

February 14, 2017

## Advocating for Patient Safety: Coalition for Patient Vision Care Safety submits comments in response to FTC Proposed Rule concerning the Contact Lens Rule

The Coalition for Patient Vision Care Safety (“Coalition”) is a group of health care providers, medical device manufacturers and academic institutions dedicated to ensuring the safe and appropriate use of contact lens so that patients achieve the best outcomes regarding vision and eye health.

The Coalition has submitted comments expressing its concerns about the recent proposed rule issued by the Federal Trade Commission (“FTC”) with respect to the Contact Lens Rule (“CLR”). In 2004, the FTC adopted the CLR to implement the Fairness to Contact Lens Consumers Act (the “Act”). In September 2015, the Commission sought public comments as part of its 10-year regulatory review of the CLR. The Coalition submitted its comments in October 2015 and raised various patient-safety issues.

In December 2016, the Commission issued a proposed rule based on its 10-year regulatory review. The comments submitted by the Coalition to the FTC on this proposed rule focused on the fact that Congress intended for the Act to safeguard patients’ eye health. We emphasized that eye care professionals (prescribers) are dedicated to protecting the well-being of their patients and act to ensure that those patients use contact lenses—a type of medical device—safely and appropriately to achieve the best outcomes regarding vision and eye health. Our comments therefore urged the Commission to address patient-safety issues concerning passive-verification robocalls, excessive-quantity sales, and lens substitution. Each of these issues has a potential significant effect on eye health. Moreover, taken together, these issues create a system whose de facto effect is to treat the purchase of contact lenses as a mere economic transaction, without sufficient regard to the need for the patient to undergo regular eye-health examinations. This is contrary to the intent of Congress and is contrary to the recommendations of the Food and Drug Administration (“FDA”) and the Centers for Disease Control and Prevention (“CDC”).

The proposed rule, however, fails to address these patient safety issues. The Coalition, through its comment letter, made various recommendations to the Commission, including the following:

1. With respect to the verification procedures, the FTC should not consider “robocalls” to be within the Act’s definition of “direct communication.” In practice, this would likely mean that emails would become the preferred method through which sellers communicate with prescribers to verify contact lenses information.
2. The Commission should implement reasonable sales quantity limits when the seller has actual knowledge of a prescription’s expiration date. Selling excessive numbers of lenses has the effect of discouraging patients from seeing their eye care professionals regularly in accordance with public health recommendations.
3. The FTC should prohibit online sellers from suggesting to a patient that reordering contact lenses before the prescription expires will avoid the need to “see your doctor” about whether an updated prescription is needed.
4. The Commission should increase its enforcement activities with respect to sellers illegally substituting contact lenses for the lenses specified in the prescription.
5. The Commission should not finalize its proposal to require a signed acknowledgement for contact lens prescriptions. This requirement would create an unnecessary regulatory burden and the Coalition believes there is not sufficient evidence to support such a significant regulatory change. If the FTC is convinced that

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some action should be taken, alternative approaches should be used, such as strengthening education campaigns.

Finally, the Coalition's comments included the recommendation that the Commission bring enforcement actions in cases where sellers knowingly violate the terms of a prescription. This includes cases, not only when the prescription has actually expired, but also when the sale is for a supply of lenses that is far in excess of the number required for the remaining life of the prescription.

The Coalition for Patient Vision Care Safety's comments submitted to the FTC can be found [here](#).

**Additional Information About the Coalition for Patient Vision Care Safety:**

The Coalition consists of: AdvaMed – the Advanced Medical Technology Association; Alcon – a Novartis Company; the Alliance for Aging Research; the American Association of Diabetes Educators; the American Optometric Association; the American Schools and Colleges of Optometry; Bausch+Lomb; the Contact Lens Institute; CooperVision, Inc.; Johnson & Johnson Vision Care, Inc., a member of Johnson & Johnson's Family of Companies; the National Medical Association; the National Optometric Association; and the Society for Women's Health Research. The law firm Brownstein Hyatt Farber Schreck, LLP assists with the development of messaging and government relations strategies.

For more information on the Coalition for Patient Vision Care Safety, please visit their website at [www.visioncaresafety.org](http://www.visioncaresafety.org).

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