Bausch & Lomb settles 600 eye fungus lawsuits

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Bausch & Lomb Inc. World Headquarters is photographed in Rochester, N.Y., Wednesday, May 27, 2009. Contact lens maker Bausch & Lomb Inc. had an overriding reason for going private in 2007: It wanted to handle a devastating recall of its flagship lens cleaner, its chief executive said, "without a lot of outside distraction." (AP Photo/David Duprey)

(AP) -- Contact lens maker Bausch & Lomb Inc. had an overriding reason for going private in 2007: It wanted to handle a devastating recall of its flagship lens cleaner, its chief executive said, "without a lot of outside distraction."

Over the past year, away from the glare of public scrutiny, the optical products company has quietly settled nearly 600 fungal-infection lawsuits - with dozens more individual claims yet to be resolved. The cost so far: Upward of $250 million.

More than 700 lens wearers in the United States and Asia say they were exposed to a potentially blinding infection known as Fusarium keratitis while using ReNu with MoistureLoc, a new-formula multipurpose solution for cleaning, storing and moistening soft contact lenses.

Sometimes, the damage was irreparable. Seven people in Florida, Maryland, New York, Oregon, Tennessee and West Virginia had to have an eye removed. At least 60 more Americans needed vision-saving corneal transplants.

The U.S. Centers for Disease Control and Prevention confirmed 180 cases in 35 states from June 2005 through September 2006, when the agency's dedicated surveillance stopped, according to Dr. Benjamin Park, a CDC epidemiologist. CDC continued to hear of sporadic, unconfirmed cases in the months after MoistureLoc was withdrawn, Park said.

"Surveillance usually captures the tip of the iceberg and sometimes it captures a larger tip than other times," Park said in an interview.

Among out-of-court settlements reached in May was a potential bellwether case brought by Andrea Martin, a Broadway actress and comedienne whose eye was scarred. In Colorado, a corneal transplant ended a race-car driver's career. In Baltimore, a chimney-sweep business owner who lost an eye got hooked on painkillers.

"It left him with a chronic pain situation where at one point he had to go through drug rehab," said attorney Andy Alonso. "His business - handed down from generation to generation in his family - has fallen apart, his marriage has fallen apart and he now lives with his mother."

The culprit, an infection so rare that most eye doctors had never seen a case, somehow eluded MoistureLoc's disinfecting defenses. The

outbreak appeared first in Hong Kong in spring 2005 and reached its peak in the United States just days after MoistureLoc was removed from domestic markets in April 2006.

Victims typically complained of eye irritation that progressed to a sudden onset of searing pain. Many were mistakenly treated with antibiotics and steroids - a delayed diagnosis that worsened the condition. A woman in New York was afflicted three months after Bausch & Lomb announced a worldwide recall in May 2006.

"She didn't know about the recall, and the infection was so aggressive, she lost her eye within two months," said her attorney, Hunter Shkolnik.

Leading eye doctors and government scientists concluded that MoistureLoc, launched in 2004 with novel disinfectant and moisturizing ingredients, was the only lens solution that contributed to the outbreak. Yet the mechanics of how it caused the problem are still not fully clear.

Some researchers theorize that the disinfectant, alexidine, absorbed into lenses at unusually high rates and the moisturizing agents created a biofilm in some circumstances that shielded and even fostered growth of the fungus to infectious levels.

With some fungal lawsuits still unresolved, the prospect of Bausch & Lomb's health care nightmare being aired in court has not entirely faded - which heartens some lawyers and doctors.

"The truth has been very carefully buried, and it appears to have been buried going back to the beginnings of the outbreak," said Dr. Arthur Epstein, who was chairman of the American Optometric Association's contact lens and cornea section during the highly publicized crisis.

"All settlements were predicated on silence about the clinical findings

and blame and so forth. My hope was that what actually happened would become part of public record in a courtroom. That way, we'd be able to learn from it and move on and make sure it never happened again."

Multipurpose solutions have been on the market for over a decade, all but replacing older systems for rinsing and cleaning lenses.

In 2007, another popular formula made by Santa Ana, Calif.-based Advanced Medical Optics, the No. 3 manufacturer behind Alcon Inc. and Bausch & Lomb, was linked to a flurry of hard-to-treat Acanthamoeba keratitis infections caused by a parasite. More than 170 people have sued the company, which was acquired this year by Abbott Laboratories.

The Food and Drug Administration is poised to lay out more comprehensive testing standards for lens solutions.

"We did take the two epidemics as very much of a wake-up call, because contact lens safety is an essential public health issue," said Dr. Malvina Eydelman, director of the agency's ophthalmic division.

Financial analysts and lawyers estimate the MoistureLoc debacle could wind up costing as much as $500 million. But far more draining for Bausch & Lomb has been losing its dominance in the lucrative lens care market: 2.3 million of the nation's 30 million soft lens wearers used MoistureLoc, generating $100 million in annual sales.

While Bausch says it has settled "the vast majority of fungal infection cases," it is challenging another 500-plus lawsuits linking MoistureLoc to assorted bacterial, viral and parasitic afflictions. A pretrial hearing set for June 3-5 in New York will decide if there's a reliable scientific basis for arguing such a link.

Alissa Lynch, 21, of Thompson, Conn., said she developed a parasitic infection while using MoistureLoc in college in New Hampshire. It left her with a vision-blurring scar that took a year to heal.

"We went through hell and spent a lot of money to save that eye," said her father, Brian, who eventually decided against seeking damages. "We're just that kind of people. I don't think anybody intentionally looked to hurt anybody's eyes."

When Bausch & Lomb was acquired by private equity firm Warburg Pincus for $3.67 billion in October 2007, Chief Executive Ronald Zarrella said the deal would allow the company "to pursue the growth path we were on ... without a lot of outside distraction." Zarrella retired last year.

The 156-year-old Rochester-based company, which posted $2.5 billion in 2007 sales, employs 13,000 people and expects to return to public ownership within the next six years.

"They can do all this out of the public eye - guys like me aren't sitting there scrutinizing the financial impact of every single settlement," said analyst Jeff Johnson of Robert W. Baird & Co. in Milwaukee. "You can completely focus on your brand and on doing what's right by the patient."

Bausch & Lomb resorted to pushing an older product, ReNu MultiPlus, to try to shore up its battered lens care business. But those sales dropped from $522 million in 2005 to about $450 million in 2008, while Alcon's rose from $297 million to $469 million, said analyst Peter Bye of Jefferies & Co. in New York.

The knock on profits was more acute. With MultiPlus already sold under generic or retailer-chain labels, Alcon's share of branded solutions is

"much higher than Bausch's," Bye said. "When you talk about (lens-care) boxes going out to new patients, it's up in the 60-70 percent range in the U.S."

Alcon's multipurpose formula was untarnished and "that's why they're cleaning up," Bye said, adding that "the stasis at the FDA means this competitive imbalance is continuing."

On the Net:

Bausch & Lomb: http://www.bausch.com

FDA: http://www.fda.gov

Alcon: http://www.alcon.com

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