

DRUG & DEVICE
BULLETIN



JULY 20, 2009

Pharmaceutical & Medical Device

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OPINIONS OF PLAINTIFFS' EXPERTS BARRED AS
"JUNK SCIENCE" FROM COORDINATED NEW YORK
PROCEEDINGS IN BAUSCH & LOMB'S CONTACT
LENS SOLUTION LITIGATION

On July 15, 2009, Justice Shirley Werner Kornreich, the New York Supreme Court Justice overseeing the New York consolidated Bausch & Lomb ReNu® with MoistureLoc® product liability litigation, issued a ruling granting Bausch & Lomb's motion to exclude the general causation opinions of plaintiffs' experts as to non-*Fusarium* infections. This ruling excludes the testimony of all of plaintiffs' proposed experts, which results in the disposition of 95% of the remaining 513 cases in New York.

Plaintiffs sought to introduce opinions of well-credentialed experts in the fields of ophthalmology, pharmaceutical microbiology and epidemiology. Following extensive briefing, a joint state and federal court *Frye/Daubert* hearing was conducted for three days, June 3-5, 2009, to assess the reliability of the experts' opinions.

At issue was whether the company's contact lens solution could cause infections other than *Fusarium* keratitis – a rare but dangerous infection that was linked to MoistureLoc® in a CDC-sponsored epidemiology study. Plaintiffs tried to extend the scientific data from that study to argue that MoistureLoc® caused many other corneal infections, including bacterial, viral *Acanthamoeba* and other fungal infections (all aggregated by the court under the term "non-*Fusarium*"). Bausch & Lomb contested these non-*Fusarium* cases because there was no scientific data or literature to support them. Justice Kornreich concluded that the plaintiff's experts' opinions did not meet the *Frye* test, which requires the scientific principle at issue to have gained "general acceptance" in the scientific community.

Justice Kornreich rejected plaintiffs' attempt "to bootstrap their experts' opinions by extrapolating from scientific data... showing an association between ReNu ML and *Fusarium*, *in vitro* studies and general theories that an increase in the microbial load can result in an increased risk of infection." In doing so, she said that "this exercise is more a leap of faith than a scientifically reliable analysis. The end product is the very 'junk science' that the court is required to exclude."

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While Justice Kornreich recognized the experts as qualified, she found their opinions unreliable because they were not based on “a single case report, clinical study, epidemiological study, or published and peer reviewed article.” In fact, one of the experts admitted that his opinion was nothing more than an hypothesis. The court further noted that experts had not conducted any tests using the contact lens solution and had “ignored testing that supports the lack of an association between ReNu ML and non-Fusarium infections.”

The case is *Bausch & Lomb Contact Lens Solution Prod. Liab. Litig.*, No. 766000/2007 (Supreme Court of the State of New York – New York County, Justice Shirley Werner Kornreich, decided July 15, 2009). Shook, Hardy & Bacon attorneys [Marie Woodbury](#), [Eric Anielak](#) and [Harvey Kaplan](#) represented Bausch & Lomb.