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TO FILE REHEARING MOTION
AND, IF FILED, DISPOSED OF.

IN THE DISTRICT COURT OF APPEAL

OF FLORIDA

THIRD DISTRICT

JULY TERM, A.D. 2001

ISABELLA RODRIGUEZ, a minor, by and through her mother and natural guardian, PENNY POSSO-RODRIGUEZ, and HENRY RODRIGUEZ, and PENNY POSSO-RODRIGUEZ, individually,	**	
Appellants,	**	
vs.		CASE NOS. 3D00-831, 3D99-2346
RICHARD J. FEINSTEIN, M.D., and RICHARD J. FEINSTEIN, M.D., P.A.	**	LOWER TRIBUNAL NO. 97-20645
Appellees.	**	

Opinion filed July 25, 2001.

An Appeal from the Circuit Court for Miami-Dade County, Eleanor Schockett, Judge.

Hersch & Talisman, and Patrice Talisman; and Spencer Marc Aronfeld, for appellants.

O'Connor & Meyers, and David R. Cassetty, for appellees.

Before SCHWARTZ, C.J., and SORONDO, and RAMIREZ, JJ.

RAMIREZ, J.

Isabella Rodriguez, a minor born with a birth defect,

appeals an order striking her experts, an adverse final summary judgment, and an order taxing costs, all of which were entered following a *Frye/Ramirez* hearing[1] in which the trial court determined that her expert testimony was not based on generally accepted scientific principles. Our *de novo* review determines that the methodology used by plaintiffs' experts is generally accepted in the scientific community. Their conclusion that exposure *in utero* to the drug prescribed by Dr. Richard Feinstein caused Isabella's birth defect is therefore admissible. Thus, we reverse.

Dr. Feinstein treated Penny Posso-Rodriguez for a toenail fungus infection by prescribing Sporanox. During her treatment, Rodriguez learned that she was pregnant and discontinued the use of the drug. Her daughter, Isabella Rodriguez, was subsequently born with a malformation in her right eye diagnosed as unilateral persistent hyperplastic primary vitreous (PHPV). Rodriguez and her husband then sued Dr. Feinstein and his medical association alleging negligence in prescribing Sporanox which resulted in Isabella's birth defect.

At the Frye hearing on the expert testimony, Rodriguez presented three witnesses: Dr. Seemanthini Hariharan, an

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[1] Frye v. United States, 293 F. 1013 (D.C. Cir. 1923); Ramirez v. State, 651 So. 2d 1164 (Fla. 1995).

obstetrician/gynecologist and maternal fetal medicine specialist; Dr. Jerry Sebag, an ophthalmologist and leading expert on the structure, function and pathology of the vitreous in the eye;[2] and Dr. Ronald Haun, a board certified geneticist on the faculty at the University of Miami. The witnesses testified that the mother's exposure to Sporanox during pregnancy more likely than not caused her daughter's PHPV. They reached this conclusion based on (1) the timing and duration of the exposure to the drug; (2) the lingering effect of the drug in the system even after the patient stops taking it due to the drug's lipophilic aspect (attraction to the fatty tissue); (3) the drug's molecular weight which is small enough to be transferred through the placenta; (4) the Federal Drug Administration's classification of the drug as a category C drug, teratogenic[3] in animals; (5) the manufacturer's package insert which warns against taking this particular drug during pregnancy; (6) animal studies which have shown the drug to cause birth defects; and (7) the statistical increase in birth defects

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[2] The vitreous is the jell that fills the center of the eye. Its function is to maintain a clear medium through which light can traverse the eye once focused by the structure of the eye.

[3] Teratogenic means "of, relating to, or causing malformations of an embryo or a fetus." THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE, 3d ed. (1996).

according to FDA adverse reaction reports. They testified that it is generally accepted in the scientific community to rely on all of these factors in arriving at an opinion.

The witnesses testified in detail about their opinions as they related to the facts of the case. Dr. Hariharan reviewed the mother's medical records and eliminated any occupational or other exposure to drugs or sprays which could be teratogenic. He explained that Isabella's birth defect was an extremely rare anomaly making it very difficult to believe that the birth defect could have occurred coincidentally in a Sporanox-exposed embryo.

Dr. Jerry Sebag, testified that the ingestion of the drug and its lingering effects coincided with fetal development of the secondary vitreous, which is clear, and normally replaces the primary vitreous, which is filled with blood vessels. He testified that the animal studies revealed teratogenicity in rats which caused major skeletal defects, and that there is a strong correlation between skeletal abnormalities and vitreous abnormalities due to the commonality of the collagen involved in the formation of both those structures.

Plaintiff's final witness was Dr. Ronald Haun, who testified that there was a statistically significant rate of congenital abnormalities making it improbable that PHPV was caused by

something other than Sporanox. He relied on the affidavit of Gerald Briggs, who authored a textbook on the effect of drugs on pregnancy and lactation, and concluded that there is data suggesting that Sporanox produces birth defects in humans.

Dr. Feinstein presented two witnesses: Dr. Aubrey Milunsky, a board certified doctor in internal medicine, pediatrics and clinical genetics; and Dr. Charles Nichols, a board certified ophthalmologist. Dr. Milunsky testified that there is a genetic component to the development of PHPV. He stated that extrapolation from a collagen defect in one area of the body to a defect in another, or from limb defects to collagen, was not generally accepted in the scientific community. He was critical of the plaintiffs' experts for relying on animal studies because, in his opinion, such studies have no scientific relevance to the issue of whether Sporanox can cause PHPV in humans. He felt that Dr. Sebag is the only person who holds the opinion that the study with mice can be extrapolated in such a manner. He also stated that there is no study to support the proposition that Sporanox can cross the placental barrier. He admitted that the lines of reasoning used by plaintiffs' experts to reach their conclusions, other than reliance on the FDA reports, were generally accepted in the scientific community to approach the question of teratogenicity.

Dr. Nichols testified that PHPV is a vascular disorder, not a disorder of the vitreous. He was also critical of reliance by the plaintiffs' experts on rodent studies and the extrapolation of musculoskeletal defects in rats to human eye defects. But he, too, admitted that all the lines of reasoning used by the plaintiffs' experts were generally accepted by the scientific community as a means of relating a birth defect to a particular drug.

The trial court determined that the plaintiffs' expert testimony on causation was inadmissible and struck the expert testimony because the conclusions reached were not based upon generally accepted scientific principles.[4]

The only issue in this case is whether the scientific evidence is "generally accepted" within the relevant scientific community. Application of *de novo* standard of review is appropriate when a Frye issue is involved. See Brim v. State, 695 So. 2d 268, 274 (Fla. 1997); Berry v. CSX Transp., Inc., 709 So. 2d 552, 557 (Fla. 1st DCA 1998) (holding that the appropriate standard of review of a Frye issue is *de novo*).

The proponent of expert testimony has the burden of proving

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[4] Summary judgment was subsequently entered in favor of Dr. Feinstein. The trial court also taxed the costs of the deposition transcripts and expert witness fees against Rodriguez in the amount of $3,518.80.

by a preponderance of the evidence the general acceptance of both the underlying scientific principle and the testing procedures used to apply that principle to the facts of the case. See Murray v. State, 692 So. 2d 157, 161 (Fla. 1997); Ramirez v. State, 651 So. 2d 1164, 1168 (Fla. 1995). Of the four-step process outlined in Ramirez, the trial court held that the plaintiffs had not met the second criteria: "whether the expert's testimony is based on a scientific principle or discovery that is 'sufficiently established to have gained general acceptance in the particular field in which it belongs.'" Id. at 1167 (quoting Frye, 293 F. at 1014). In Hadden v. State, 690 So. 2d 573, 576 (Fla. 1997), the Florida Supreme Court further explained: "[t]his test requires that the scientific principles undergirding this evidence be found by the trial court to be generally accepted by the relevant members of its particular field." In language especially applicable to this case, the First District in Berry stated that "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, 709 So. 2d at 567 (emphasis added).

The trial court relied heavily on this Court's recent case of E.I. DuPont De Nemours & Co., Inc. v. Castillo, 748 So. 2d

1108 (Fla. 3d DCA 2000), in which a pregnant woman was exposed to an agricultural fungicide (Benlate) when it was sprayed on a field and later gave birth to a child with a rare birth defect. The expert testified that fetal exposure to benomyl (an active ingredient in the fungicide) at a concentration of twenty parts per billion in the maternal bloodstream would cause microphthalmia in humans. He based his conclusion on two sources: 1) rat gavage studies, and 2) laboratory experiments on human and rat cells. The defendant objected to this testimony on the ground that the expert's *methodology* for determining whether and at what level Benlate could cause birth defects in humans was not generally accepted in the scientific community and thus the testimony was inadmissible. The court concluded that where "plaintiffs wish to establish a substance's teratogenicity in human beings based on animal and *in vitro* studies, the methodology used in the studies, including the method of extrapolating from the achieved results, must be generally accepted in the relevant scientific community." Id. at 1120.

In this case, the cross-examination of the plaintiffs' experts and the testimony of the defense experts may have created "two legitimate but conflicting scientific views." Id. at 1118. However, to involve judges in an evaluation of the

acceptability of an expert's opinions and conclusions would convert judges into fact-finders to an extent not envisioned by Frye, Ramirez, Castillo, or any other Florida case. To the contrary:

> Although the trial court must analyze the science and not merely the qualifications, demeanor or conclusions of experts, the court need not weigh or choose between two legitimate but conflicting scientific views. The court instead must assure itself that the opinions are based on relevant scientific methods, processes, and data, and not upon an expert's mere speculation .... [I]t is important to emphasize that the weight to be given to stated scientific theories, and the resolution of legitimate but competing scientific views, are matters appropriately entrusted to the trier of fact.

Berry, 709 So. 2d at 569 n.14.

Dr. Feinstein's own experts admitted that all the lines of reasoning used by the plaintiffs' experts are generally accepted by the scientific community as a means of establishing the teratogenicity of a particular drug. Their disagreement was only with the plaintiffs' experts' conclusions. Therefore, because the methodology used by plaintiffs' experts is generally accepted by the scientific community, we hold that the plaintiffs' scientific evidence should not have been excluded.

Reversed and remanded.