REDACTED

In the

United States Court of Appeals

For the Seventh Circuit

No. 94-1998

PEGGY GROCA, formerly known as Peggy Poole, individually and as administrator of the Estate of Stephen Poole, deceased, HEATHER REKAH POOLE and KELLY JEAN POOLE, minors, by their mother, PEGGY GROCA, formerly known as Peggy Poole, as next friend,

Plaintiffs-Appellants,

v.

ALPHA THERAPEUTIC CORPORATION, a foreign corporation, MILES LABORATORIES, INC., a foreign corporation doing business as CUTTER LABORATORIES, INC., a foreign corporation, ARMOUR PHARMACEUTICAL COMPANY, a division of Rorer, Inc., a foreign corporation, and BAXTER TRAVENOL LABORATORIES, INC., doing business as HYLAND THERAPEUTICS DIVISION,

Defendants-Appellees.

Appeal from the United States District Court
for the Northern District of Illinois, Eastern Division.
No. 86 C 1825—John F. Grady, *Judge.*

ARGUED JANUARY 17, 1996—DECIDED MARCH 28, 1995

Before BAUER, CUDAHY and KANNE, *Circuit Judges.*

BAUER, *Circuit Judge.* During closing argument of a seven-week jury trial, the defendants' lead counsel as-

sorted that the plaintiffs' attorney "selected the defendants. He could have sued the FDA." Rather than sustaining the plaintiffs' immediate objection, the district court overruled it, instructing the jury that "[g]overnment entities are sued all the time." Because these improper remarks and the district court's erroneous instruction substantially prejudiced the plaintiffs, we reverse the jury's verdict in favor of the defendants and remand for a new trial.

I.

Hemophilia is a congenital disorder of blood clotting. Stephen Poole was a hemophiliac who had a severe deficiency of Factor VIII, a protein necessary for clotting, in his plasma, the liquid portion of blood. From 1972 until his death in 1987, Poole used a commercially prepared product called Factor VIII concentrate prescribed by his physician to treat bleeding episodes. Factor VIII concentrate is a highly condensed, freeze-dried form of cryoprecipitate, which is a portion of plasma rich in the Factor VIII protein. Cryoprecipitate is produced by spinning the plasma of thousands of donors in a centrifuge. Factor VIII concentrate is administered through intravenous injection after being mixed with sterile water.

Manufacturers of Factor VIII concentrate, or "fractionators," are regulated by the Food and Drug Administration ("FDA"). Each fractionator is licensed by the FDA to process and distribute Factor VIII concentrate. The FDA must approve the release of each lot of Factor VIII concentrate before the lot may be distributed for use. The FDA must further approve any change in a fractionator's manufacturing process or in the labeling of the product. The FDA also regulates the plasma centers from which each fractionator obtains plasma.

From 1978 until late 1984, Poole used Factor VIII concentrate manufactured exclusively by the defendant Alpha Therapeutic Corporation ("Alpha"). Poole began using Factor VIII concentrate manufactured by the defendant

Cutter Laboratories, Inc. ("Cutter") in September or October 1984. Poole had knee surgery in Chicago in January 1985. During his hospitalization for the surgery, Poole received Factor VIII concentrate manufactured by the defendant Baxter Travenol Laboratories, Inc. ("Baxter"). Poole also testified in a deposition that he received one vial of Factor VIII concentrate manufactured by the defendant Armour Pharmaceutical Company ("Armour") during his hospitalization, although this fact was disputed by Armour at trial.

Poole was diagnosed with Acquired Immune Deficiency Syndrome ("AIDS") in March 1986 after his physician discovered that Poole had an opportunistic infection resulting from a weakened immune system, or an AIDS-related illness. Poole then tested positive for the presence of antibodies to the Human Immunodeficiency Virus ("HIV"), the virus which causes AIDS. Poole developed several other opportunistic infections after this diagnosis and died of an AIDS-related illness on July 10, 1987, at the age of thirty-two.

Peggy Gruca, Poole's widow, filed suit in the district court on behalf of herself, Poole's estate, and their two minor children, Heather Renae Poole and Kelly Jean Poole, against the defendants, all manufacturers of Factor VIII concentrate possibly used by Poole during his lifetime. Jurisdiction was premised upon diversity of citizenship. The complaint sought damages for (1) Poole's pain and suffering from the time Poole was diagnosed with AIDS until his death; (2) Poole's wrongful death; (3) Poole's funeral and burial expenses under the Illinois Family Expense Act, 750 ILCS 65/15; and (4) Gruca's emotional distress resulting from her risk of contracting HIV during her marriage to Poole.

The complaint alleged that the defendants negligently (1) solicited plasma from paid donors who had a high risk of transmitting hepatitis, AIDS, and other viral diseases; (2) failed to warn users of the risk of contracting hepatitis, AIDS, and other viral diseases through Factor VIII concentrate; (3) failed to treat Factor VIII concentrate t

reduce the presence of viruses in the product; (4) marketed untreated and heat-treated Factor VIII concentrate made from the plasma of paid donors who had a high risk of transmitting HIV, despite industry-wide knowledge of the risk; and (5) failed to determine whether any lots of Factor VIII concentrate contained plasma from a paid donor whose blood was later rejected at a plasma center because of the donor's risk of transmitting HIV.

The complaint sought damages under two theories of liability, negligence[1] and alternative liability.[2] Although these counts were treated separately in the complaint, the underlying tortious conduct of the plaintiffs' alternative liability claims was negligence. At the close of all the evidence, the district court, with the plaintiffs' consent, directed a verdict in favor of the defendants with respect to the plaintiffs' negligence claims. The district court also directed a verdict in favor of the defendants on the plaintiffs' claim that Poole's death was hastened by additional exposure to HIV after his initial infection. The jury returned a verdict in favor of all defendants on the plaintiffs' remaining alternative liability claims. In response to a special verdict form submitted by the district court, the

[1] To properly state a cause of action for negligence under Illinois law, a plaintiff must establish that the defendant owed a duty of care, a breach of that duty, and an injury proximately caused by the breach. *Cunis v. Village of Niles*, 608 N.E.2d 862, 865 (Ill. 1993).

[2] Under the doctrine of alternative liability,

> [w]here the conduct of two or more actors is tortious, and it is proved that harm has been caused to the plaintiff by only one of them, but there is uncertainty as to which one has caused it, the burden is upon each such actor to prove that he has not caused the harm.

Restatement (Second) of Torts § 433B(3) (1965); *see also Summers v. Tice*, 199 P.2d 1 (Cal. 1948). The district court, in granting the plaintiffs leave to amend an earlier complaint, ruled that the Supreme Court of Illinois would allow the plaintiffs to proceed under this doctrine. 826 F. Supp. 251, 255 (N.D. Ill. 1993).

jury found that none of the defendants had been negligent in any of the ways charged by the plaintiffs. The plaintiffs filed a motion for a new trial on several grounds, which the district court denied.

II.

The parties agree that Illinois substantive law governs in this diversity case. *See Heller Int'l Corp. v. Sharp*, 974 F.2d 850, 856 (7th Cir. 1992) (federal courts sitting in diversity apply the substantive law of the state in which the suit is filed, including the state's choice of law rules). Although the plaintiffs assert several grounds of error, our disposition of this appeal requires us to consider only two issues.

The plaintiffs challenge the district court's directed verdict in favor of the defendants on their wrongful death claim brought under the theory of "antigenic stimulation." A person who is infected with HIV at first suffers no symptoms of any AIDS-related illness while the virus is replicating itself in sequestered sites within the body. The plaintiffs presented expert scientific testimony at trial that, under the theory of antigenic stimulation, an infected person's exposure to additional HIV, other viruses, or foreign proteins shortens this asymptomatic period, provokes increased replication of HIV, and leads to a quicker death from an AIDS-related illness. The plaintiffs assert that, under this theory, Poole's death was hastened through his use of Factor VIII concentrate manufactured by the defendants after his initial HIV infection.

The district court directed a verdict on this claim, instructing the jury as follows:

> One of the issues raised by the testimony in this case is whether the disease process in a person infected with the HIV virus can be accelerated or aggravated by additional exposure to the same or a different strain of the virus. Whatever the merits of this dispute as a scientific matter, I instruct you that there is insufficient evidence in this case that Steph

Poole's disease process was, in fact, accelerated or aggravated by multiple exposures.

The evidence is undisputed that he was infected with the HIV virus, but there is insufficient evidence of any reinfection. Therefore you should not find any defendant liable on the theory of aggravation, acceleration, or reinfection.

Tr. at 5050-51. As a result of this directed verdict, the only issue before the jury on the plaintiffs' wrongful death claim was whether any defendant was liable for Poole's initial HIV infection under the alternative liability doctrine.

Illinois law controls our review of the district court's directed verdict. *Davis v. FMC Corp., Food Processing Mach. Div.*, 771 F.2d 224, 229 (7th Cir. 1985). "Under Illinois law, a directed verdict should be granted only 'when all of the evidence, viewed in its light most favorable to the nonmoving party, so overwhelmingly favors the movant that no contrary verdict based on the evidence could ever stand.'" *Estate of Carey by Carey v. Hy-Tower Mfg., Inc.*, 929 F.2d 1229, 1234 (7th Cir. 1991) (citation omitted); *see also Pedrick v. Peoria & E. R.R. Co.*, 239 N.E.2d 504, 513-14 (Ill. 1967). This standard "does not require a complete absence of evidence supporting the side against whom the verdict is directed; however, there must be a substantial factual dispute before a jury trial is required." *Cincinnati Ins. Co. v. City of Taylorville*, 818 F.2d 1345, 1348 (7th Cir. 1987). We conclude that the directed verdict was erroneous under this standard and therefore reverse.[6]

[6] The defendants assert that the plaintiffs have waived any challenge to the directed verdict on their antigenic stimulation claim by failing to object to the district court's instruction. Waiver is the intentional relinquishment of a known right. *Heller*, 974 F.2d at 962. Our review of the transcript of the jury instructions conference reveals that the defendants' position is incorrect as a matter of law and is simply not worthy of extended discussion.

The plaintiffs presented evidence that only a very small fraction, probably less than two percent, of persons infected with HIV develop an AIDS-related illness within one year, and the approximate average time between HIV infection and development of an AIDS-related illness is between seven and ten years. A person in this stage of AIDS has a reduced number of red blood cells and certain white blood cells called lymphocytes. When Poole was hospitalized for knee surgery in January 1985, his red and white blood cell counts were normal. Poole was not tested for the presence of antibodies to HIV during this hospitalization because he had no symptoms of any AIDS-related illness. Yet fourteen months later, in March 1986, Poole had an opportunistic infection. A lymphocyte count performed on Poole in April 1986 was extremely low. The plaintiffs also presented evidence that the Factor VIII concentrate used by Poole from January 1985 until his death, which was manufactured by Baxter, Cutter, and Armour, contained HIV and other viruses.

None of the evidence at trial established the date of Poole's initial HIV infection. Poole could have been infected with HIV several years prior to March 1986 and developed AIDS in a normal manner. The jury, however could have found from the circumstantial evidence presented by the plaintiffs that Poole's sudden decline in health after January 1985 was caused by exposure to additional viruses through his use of Factor VIII concentrate. The district court's directed verdict resolved this factual dispute and therefore was improper.

Perhaps anticipating our conclusion that the directed verdict was erroneous, the defendants assert that the district court should have excluded the plaintiffs' expert scientific testimony concerning the antigenic stimulation theory under *Daubert v. Merrell Dow Pharmaceutical Inc.*, 113 S. Ct. 2786 (1993). In *Daubert*, the Supreme Court established the standard for the admissibility of expert scientific testimony under Rule 702 of the Feder

Rules of Evidence.[4] The Court concluded that the test set forth in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), which held "inadmissible expert testimony based on a scientific technique unless that technique is generally accepted as reliable in the relevant scientific community," *Porter v. Whitehall Labs., Inc.*, 9 F.3d 607, 612-13 n.8 (7th Cir. 1993), did not survive the enactment of the Federal Rules of Evidence. *Daubert*, 113 S. Ct. at 2794.

Under *Daubert*, the district court must conduct a two-part analysis. First, the district court must "determine whether the expert's testimony pertains to scientific knowledge. This task requires that the district court consider whether the testimony has been subjected to the scientific method; it must rule out 'subjective belief or unsupported speculation.'" *Porter*, 9 F.3d at 614 (quoting *Daubert*, 113 S. Ct. at 2795). The Court in *Daubert* set forth a nonexclusive list of factors which the district court should consider when making this determination: (1) whether the theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error; and (4) the general acceptance of the theory in the scientific community. *Daubert*, 113 S. Ct. at 2796-97. Under the second prong of the *Daubert* test, the district court must "determine whether the evidence or testimony assists the trier of fact in understanding the evidence or in determining a fact in issue. That is, the suggested scientific testimony must 'fit' the issue to which the expert is testifying." *Porter*, 9 F.3d at 616. *See also Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995); *O'Conner v. Commonwealth Edison Co.*, 13 F.3d 1090, 1106 (7th Cir.), *cert. denied*, 114 S. Ct. 2711 (1994). The

[4] Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

defendants contend that the plaintiffs' expert scientific testimony does not meet the first prong of the *Daubert* test.

Although the defendants' challenge to the admissibility of the plaintiffs' scientific testimony concerning antigenic stimulation under *Daubert* was raised below, the district court expressly declined to rule on it and instead directed a verdict on the merits of the plaintiffs' claim. This approach was improper. When "[f]aced with a proffer of expert scientific testimony," the district court must determine at the outset, pursuant to Federal Rule of Evidence 104(a),[5] whether the reasoning or methodology underlying the testimony satisfies the *Daubert* test. *Daubert*, 113 S. Ct. at 2796. Under *Daubert*, the district court is to perform a gatekeeping function with respect to the admission of scientific evidence. *Id.* at 2798; *id.* at 2800 (Rehnquist, C.J., concurring in part and dissenting in part) ("I do not doubt that Rule 702 confides to the judge some gatekeeping responsibility in deciding questions of the admissibility of proffered expert testimony."). The district court abdicated its responsibilities under Rule 104(a) by failing to conduct a preliminary assessment of the admissibility of the plaintiffs' expert testimony concerning antigenic stimulation before permitting the plaintiffs' experts to testify. We therefore remand the plaintiffs' antigenic stimulation claim to the district court with directions to evaluate this evidence under the *Daubert* framework.

Our conclusion that the district court's directed verdict on the plaintiffs' antigenic stimulation claim was erroneous should not be read as an implied endorsement of the theo

[5] Rule 104(a) provides:

> Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.

under *Daubert*. We merely hold that, assuming the admissibility of the plaintiffs' expert testimony under Rule 702, the plaintiffs introduced sufficient evidence of antigenic stimulation to present their claim to the jury. We leave to the district court the task of determining the admissibility of the plaintiffs' expert testimony in the first instance, as *Daubert* contemplates.

III.

At the close of all the evidence, the district court granted each defendant ten minutes of surrebuttal argument limited solely to the issue of proximate causation, on which the defendants bore the burden of proof under the alternative liability doctrine. During Alpha's surrebuttal argument, its counsel argued as follows:

> MR. GREEN [counsel for Alpha]: This case is merely one between these defendants. Mr. Ring selected the defendants. He could have sued the FDA. He could have sued any one of these defendants.
>
> MR. RING [counsel for the plaintiffs][a]: Judge, I object to that, who I could have sued. The FDA is not one that he could have sued. It is a government entity.
>
> THE COURT: Well, I don't know that you can't sue a government entity. Government entities are sued all the time, but I will overrule the objection.
>
> MR. GREEN: The point here is, ladies and gentlemen, the array of defendants that you see are solely the selection of Mr. Ring.

Tr. at 5024-25. The plaintiffs contend that these remarks and the district court's instruction deprived them of a fair trial. We agree.

[a] The plaintiffs were represented by attorney Leonard M. Ring in the district court, who died during the pendency of this appeal.

Federal law governs our review of the district court's denial of the plaintiffs' motion for a new trial. *Davis*, 771 F.2d at 282. We review the district court's denial of the plaintiffs' motion for an abuse of discretion. *Canada Dry Corp. v. Nehi Beverage Co., Inc. of Indianapolis*, 723 F.2d 512, 527 (7th Cir. 1983). Improper remarks during a closing argument warrant reversal of the judgment only if the remarks " 'influenced the jury in such a way that substantial prejudice resulted to' the opposing party."[7] *Arcor, Inc. v. Textron, Inc.*, 900 F.2d 710, 712 (7th Cir. 1990) (quoting *Fanello v. Smith*, 802 F.2d 266, 268 (7th Cir. 1986)). Statements made during closing argument must be plainly unwarranted and clearly injurious to constitute reversible error. *Lockley v. Deere & Co.*, 933 F.2d 1378, 1388 (8th Cir. 1991).

An incorrect jury instruction is reversible error if, " 'considering all the instructions, the evidence and the arguments that the jury heard, it appears that the jury was misled or did not have a sufficient understanding of the issues and its duty to determine them.' " *Haller*, 874 F.2d at 856 (quoting *Simmons, Inc. v. Pinkerton's, Inc.*, 762 F.2d 591, 597 (7th Cir. 1985)). Reversal of the judgment " 'is inappropriate unless the jury's understanding of the issues was seriously affected to the prejudice of the complaining party.' " *Id.* (quoting *Wilk v. American Medical Ass'n*, 719 F.2d 207, 218-19 (7th Cir. 1983), *cert. denied*, 467 U.S. 1210 (1984)).

The defendants at trial presented evidence and argued that their ability to improve the safety of Factor VIII concentrate was limited by the FDA, which was slow to react to the onset of AIDS in the early 1980s. For example, the FDA did not require plasma collection centers

[7] The district court, in denying the plaintiffs' motion for a new trial, acknowledged that Alpha's remarks were improper but concluded that no prejudice resulted to the plaintiffs. We also review this finding for an abuse of discretion. *Canada Dry*, 723 F.2d at 527.

o screen donors who had a high risk of transmitting HIV until March 1988. The FDA refused requests to perform surrogate tests on Factor VIII concentrate. A surrogate est is a test for the presence of a "marker" that may have been associated with the presence of HIV. The FDA's position was that there was no data demonstrating that surrogate tests would prevent the spread of AIDS. The FDA also did not approve any warning of the risk of AIDS on the labels of Factor VIII concentrate until December 1988.

The district court's instruction defining "reasonable care" permitted the jury to consider the FDA's regulatory conduct in determining the defendants' liability. This instruction stated as follows:

> When I use the words "reasonable care," I mean the care that would be used by reasonably careful collectors of blood or plasma and processors of Factor VIII concentrate under circumstances similar to those shown by the evidence at and prior to the time Stephen Poole contracted the HIV virus.
>
> The law does not say how reasonably careful collectors of blood or plasma and processors of Factor VIII concentrate would act under those circumstances. That is for you to decide.
>
> In determining whether any defendant exercised reasonable care under the circumstances, you may consider the following:
>
> * * *
>
> The Food and Drug Administration's regulations governing licensing, manufacturing methods, and labeling.

Tr. at 6047. During their closing arguments, each of the defendants emphasized the FDA's regulatory role. For example, Alpha's counsel argued that "you can't just dream up an idea and put it to the FDA who regulates this industry on behalf of you and me and the hemophiliacs and everyone else and get their approval." Tr. at 4858.

Alpha's surrebuttal argument that the plaintiffs' counsel "selected the defendants" and "could have sued the FDA," was improper, unwarranted, and a misstatement of law. The only question before the jury was whether any of the defendants was negligent in any of the ways charged by the plaintiffs. The plaintiffs did not allege, and did not attempt to prove, that the defendants' negligence related to the conduct of the FDA prior to the time Poole was infected with HIV. Whether the FDA was negligent in its regulation of fractionators was not an issue before the jury. By directing the jury's attention to the FDA's regulatory role and away from the defendants' own conduct, Alpha suggested that the FDA's actions absolved the defendants from liability for negligence. Such an argument is impermissible. *Davis*, 771 F.2d at 233. Nothing in the plaintiffs' closing argument invited these improper comments. The district court erred by overruling the plaintiffs' objection to these remarks.

Alpha's statement that the plaintiffs "could have sued the FDA" became a statement of the district court when the plaintiffs' objection was overruled. The district court then compounded its error by instructing the jury that "[g]overnment entities are sued all the time." Both statements were misstatements of law. Although negligence claims are actionable under the Federal Tort Claims Act ("FTCA"), 28 U.S.C. §§ 1346(b), 2671 *et seq.*, the FDA is immune from suit under the FTCA for discretionary administrative functions. 28 U.S.C. § 2680(a);[9] *see United*

[9] Section 2680(a) provides:

> The provisions of this chapter and section 1346(b) of this title shall not apply to-
>
> (a) Any claim based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.

States v. Varig Airlines, 467 U.S. 797, 813-14 (1984); *cf. Heckler v. Chaney*, 470 U.S. 821, 837-38 (1985) (holding that the FDA's decision not to take enforcement actions to prevent violations of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, is not subject to judicial review under the Administrative Procedure Act, 5 U.S.C. § 500 *et seq.*).

Alpha's improper remarks and the district court's erroneous instruction substantially prejudiced the plaintiffs and therefore compel a new trial. The jury was instructed that it could consider the FDA's regulations in determining whether any defendant exercised reasonable care. Alpha's statement that the plaintiffs "could have sued the FDA" implied that the FDA was the only party to blame for Poole's HIV infection. This misstatement of law was adopted by the district court, which overruled the plaintiffs' objection and instructed that "[g]overnment entities are sued all the time." Alpha then repeated this point, asserting that "the array of defendants that you see are solely the selection of Mr. Ring." Since these statements were made during surrebuttal argument, the plaintiffs had no opportunity to reply. The jury thus was left with the misimpression that the FDA's failure to respond to the outbreak of AIDS more quickly negated the defendants' liability. This mistaken view of the law could have directly resulted in the jury's verdict in favor of the defendants.

In its order denying the plaintiffs' motion for a new trial, the district court wrote that it "was impressed with the high quality of this jury. They were attentive and took extensive notes and listened with obvious amusement to the banter that occurred from time to time during the long trial." If the district court's observations are accurate, then neither Alpha's remarks nor the district court's instruction escaped the jury's attention. The resulting prejudice to the plaintiffs is clear and substantial. The district court abused its discretion in denying the plaintiffs' motion for a new trial.

The judgment of the district court is reversed, and t
case is remanded for further proceedings consistent wi
this opinion. The case will be assigned pursuant to Ci
cuit Rule 36.

REVERSED AND REMAND

A true Copy:
Teste:

Clerk of the United States Court of Appeals for the Seventh Circuit

USCA AO?XXXC42-001—Midwest Law Printing Co., Inc., Chicago—9