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**FTC Public Workshop Testimony
The Contact Lens Rule and the Evolving Contact Lens Marketplace**

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Introduction: Background and Opportunity to Participate

Good morning. My name is Dr. Carol Lakkis, and I'm representing Johnson & Johnson Vision Care, Inc. As the head of applied clinical sciences within the contact lens research and development group, I'm responsible for leading exploratory research to support new product development.

In my role at Johnson & Johnson Vision, I bring decades of experience as both an ocular microbiologist and an optometrist—and have spent more than twenty years conducting research on contact lens-related infection and inflammation, disinfection and discomfort, and the therapeutic management of ocular disease. In short: I've dedicated my career and my work at Johnson & Johnson Vision to improving patients' overall eye health and the contact lens wearing experience.

Today, I'm pleased to be here to offer my perspective on why it's vital that our vision care regulatory framework continues to preserve the eye doctor-patient relationship to achieve two important goals: first and foremost, to minimize health-related risks and complications associated with contact lens wear; and secondly, to bring new and innovative contact lens technologies for physicians and patients.

Preserving the Eye Doctor-Patient Relationship

Over the past three decades, as the contact lens landscape has grown, eye doctors continue to play a critical role, not only in promoting eye health, but also in working with

individual patients to find the most appropriate contact lenses to meet their unique and evolving needs.

Ensuring patient access to an eye doctor for a contact lens fitting and evaluation is critical because contact lenses are applied directly onto the ocular surface, and these complex lens materials can interact with the eye environment, including the patient's cornea, tear film, and eyelids. In clinical practice, I would regularly explain to my patients that finding the appropriate lenses for their eyes doesn't just promote their overall comfort and enhance their lens wearing experience, but more importantly, it can minimize the negative impact on their eye health not just over the next year, but for the next 50 years.

That's why wearing any type of contact lens not prescribed by an eye doctor could lead to a variety of complications, from mild discomfort to severe adverse events, like inflammation and infection. Current research suggests that inflammation and infection are on a continuous spectrum.

So, while an issue —like inflammation—may not sound like a critical health condition, it's important to address as quickly as possible so that it doesn't develop into something more serious, or cause any permanent damage to the eye. In fact, because clinical complications can arise prior to the onset of symptoms, a regular comprehensive exam with an eye doctor is critical to minimizing risks and impacts on eye health, and reducing unnecessary costs to our health care system.

While we know the value of regular patient visits to their eye doctor, one of the most significant challenges we face stems from the fact that contact lenses have become widely used and, as technology has evolved, doctors and scientists like myself have focused on ways to minimize the risks associated with wearing lenses. And we've had great success. However, these successes also make it easy to underestimate the importance of consistently going to the eye doctor for a comprehensive eye exam—even when a patient's current lens prescription *seems* to be working and their eyes *seem* to be healthy enough to continue to wear their contact

lenses. Furthermore, a patient's eyes are a window to their overall health and need ongoing care to keep avoidable health risks low.

Contact Lens Safety Across Various Markets and Retail Channels

Importantly, the challenge of reducing contact lens adverse events isn't unique to the U.S. We have some notable advantages in how our current regulatory system balances access and choice with patient eye health and safety.

In fact, when looking at adverse events globally, the research suggests there are higher risks in markets where patients don't need prescriptions for contact lenses, or in those markets that don't require a comprehensive exam with an eye care professional.

- For example, in many Asian countries, patients don't need prescriptions for contact lenses, and as a result, higher infection rates are reported.^{i ii}
- In addition, contact lenses can be the leading cause of corneal infections, in unregulated markets such as in Taiwan,ⁱⁱⁱ which is not always the case in studies from regulated markets like the U.S. and Australia, where ocular surface trauma and disease are common causes of infection.

It is extremely important to balance source of supply with an eye doctor's guidance and supervision, to make sure the lenses are correctly fitted and maintain biocompatibility with the patient's eyes.

Closing Remarks & Key Recommendations

In closing, at Johnson & Johnson Vision, we take our role as a leader in eye health seriously. It provides us with a platform to advocate for better standards of care for all patients. As part of this commitment, we support the eye doctor-patient relationship and continued patient access to innovative lenses, which best address their evolving eye health needs.

I'd like to thank the Commission for this opportunity to share my comments here today, and I'm happy to address any questions during the panel discussion.

ⁱ Watt KG, Swarbrick HA. Trends in microbial keratitis associated with orthokeratology. *Eye Contact Lens*. 2007;33:373–377. doi: 10.1097/ICL.0b013e318157cd8d.

ⁱⁱ Young G, et al. Review of Complications Associated With Contact Lenses From Unregulated Sources of Supply. *Eye and Contact Lens*. 2014; Volume 40, Number 1.

ⁱⁱⁱ Lin TY, Yeh LK, Ma DH, Chen PY, Lin HC, Sun CC, et al. Risk Factors and Microbiological Features of Patients Hospitalized for Microbial Keratitis: A 10-Year Study in a Referral Center in Taiwan. *Medicine (Baltimore)* 2015;94(43):e1905.