

# Medical Device Case Studies

**AHWP Pre-Meeting Workshop,  
25 October 2007  
Chengdu, China  
Sharon W. Adams  
Bausch & Lomb, Inc.**

# Case Study #1

## Hydroview Intraocular Lenses

## Investigation of the Calcification

### Data in hand:

- **Package differences - Original to SureFold**
  - **Clustered nature of the occurrences**
  - **Specific sites experiencing highest rates**

## Investigation of the Calcification

**Two major investigations carried out:**

- 1. Retrospective Case Control Study**
- 2. In Vitro model to emulate calcification**

## Case Control Study

- **Seldom provide definitive cause /effect relationship**
  - **Distinguish trends and associations**
  - **Identify potential risk factors**

## Case Control Study

### Study Design:

- Carried out at centers with highest rates
- Cases defines as Hydroview patients with Ca
- Controls defined as Hydroview patients with no Ca
- Similar time frames
- Same surgeon performing surgeries

## Case Control Study

### Study Parameters:

- Patient profiles (including medical hx, ophthalmic hx, race, gender, age etc)
- Demographics (including site location, environment, etc.)
- Surgical parameters (including anesthesia, technique and meds)
- Follow-up parameters (time, complications, yag, lens condition, IOP, fundus visibility etc.)

## Case Control Study

### Results of the study

Associations and Trends were found for the following:

- **Diabetic retinopathy**
- **Other Ocular Surgeries**
- **Specific Viscoelastic (Viscoat)**



## Case Control Study

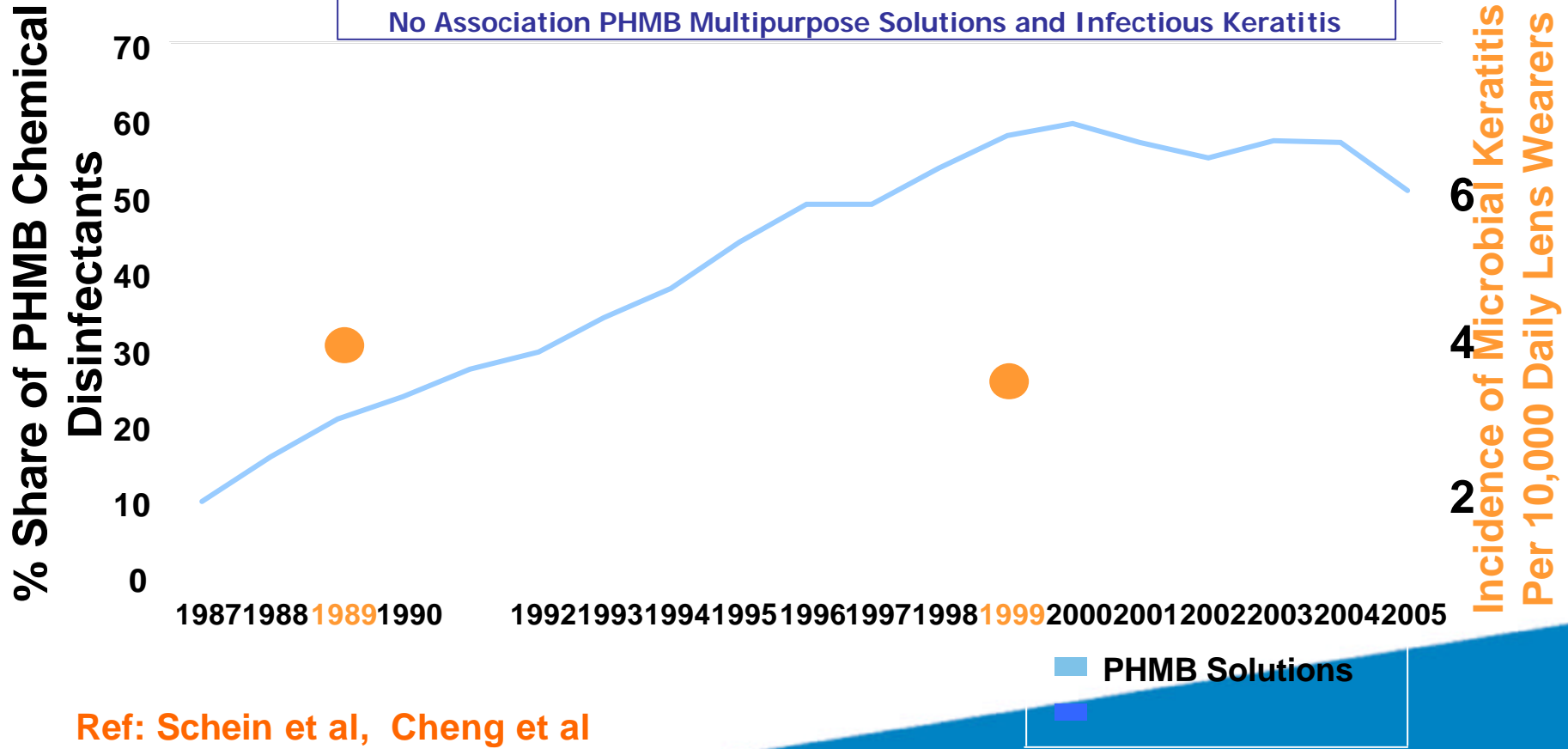
- **Diabetic Retinopathy and “ other ocular surgeries” predispose to compromise of the blood/retinal barrier  
(These findings particularly important wrt In Vitro data)**
- **Viscoat finding potentially confounded by the fact that Viscoat frequently utilized in patients with pre-existing co-morbidities.**
- **Another factor is the removal at surgery making it unlikely to have an effect +/- 1 year later**

## Case Study #2

### ReNu MoistureLoc

There is only one sight threatening event related to Contact lens Wear –  
**Infectious Keratitis**  
 Rates: 4/10,000 for daily wear  
 20/10,000 for extended wear

No Association PHMB Multipurpose Solutions and Infectious Keratitis



Ref: Schein et al, Cheng et al

# Surveillance/Epidemiology

**The market is the final arbiter of safety!**

- **Vioxx (Increased CV morbidity)**
- **Drug Eluting Stents (Blood Clots)**
- **HRT – Dogma! – PM epidemiological data!  
(2002-2003 breast cancer rates down 7%)**
- **Oxygen permeability through contact lenses will reduce infection!  
PM data indicates this is not the case**

**Include longer term PM epidemiological data important to guide  
risk/benefit decisions for patients!**

# Increased Vigilance

- Events at Bausch & Lomb highlighted the value of long-term vigilance
- Enhanced processes to improve risk assessment and management
- Reinforced value of good science, medical integrity/ethics and standards in the development & marketing of products with particular regard to patient needs and safety
- Provided further insight into importance of signal detection and PMS
- Greater focus on global training programs
- Global harmonization of regulations – reduce burden by reducing inconsistencies amongst countries to allow greater focus on safety

# Safety Review Team

- Expert evaluation of emergent safety data
- Central and dedicated forum where all safety issues are channeled for review
- Determine if potential risk requires notification to appropriate Health Authorities (changes to risk/benefit or potential public health concern)
- Initiate follow-up (escalation) or further exploration of any potential safety issues
- Ensure appropriate actions are implemented to minimize risk to patients

# Risk Communication

- Increase collaboration with Health Authorities
  - **Evidence-based approach**
- Interaction with Media
  - **Triggering health “scares” do not benefit public**
- Communication to Health Authorities, HealthCare professionals and patients should provide both the product benefit and risk
- Be transparent, accountable, and provide prompt communications
- **Effective risk communication leads to risk reduction**

# Keys to Vigilance

- Ensure appropriate experts are involved
- Institute effective training programs
- Make ethical behavior the principle element of daily corporate life
- Enable clinical/medical judgment which cannot be influenced by commercial considerations
- Create a system which furthers well-written, documented proof that the right processes were followed and the commitment of care was undertaken
- Facilitate a vigilance system which ensures appropriate escalation of the potential risk based on importance
- Do the right thing, and be able to demonstrate you did the right thing
  - **Diligence in routinely assessing safety on a consistent and regular basis**
  - **Evidence to show your aim to discover safety signals and take appropriate action on response**
  - **Be transparent – audit trail of reviews, decision making, actions**



Increased diligence in the collection, evaluation and reporting of product risks along with collaboration between Industry and Health Authorities will help us reach our ultimate goal

# Patient Safety!