In the
United States Court of Appeals
For the Seventh Circuit

No. 06-2820

MICKEY ERVIN,

Plaintiff-Appellant,

v.

JOHNSON & JOHNSON, INCORPORATED
and CENTOCOR, INCORPORATED,

Defendants-Appellees.

Appeal from the United States District Court
for the Southern District of Indiana, Terre Haute Division.
No. 04 C 205—**John Daniel Tinder**, *Judge.*

ARGUED JANUARY 3, 2007—DECIDED JULY 9, 2007

Before, BAUER, KANNE, and EVANS *Circuit Judges.*[1]

BAUER, *Circuit Judge.* Mickey Ervin brought a products liability action against Johnson & Johnson, Inc. and Centocor, Inc., claiming that his prescription medication Remicade caused a blood clot that required the partial amputation of his leg. Defendants moved *in limine* to exclude testimony from plaintiff's expert and filed a motion for summary judgment. The district court granted both motions. Ervin now appeals these rulings. We affirm.

[1] Judge Rovner was a member of the original panel. She recused herself after oral argument and has not participated in the decision of the appeal. Judge Bauer took her place.

I. Background

Ervin suffers from Crohn's disease, autoimmune hypothyroidism, and diabetes. His doctors tried various medications to manage his diseases, without success. In January 2001, Dr. Lee McKinley, Ervin's internist and critical care specialist, suggested treating Ervin with Remicade. Remicade is a prescription drug approved by the FDA for treatment of Crohn's disease and is manufactured by Centor, a wholly-owned subsidiary of Johnson & Johnson. Ervin's gastroenterologist discussed with Ervin the option of treating him with Remicade. Ervin agreed to the treatment and underwent his first infusion of Remicade on March 21, 2001 and his second infusion on April 25, 2001.

On April 30, 2001, Ervin complained to Dr. McKinley of pain in his hands and legs. The next day, Ervin was hospitalized and diagnosed with arterial thrombosis, which are blood clots located in the artery of his left leg. Dr. Laurie Morrison, a vascular surgeon, performed three thrombectomies, attempting to remove the clots from the arteries of his left lower leg. These efforts failed, and Ervin underwent a below-the-knee amputation.

Lab reports taken from his hospitalization in May 2001 indicated that Ervin had a low Protein S activity level of 61%. Protein S is a naturally-occurring anticoagulant, which is a substance that prevents clotting. Low Protein S indicates a higher tendency to clot. Ervin also had an elevated platelet count of 674,000, which also increases the risk of blood clots.

On the issue of causation, Ervin relied on a single expert: Dr. Lee McKinley. At his deposition, Dr. McKinley opined that "to a reasonable degree of medical certainty . . . the use of the Remicade was the major contributing factor to Ervin's thrombotic arterial occlusion and subsequent below knee amputation." In reaching this conclu-

sion, Dr. McKinley relied on the process of differential diagnosis. Differential diagnosis generally provides a framework in which all reasonable hypotheses are "ruled in" as possible causes of a medical problem and some of these possible causes are then "ruled out" to the extent scientific evidence makes it appropriate to do so. The goal is to identify the last remaining, or most probable, "ruled in" cause of a medical problem.

Dr. McKinley "ruled in" Remicade as a possible cause of Ervin's arterial thrombosis. In support of this opinion, Dr. McKinley relied on the temporal proximity between the drug infusion and the development of the clot and an Internet Google search that revealed one case report of an arterial clot following Remicade infusion. He also relied on a handful of "line entries" from FDA printouts. The line entries contained basic information that omitted patient histories, descriptions of treatment, and analysis. Dr. McKinley admitted that the line entries do not account for preexisting diseases or co-morbidities that could have causes the patients' problems. He did not rely on any study, textbook, medical article, or paper indicating that Remicade is associated with an increased risk of thrombosis.

Dr. McKinley testified that he did not "rule in" Crohn's disease as a possible cause because he was not aware of the association between Crohn's disease and arterial thrombosis. He believed that Crohn's disease predisposes patients to venous thrombosis but not to arterial thrombosis. When Dr. McKinely was shown evidence demonstrating the association between Crohn's disease and arterial thrombosis, he testified that he wished he had known about this association earlier and that this evidence required him to "reinterpret this case in a completely different way."

Dr. McKinley testified that he did not "rule in" Ervin's elevated platelet count or his diabetes as a possible cause

of his thrombosis, even though both of these conditions are associated with an increased risk of clotting. Dr. McKinley even acknowledged that Ervin's prior episodes of diabetic ketoacidosis are associated with an increased risk of clotting.

While acknowledging that a Protein S deficiency can cause arterial clotting, Dr. McKinley testified that he ruled it out as a possible cause of the thrombosis because Ervin's Protein S profile was "normal." When he was shown May 2001 lab reports that indicated that Ervin's Protein S profile was abnormally low, he asserted that it was not "clinically significant." When he was shown an August 2002 report indicating that Ervin's Protein S level was abnormally low in a "clinically relevant" way, he changed his opinion and testified that he could not "rule out" the underlying Protein S deficiency as a possible cause of Ervin's thrombosis.

Dr. McKinley's initial opinion on causation changed during his deposition. He admitted that he "didn't know if [Remicade] caused [the thrombosis] . . . I didn't know. I still don't know." Following his deposition, Dr. McKinley executed an affidavit stating that he reviewed additional materials and that they "seem to further support his opinion" that Remicade was "one of the substantial factors in contributing to Mr. Ervin's thrombotic arterial occlusion and subsequent below the knee amputation."

The district court found the expert's opinion unreliable and dismissed the case. Ervin filed this timely appeal.

II. Discussion

We first review the district court's implementation of the *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993), framework *de novo*. *United States v. Hall*, 165 F.3d 1095, 1101 (7th Cir. 1999).

The first step is satisfied here because, in accordance with the *Daubert* framework, the district court identified the relevant analysis and focused its inquiry on whether Dr. McKinley's testimony was reliable. *Durkin v. Equifax Check Servs.*, 406 F.3d 410, 420 (7th Cir. 2005) (citing *Ammons v. Aramark Unif. Servs.*, 368 F.3d 809, 816 (7th Cir. 2004)).

Having determined that the district court properly applied *Daubert*, we next review the district court's decision to bar an expert for an abuse of discretion. *United States v. Young*, 316 F.3d 649, 656 (7th Cir. 2002). District court judges "enjoy wide latitude and discretion when determining whether to admit expert testimony." *Wintz by & Through Wintz v. Northrop Corp.*, 110 F.3d 508, 512 (7th Cir. 1997).

The admissibility of expert testimony is governed by Federal Rule of Evidence 702 and *Daubert*. Under this framework, courts determine whether the expert testimony is both relevant and reliable. It is a three-step analysis: the witness must be qualified "as an expert by knowledge, skill, experience, training, or education," Fed. R. Evid. 702; the expert's reasoning or methodology underlying the testimony must be scientifically reliable, *Daubert*, 509 U.S. at 592-93; and the testimony must assist the trier of fact to understand the evidence or to determine a fact in issue. Fed. R. Evid. 702. In determining reliability, *Daubert* also sets forth the following non-exhaustive list of guideposts: (1) whether the scientific theory can be or has been tested; (2) whether the theory has been subjected to peer review and publication; (3) whether the theory has been generally accepted in the scientific community. *Daubert*, 509 U.S. at 593-94. The district court found that Dr. McKinley was qualified to provide an expert opinion but his methodology was unreliable. Specifically, the district court found that Dr. McKinley's differential diagnosis was tainted by "critical flaws"

leaving "his opinions unreliable under the standards set forth in Rule 702 and *Daubert*." We agree.

A differential diagnosis satisfies a *Daubert* analysis if the expert uses reliable methods. Under *Daubert*, expert opinions employing differential diagnosis must be based on scientifically valid decisions as to which potential causes should be "ruled in" and "ruled out." *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005). Determining the reliability of an expert's differential diagnosis is a case-by-case determination.

We agree with the district court that Dr. McKinley had no reliable basis for his expert opinion. He could not point to any epidemiological data supporting his opinion, and he was not able to articulate any scientifically physiological explanation as to how Remicade would cause arterial thrombosis. The mere existence of a temporal relationship between taking a medication and the onset of symptoms does not show a sufficient causal relationship. The district court did not abuse its discretion in finding that Dr. McKinley's testimony was unreliable. In the absence of any other expert evidence supporting Ervin's causation theory, the district court properly granted summary judgment.

III. Conclusion

For the foregoing reasons, we AFFIRM the district court.

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Teste:

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