributed to the patient's ability to engage through and with the patient portal. The study concluded that adoption by patients and endorsement by providers will come when existing patient portal features align with patients' and providers' information needs and functionality. Consumers are most positive about features that increased convenience, such as making appointments and refilling prescriptions.

Provider endorsement and continued engagement with the patient portal have been identified as important factors in a patient's decision to adopt and continue to use the patient portal functions to achieve and sustain anticipated positive outcomes. Perceived usefulness of the portal was strong, especially if linked to a self-care action. [Gu and Day. Stud Health Technol Inform 2013;188:46-51.] Users reported using the portal to request prescription refills and reauthorizations and to view their medication list, and are enthusiastic about the idea of added refill reminder functionality [Osborn et al. J Med Internet Res 2013;15(7):e133].

Patient portal adoption still has a long way to go however. Athena Health's research indicates 87% of patients want electronic access to their health records, but just 37% have access through a patient portal. Average overall portal adoption rate across the country is only 29% and far less in many healthcare systems.

The current principal driver of patient portal development is CMS and Medicaid EHR incentive program meaningful use (MU) criteria. While MU criteria clearly outline requirements of basic functionality and targeted adoption rates, they do not delineate the steps or features required to engage patients in a sustained and relevant way. Collaborative communication and the ability for patients and providers to share timely and pertinent information, enables patients to participate as active members of the care team beyond the clinic setting. These functions also pose the greatest potential changes to provider workflow and overall impact on the patient-provider relationship. Together, by making the patient a partner in the team managing her health care and health care information, she can act as her own advocate to access and utilize her prescription, reducing the potential burden of automatic prescription release on the practitioner.

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