

# Avastin Injections Are Reported to Cause Blindness

By ANDREW POLLACK

At least 16 people in two states have gotten severe eye infections, and some have been blinded, from injections of the drug Avastin, according to health authorities and to lawyers representing the patients.

The incidents, in Florida and Tennessee, demonstrate the risks associated with the money-saving practice of injecting Avastin into the eye to treat the wet form of age-related macular degeneration, a common cause of severe vision loss in the elderly.

Avastin, sold by Genentech, is approved to treat cancer, not eye disease. But many retina specialists use Avastin off label because it costs only about \$50 an injection, compared with \$2,000 for Lucentis, another Genentech drug that has the same mode of action and is approved as an eye treatment.

The off-label use of Avastin has saved Medicare and patients hundreds of millions of dollars a year. But dividing a vial of Avastin into numerous tiny doses for injection into the eye introduces the risk of bacterial contamination.

That is apparently what has happened in the cases in Florida and Tennessee.

The Food and Drug Administration issued an alert late Tuesday saying that at least 12 patients in Miami, treated at three clinics, had suffered eye inflammations. While all had impaired eyesight to begin with, some lost all remaining vision in the treated eye, the agency said.

The F.D.A. said all the infections involved a single lot of Avastin and had been traced to a single pharmacy in Hollywood, Fla., that had repackaged the drug for use in the eye.

In Tennessee, four patients received shots contaminated by bacteria, according to a statement provided to The Tennessee newspaper by the Tennessee Valley Healthcare System, part of the United States Department of Veterans Affairs. The Avastin doses were prepared in the pharmacy of the V.A. hospital in Nashville.

One of the patients, Lloyd Mason Sylvis, 77, suffered an eye infection of *Streptococcus viridans* that spread to his brain, according to a claim for \$4 million in

damages that his family has filed with the V.A. Mr. Sylvis received the injection on March 29, but his family went public with its complaint only recently.

"He's permanently blinded, permanently brain damaged," said his son, Lloyd Mason Sylvis Jr. "He came in walking and talking, and he remains in a vegeta-

**To save money, using a drug not approved for eye treatments.**

tive state as we speak."

The Florida patients received their injections in early July and were apparently infected with *Streptococcus oralis*.

Last week, the F.D.A. announced a recall of syringes containing Avastin from Chroniscript, a part of Walgreens pharmacy in Miami.

Jim Cohn, a spokesman for Walgreens, said the syringes had been supplied to "a limited num-

ber of physician offices in Miami-Dade and Broward counties."

Antonio Salgado, 79, of Miami got an injection of Avastin into his right eye on July 8. While there were no problems with the seven previous injections of the drug, this one caused tremendous pain and caused a white film to grow over his eye, according to his lawyer, Philip A. Gold.

"There was a point in time where his eye was completely white, without coloration, no pupil, no nothing," Mr. Gold said.

Mr. Salgado has filed a lawsuit in state court in Miami-Dade County. Among those sued was Infupharma, a compounding pharmacy that was said to have divided the Avastin into tiny doses. It is not clear what the relationship was between Infupharma and Chroniscript.

Another lawyer, Gary Alan Friedman, said he represented six patients, four of whom have already filed suit.

"They all have either significantly lost vision or have been blinded completely by the contamination," Mr. Friedman said.

Infupharma said it would not discuss details because of the



GENENTECH, VIA ASSOCIATED PRESS

The cancer drug Avastin has been used by some doctors to treat macular degeneration, an off-label application.

ny said Tuesday.

While the company is being sued, it could benefit overall if the incidents discourage use of Avastin in favor of the far more lucrative Lucentis.

Eye doctors who use Avastin have played down concerns about the risk of bacterial contamination.

Dr. Philip Rosenfeld, a retina specialist at the University of Miami who pioneered the use of Avastin for macular degeneration, said the recent incidents apparently stemmed from careless procedures by pharmacies and should not discourage the use of the drug.

"It took six years for something like this to happen," he said, noting that there have been more than two million injections of Avastin into eyes in the United States alone since the practice began in 2005.

A clinical trial sponsored by the National Eye Institute found that Avastin and Lucentis were equivalent in preserving or improving vision after one year.

continuing investigation and litigation.

Genentech said it would not comment on the litigation, but said that it had always cautioned against use of Avastin in the eye.

"Avastin is not manufactured or approved and to date has not been proven safe for use in the eye," a spokesman for the compa-