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Historical Perspective

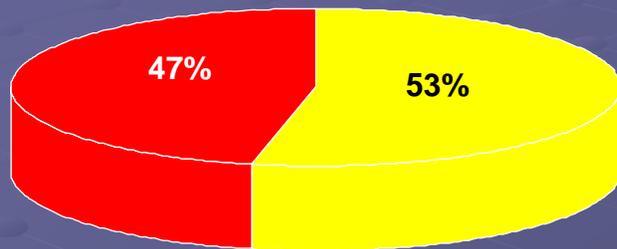
- Contact lenses are medical devices with an excellent overall safety profile but not without risk
- 2 Product Recalls in 3 years
 - 1 Associated with reports of *Fusarium* Keratitis
 - 1 Associated with reports of *Acanthamoeba* Keratitis
- Historical Rates of Contact Lens Microbial Keratitis (US)
 - 4/10,000 year daily wear Bacterial¹
 - 20/10,000 year extended wear Bacterial¹
 - 1-2/1,000,000 year *Acanthamoeba*²
- Rate of Infectious Keratitis during Outbreaks
 - 2.35/10,000 *Fusarium* Keratitis in Singapore³
 - 154 confirmed cases of *Fusarium* Keratitis in the US⁴
 - 138 confirmed cases of *Acanthamoeba* Keratitis in the US⁵

Was Patient Compliance the Issue?

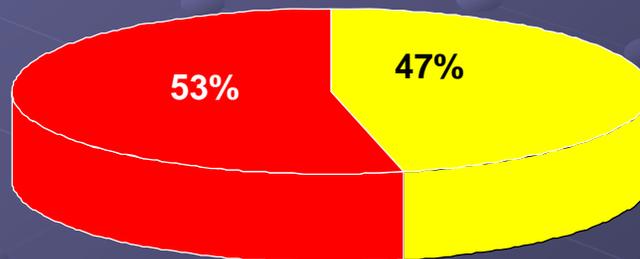
- Patient compliance is poor and has always been poor.
- Patient compliance remains poor despite product labeling and doctor recommendation.

Labeling Changes have had Minimal Impact on Patient Compliance

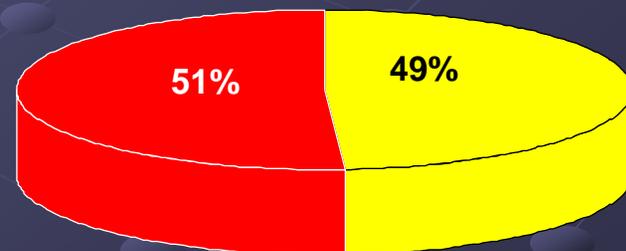
*1998 Before No Rub



^2002 After No Rub



o2006 After Major Product Recall



*1998 Consumer Rub Study-NPD Group
^Taylor/Nelson/Sofres-Greenfield Online
oCiba Vision Consumer Research

■ Rub
■ Did Not Rub

Was Patient Compliance the Issue?

- No correlation⁴ to:

- Washing hands
- Rubbing & rinsing
- Lens case rinsing

- Modest correlation^{2, 4} to:

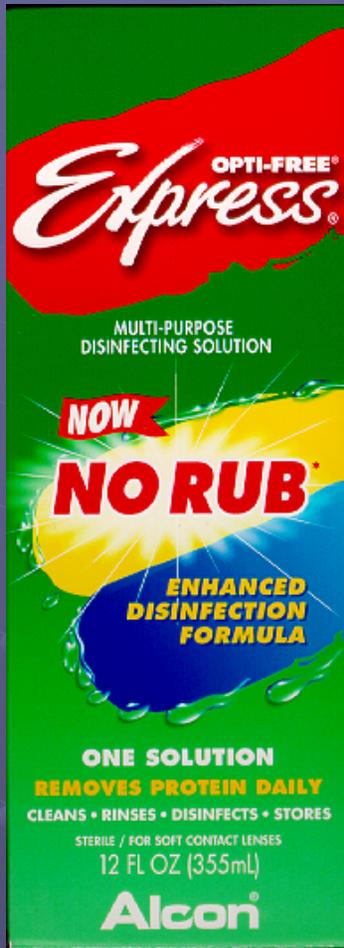
- “Topping Off”

“No single hygiene practice was independently associated with disease in our multi-variable model and our case control studies revealed that sub-optimal hygiene practices were common and similar among case patients and controls.”⁴

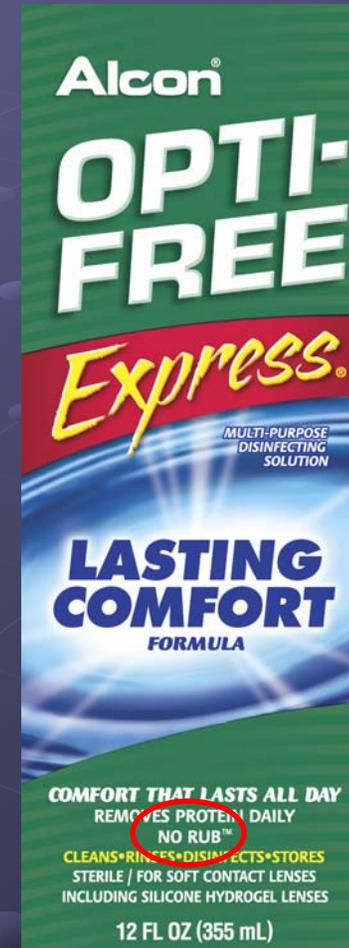
Product Labeling

- Despite the fact that there's no correlation with compliance in the 2 recent outbreaks:
 - The industry has recognized that good lens care practice is important.
 - The industry has made changes to its branded labeling to de-emphasize the promotion of the no rub option in support of practitioner directed patient education.

ALCON Approach To “NO RUB”



2001



2007

Directions Of Use

OPTI-FREE® Express®

2001

**Directions for care of your lenses with
OPTI-FREE® EXPRESS® MPDS**

**To clean, disinfect and remove protein from your
contact lenses:**

If your eye care professional directs you to rub your lenses, place several drops on the lens and rub for several seconds (up to 20). Then follow the directions above. If using SUPRACLENS® Daily Protein Remover, follow those directions, including rinsing before putting the lenses on your eyes.

2007

**Directions for care of your lenses with
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RUB & RINSE



Recommendations

- Testing and labeling must better reflect real world challenges and patterns of actual use (compliance).
- New or revised standards should reflect collaboration amongst FDA/ANSI/ISO, industry and the eyecare community.
- Testing for *Acanthamoeba* disinfection efficacy should be adopted once standards are established and validated.

Recommendations

- Testing of traditional hydrogel lenses based on existing Groups I and IV should continue.
- Testing of representative silicone hydrogel lenses should be required.

Recommendations

- Disinfectant uptake & release testing should determine the optimum time to accurately evaluate corneal staining.
- The ocular environment is complex and corneal staining represents a clinically relevant measure of biocompatibility.

Labeling & Care Instructions

- Labeling should be based on science & product testing – NOT "class labeling" with mandated rubbing and/or rinsing times.
- Class labeling, with mandated regimen steps, is unnecessary for the safe and effective use of products and will stifle innovation.
- Ideally, promotional claims regarding directions of use should be removed from front panel.

Where do we go from here?

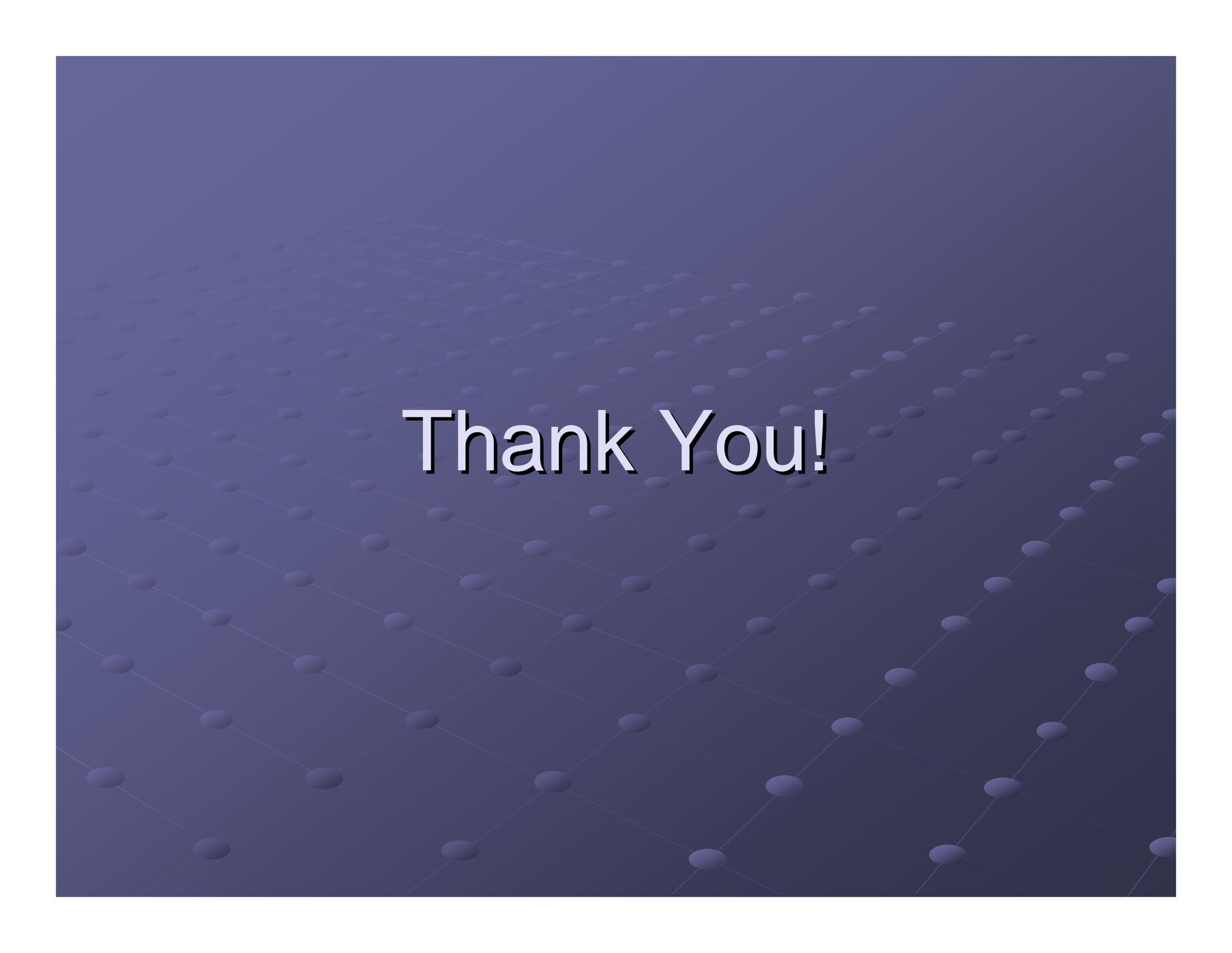
- Practitioners must emphasize the importance of patients following instructions for lens care.
 - Hand Washing
 - Lens Case Care & Replacement
 - Inappropriateness of “Topping Off”
- Labeling should reinforce the practitioner-patient relationship while providing essential lens care directions.

Final Thought...

Recommendations from this panel meeting should take into account real world patterns of use and be based upon scientific data and evidence.

References

1. EC Poggio, RJ Glenn, OD Schein, et al. The incidence of ulcerative keratitis among users of daily-wear and extended-wear soft contact lens. N Engl. J Med. 1989; 321:779-783.
2. CE Joslin, EY Tu, ME Shoff et al. The Association of Contact Lens Solution Use and Acanthamoeba Keratitis AJO 2007; 144(2): 169-180.
3. W-B Khor and co-workers. An Outbreak of Fusarium Keratitis associated with contact lens wear in Singapore. JAMA 2006; 295(24): 2867-2873
4. DC Chang, GB Grant, K O'Donnell et al. Multistate Outbreak of Fusarium Keratitis Associated with Use of a Contact Lens Solution. JAMA 2006; 296(8): 952-963.
5. CDC MMWR dispatch May 26, 2007/56 (dispatch);1-3



Thank You!