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IN THE DISTRICT COURT OF APPEAL

OF FLORIDA

THIRD DISTRICT

JANUARY TERM, A.D. 2002

HECTOR CONRADO CERNA,	**	
Appellant,	**	CASE NO. 3D00-2126
vs.	**	
SOUTH FLORIDA BIOAVAILABILITY CLINIC, INC., a Florida corporation, PFIZER, INC., a foreign corporation, STUART HARRIS, M.D., and IRWIN S. MORSE, M.D.,	**	
	**	LOWER TRIBUNAL CASE NO. 96-22084
Appellees.	**	

Opinion filed January 30, 2002.

An appeal from the Circuit Court of Dade County, Paul Siegel, Judge.

Hoffman & Hoffman and John Hoffman and Laetitia C. Bona; Lars O. Bodnieks, for appellant.

Hunton & Williams and Marty Steinberg, Thomas R. Julin and Eduardo W. Gonzalez, for appellees.

Before JORGENSON, GODERICH, and FLETCHER, JJ.

FLETCHER, Judge.

Hector Conrado Cerna has appealed an order which excludes his expert witness from testifying and grants final summary

judgment for the appellees. We affirm the exclusion and the judgment.

Cerna alleged that he became legally blind as a result of his ingestion of two pharmaceuticals, erythromycin and cetirizine, while participating in a 1992 Pfizer-sponsored study. In 1996, Cerna initiated this product liability and negligence action in which the sole basis for his theory of causation is predicated upon the opinion of ophthalmologist Dr. Harry Hamburger, whose testimony the defendants moved to exclude.

Cerna claims that his blindness was the result of the onset of a specific hereditary disease, Leber's hereditary optic neuropathy [Leber's]. Dr. Hamburger's opinion is that the onset of Leber's in Cerna was caused by Cerna's ingestion of erythromycin and cetirizine. To reach this opinion, Dr. Hamburger first focused on the temporal proximity between Cerna's ingestion of the pharmaceutical drugs and the onset of Cerna's blindness. That is, Dr. Hamburger opined that since Cerna's alleged blindness manifested itself after he ingested the drugs then the drugs must have caused the blindness. Second, Dr. Hamburger relied on (1) a number of scientific articles linking the onset of Leber's to environmental toxins; and (2) extrapolation from two separate and distinct articles

dealing with in vitro experiments using high doses of erythromycin under altered pH conditions. From these he developed his opinion as to the effect of the lower doses of erythromycin given to Cerna, with no evidence of an altered pH level.

Dr. Hamburger admitted, however, that there exist no epidemiological studies linking either erythromycin or cetirizine to Leber's or any other optic nerve problem; that he has never had peer reviewed articles published regarding erythromycin or the onset of Leber's; that he formulated his opinion solely as a result of this litigation; that he did not know at what dosage erythromycin becomes toxic; that he did not determine the effect a normal dosage would have on a human being; and that he did not rule out other potential causes of Cerna's alleged injury. Additionally, Dr. Hamburger (who is not a pharmacologist) admitted that he has done no testing or experimentation as to the onset or causes of Leber's, has never before this case opined on Leber's or the causes of Leber's, and did not diagnose the onset of Leber's in Cerna. His prior experience with Leber's consisted largely of seeing a few Leber's patients years ago while in medical school. In none of those cases did Dr. Hamburger independently diagnose the onset of Leber's. After finishing his medical fellowship in 1986, he

may have seen perhaps two or three additional patients with Leber's. In none of these cases did he diagnose the cause of the onset of Leber's.

Dr. Hamburger could point to no scientific evidence relating cetirizine to Cerna's condition. The only two scientific articles Dr. Hamburger obtained involving erythromycin dealt with in vitro experiments, that is, petri dish experiments on cells. The articles dealt with high dosages of erythromycin under altered pH (acid/base) conditions under which (these articles implied) erythromycin affected the mitochondria. Because, Dr. Hamburger stated, other medical articles associated the onset of Leber's with a mitochondrial problem, he concluded that Cerna's ingestion of erythromycin caused the onset of Leber's.

In short, Dr. Hamburger's methodology consisted of an extrapolation from (1) the temporal relationship between the ingestion of the drugs at issue and the alleged onset of Leber's; (2) the articles discussing environmental toxins which may cause the onset of Leber's; (3) his examination of Cerna as an expert witness; and (4) in vitro high dosage tests of erythromycin under altered pH conditions.

Although the general focus under Florida law is on the reliability of the proffered expert testimony, Florida courts

additionally require that both the basic underlying principles and the methodology of scientific evidence are "sufficiently tested and accepted by the relevant scientific community." Brim v. State, 695 So. 2d 268, 272 (Fla. 1997), citing Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923)(e.s.). This "general acceptance" requirement is commonly referred to as the Frye standard.

Cerna argues that Dr. Hamburger's testimony on his causation theory should be allowed without determining whether his testimony is admissible under Frye. In support of this argument, Cerna cites Florida Power & Light Co. v. Tursi, 729 So. 2d 995 (Fla. 4th DCA 1999). Tursi, however, is not comparable to the present situation in that it involved an admittedly "harmful toxin" which directly impacted a plaintiff's eye, causing an immediate injury and, eventually, cataracts at the point of impact. In Tursi, the court concluded that the testimony of the plaintiff's treating ophthalmologist, who had diagnosed and treated thousands of cataract patients, was admissible without an analysis under the Frye test. The court reasoned that, as Tursi involved one incident of trauma with an immediate injury, and a more serious injury developing four years later at the trauma site, its result was no more novel than allowing an orthopedist to testify that a neck injury,

which did not manifest itself with symptoms until four years after a rear-end collision, was caused by the collision.

Unlike Tursi, this is not an impact case. Here Cerna orally ingested pharmaceutical drugs never previously linked to Cerna's apparent illness. In pharmaceutical and chemical ingestion cases, Florida courts uniformly test a proposed expert's opinion under Frye. See E. I. DuPont De Nemours & Co. v. Castillo, 748 So. 2d 1108 (Fla. 3d DCA 2000) review granted (Aug. 31, 2000); Berry v. CSX Transp., Inc., 709 So. 2d 552 (Fla. 1st DCA 1998).

Cerna also argues that Dr. Hamburger's testimony is admissible under Florida's Frye test. Here Cerna relies primarily on one case, Berry v. CSX Transp., Inc., 709 So. 2d 552 (Fla. 1st DCA 1998), and argues that Dr. Hamburger's methodology is generally accepted even if his ultimate conclusion is not. ("When the expert's opinion is well-founded and based upon generally accepted scientific principles and methodology, it is not necessary that the expert's opinion be generally accepted as well." Berry, at 567.) Berry, however, supports the conclusion that Dr. Hamburger's testimony is inadmissible:

> "As stated by the court in Daubert v. Merrell Dow Pharm., Inc., 43 F. 3d 1311, 1317 (9th Cir. 1995):
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> > 'One very significant fact to be considered is whether the experts

> are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying. . . . [I]n determining whether proposed expert testimony amounts to good science, we may not ignore the fact that a scientists's normal workplace is the lab or the field, not the courtroom or the lawyer's office. That an expert testifies based on research he has conducted independent of the litigation provides important, objective proof that the research comports with the dictates of good science.'"

Berry, 709 So. 2d at 561, n.8. Dr. Hamburger is not a research scientist, but rather a community neuro-ophthalmologist retained for the purpose of preparing his opinion in this litigation.

In Berry, the court reasoned (and we agree) that the first step in any expert analysis is to determine whether there exists a mature epidemiological (human tests) association between the chemical ingestion and the injury suffered. Here, no epidemiological or scientific tests exist associating erythromycin with Leber's or any optic nerve injury. In Berry, the court stated (and we again agree) that a court "must assure itself that the [expert] opinions are based on relevant scientific methods, processes, and data, and not upon an expert's mere speculation." Berry, at 569 n.14. Accordingly,

a trial court must examine the methodology and science underlying the expert's opinion and be satisfied in relation thereto in order to admit the opinion testimony into evidence.

As previously observed, Dr. Hamburger's opinion is bottomed in part on the temporal relationship between Cerna's ingestion of the pharmaceutical drugs at issue and the onset of Leber's disease. Expert causation theories based solely on the temporal proximity between an ingested pharmaceutical and the resulting injury are not methodologically sound. An opinion based on such methodology is akin to a rooster's belief that because dawn breaks shortly after he stands on the weathercock and sounds his morning crow, he, the rooster, causes the sun to rise each day. What the rooster doesn't know is that temporal proximity alone does not prove causation.

In an additional (and faulty) analysis, Dr. Hamburger also opines that (1) environmental toxins cause the onset of Leber's; and (2) erythromycin is one of the environmental toxins causing Leber's. Although there may be support in the scientific literature for the first step, that environmental toxins can precipitate Leber's, there is no support here for the second step, that erythromycin is in fact one of the environmental toxins precipitating Leber's.

The problem with Dr. Hamburger's additional methodology is his extrapolation from articles on erythromycin involving in vitro experiments which involved high dosages and altered pH conditions in order to opine on erythromycin's effect on humans. Extrapolating from such studies in order to opine on erythromycin's effects on humans at normal dosages and normal pH conditions is not methodologically sound or accepted. In E. I. DuPont, this court rejected expert opinion testimony based on such extrapolations, concluding that extrapolating from animal and in vitro tests in order to establish a chemical's effects on humans is not a generally accepted methodology. Thus the trial court correctly excluded Dr. Hamburger's testimony because his methodologies are not generally accepted in the scientific community. Dr. Hamburger's opinions provide no proof of causation for Cerna's alleged injuries.

The final summary judgment is affirmed.