



Are Injured Contact Lens Wearers Really to Blame For Not Keeping Their Cleaning Solution Clean?



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On May 15, Bausch & Lomb recalled its ReNu with MoistureLoc® contact lens cleaning solution due to an alleged link with a rare type of eye infection. Could this be a classic case of “user error” or have medical advancements actually hindered the efficacy of cleaning products?

Developing ReNu®

In the past, the cleaning and storing of contact lenses consisted of several steps that required using different products, sometimes even heat, for each stage of the cleaning process. During this time, poor hygiene was typically the scapegoat when eye infections would arise. In the 1980s, the contact lens industry developed multipurpose solutions to rid consumers of this time-consuming process. The manufacturers boasted that these new multipurpose solutions, which do not require rubbing or rinsing the lenses, effectively kill bacteria and prevent infection.

Bausch & Lomb, a leader in the contact lens industry, was one of the first to develop a multipurpose solution in response to consumers’ decreasing willingness to spend much time cleaning their lenses. The company’s Web site claimed that ReNu was a “multi-purpose solution for cleaning, rinsing, disinfecting, and storing your soft contact lenses” and that “ReNu multi-purpose solution makes daily lens care easy.”

MoistureLoc contained both a disinfectant (alexidine) and a moisture-retaining component (polyquarternium). Neither the alexidine nor polyquarternium had ever before been used in a contact solution.

Fusarium Keratitis

After receiving a report in February that indicated an unusual number of cases of *Fusarium keratitis* among lens wearers in Singapore, Bausch & Lomb notified the Food and Drug Administration (FDA) of the potential problem. As early as March, the Centers for Disease Control and Prevention (CDC) began receiving reports of corneal infections among contact lens wearers. *Fusarium keratitis* is a serious inflammatory condition of the cornea that can lead to corneal surgery and even blindness. Subsequent to filing a report with the FDA on April 7, Bausch & Lomb halted shipments of ReNu to the United States on April 13. The solution was completely recalled in May 2006.

Following a thorough investigation, the CDC revealed in its Aug. 22 report that from June 1, 2005, through June 30, 2006, 164 patients in 33 states were diagnosed with *Fusarium keratitis*. Of the 164 individuals, 34 percent required corneal transplants. Although several companies manufacture multipurpose solutions, the CDC only found a link between *Fusarium keratitis* and Bausch & Lomb’s ReNu with MoistureLoc,

which was used by more than 2.3 million people. Of the 118 patients providing information to the CDC, 64 percent had used only ReNu with MoistureLoc and 12 percent had used ReNu with MoistureLoc in addition to another Bausch & Lomb product. Federal investigators found no evidence of tampering at Bausch & Lomb's plant. The CDC opined that neither intrinsic nor extrinsic contamination was likely. Instead, the consumers' home environments, coupled with the unique nature of the solution, were determined to be the likely cause of the contamination.

Immediately following the recall, lawsuits were filed on behalf of contact lens wearers suffering from cornea scarring, ulcers and blindness, and the Judicial Panel on Multi-District Litigation created MDL 1785, *In Re: Bausch & Lomb, Inc. Contact Lens Solution Product Liability Litigation*, to be run by Judge David Norton in the U.S. District Court for the District of South Carolina.

Product liability defense attorneys have been quick to publicly blame the consumers themselves — either for sleeping in the contacts, for not rinsing the lenses or for failing to change the solution in the lens case. Because poor hygiene was believed to be a cause of eye infections in the past, it seemed logical that the same could be said in this case. Ironically, consumers have been accused of not keeping their cleaning solution clean enough. Although the multipurpose solutions were designed to make caring for contact lenses easier, it appears it may have had the opposite effect. The CDC report indicates that lenses absorb the disinfectant contained within the solution, which is then absorbed into the eye itself. It is believed that this absorption increases the risk for infection.

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The CDC rejected the theory that poor hygiene alone was the cause of the fungal growth as suboptimal hygiene was present in both the control and test groups. Instead, the CDC concluded that an undetermined interaction among the ingredients of MoistureLoc may have made the solution more susceptible to fungal growth in situations, such as those where lenses were stored in the case for several days at a time. In fact, the CDC indicated that wearers using ReNu MoistureLoc were more than 20 times as likely to develop the infection as non-users.

FDA Regulations

It is not uncommon for contact lens wearers to store their lenses while taking a break from usage. It is also not uncommon for wearers to fail to rinse or rub the lenses prior to wearing them. Unfortunately, the current FDA mandated testing will not prevent solutions susceptible to fungal growth from hitting the U.S. market. To determine if a particular solution will be approved, the FDA injects individual organisms into the sterile contact solution and then analyzes whether the solution successfully eliminates the bacteria. What the test does not determine is the solution's ability to disinfect after the contact lenses have been left in the solution for several days, which occurs frequently with most

contact lens wearers. As such, the laboratory testing does not sufficiently coincide with real life wear.

These multipurpose solutions were developed in response to the undeniable reality that contact lens wearers are not going to consistently exercise proper lens hygiene. Companies are marketing these products as both easy and effective. It is hardly appropriate to blame consumers, who trust that the cleaning products do what is promised, for doing the very thing the manufacturers anticipated — simply storing the lenses. Instead, manufacturers and the FDA need to jointly develop a method to test whether a solution can fight off fungal growth in typical environments found in users' homes. Indeed, this is a case of poor testing, not user error.

