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States, but in Singapore. All patients had developed *Fusarium* keratitis corneal ulcers caused by a specific fungus – *Fusarium*. Further, nearly all 40 had used *ReNu* containing *MoistureLoc*, a contact lens solution produced by Bausch and Lomb. The two Dayton patients checked out identically - same disease, same *ReNu* usage. Seemingly, a global situation existed.

Bullock reported the findings to the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA); both agencies also had received reports of the disease, three of them in New Jersey, an anomaly since the *Fusarium* fungus is rarely found in northern climates. Since all bottles originally shipped were made in the Bausch and Lomb Greenville, S.C. plant, the FDA launched an investigation there. No contamination was found, but to play it safe, a total recall of the product followed.

The question remained. What caused the infections? To Bullock, the official answers given by the CDC and FDA – that they were due to the combination of ingredients - didn't make sense. Bullock began his own investigation.

ReNu was manufactured in four factories – China, India, Italy and South Carolina. The faulted solution came only from the South Carolina plant, yet a thorough investigation of the plant revealed no contamination. Also, stricken patients in different locations were affected by different strains of the fungus, which ruled out a single central source of the fungus. The company decided it was due to improper use of its product. But Bullock didn't buy that answer, either.

Reading the FDA report of their investigation, Bullock looked closely for clues to the problem. He found that the company had failed to regulate the storage and shipment temperature of the solution, even though the bottle said to “store at room temperature.” The FDA didn't consider storage temperature as a possible cause, but Bullock had uncovered a 1997 FDA document that noted an 18-degree Fahrenheit rise in temperature would cut the shelf life of contact solutions by one-half.

Because fungi exist everywhere, all contact lens solutions contain fungus-inhibiting ingredients. Could the summer heat in the temperature-uncontrolled Greenville warehouse and the transport vehicles raise the temperature to destroy the fungus-inhibiting ingredients? Bullock tested the hypothesis by using his own car. On an Ohio summer day he placed a thermometer in his car. Outside it was 91 degrees Fahrenheit. When he returned later in the day, the temperature inside the car had risen to 166 degrees.

Now it was time to turn to the laboratory. Enlisting B. Laurel Elder, Ph.D., a Wright State University microbiologist with advanced training at the Mayo Clinic, the researchers placed several current and recalled contact lens solutions at a constant temperature of 140 degrees Fahrenheit for four weeks. The biggest difference in the fungal-inhibiting ability occurred with the Bausch and Lomb product. The test then was expanded to include 11 strains of *Fusarium* added to xfour contact lens solutions. Reaction of the *Fusarium* fungus in the *ReNu* with *Moisture Loc* stored at a high temperature tested the worst. The conclusion was set. The outbreak of the *Fusarium*

infections was suspected to result from the high temperature at which the Bausch and Lomb solution was stored. The year was 2007.

With these findings confirmed, Bullock and Warwar presented their results to the annual meeting of the American Ophthalmological Society. In 2008 the American Medical Association published their report, and from there the word was out globally. Finally, in May of 2009, three years after his first knowledge of the keratitis outbreak, he

again went before the American Ophthalmological Society with his paper confirming its root cause.

In all, hundreds of patients worldwide contracted *Fusarium* keratitis with some resulting in blindness. Bullock continues to work on more detailed studies to serve his mission of preventing further outbreaks of this and other eye diseases, a noble mission, indeed, for an experienced, determined “medical sleuth.”

(Dr. Bullock is going to present additional findings at an American

Academy of Ophthalmology meeting in San Francisco later this month, at the American Public Health Assn. meeting in Philadelphia in November and to an international ophthalmological meeting in Rome in December. “We are very excited about our new findings which will have even more important public health ramifications,” Bullock said.) (Some factual data in this article was derived from a story published in WSU Medical School's Vital Signs)

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