United States District Court for the District of Montana

Barbara BRUMBAUGH, Plaintiff,
v.
SANDOZ PHARMACEUTICAL CORPORATION, Defendant

No. CV 97-088-GF-DWM

Decided Sept. 27, 1999.

Counsel:

William J. Gregoire, Stephanie A. Reinhardt, Smith, Walsh, Clarke & Gregoire, Great Falls, MT, for Barbara Brumbaugh, plaintiff.

William D. Jacobsen, Steven T. Potts, Thompson, Jacobsen & Potts, Great Falls, MT, Joe G. Hollingsworth, Katharine R. Latimer, Gary I. Rubin, Kirby T. Griffis, Spriggs & Hollingsworth, Washington, DC, for Sandoz Pharmaceutical Corp, defendant.

ORDER

MOLLOY, District Judge.

This case is about a postpartum drug that allegedly causes significant medical problems in some women who use it. The crux of the issue before me is the Daubert question: should plaintiff's expert be allowed to testify.

Defendant Sandoz moves the Court for summary judgment on the issue of medical causation since the expected testimony of plaintiff's medical causation expert is unreliable and not based on accepted scientific methodology. The matter was fully briefed by the parties. An evidentiary hearing was set and oral argument was heard on September 3, 1999. Dr. Iffy, the challenged expert, was not present and did not testify. My findings as to the basis of his opinions are based

on sworn deposition testimony he has given in this and related cases. For the reasons set out below, and for the reasons I stated in the record, the motion for summary judgment is granted and judgment is entered for the defendant.

I. Background Facts

On April 4, 1994, plaintiff was twenty three weeks pregnant when she was attacked by her boyfriend and admitted to the hospital suffering from a traumatically induced premature separation of her placenta. Her baby was delivered by cesarean section but died two days later due to its prematurity. Brumbaugh's treating OB/GYN prescribed Parlodel to reduce her breast engorgement and associated pain. [FN1] She was released from the hospital four days later.

On April 11, plaintiff attended her baby's funeral. A short time later she suffered a seizure. She was treated and released from the hospital, but suffered an additional seizure on April 12 so she was once again hospitalized. Brumbaugh's OB/GYN recommended to the treating neurosurgeon that Parlodel be discontinued due to the fact that the Physician's Desk Reference indicated that seizure had been reported in temporal association with Parlodel's use.

Parlodel's active ingredient prevents lactation from occurring by blocking the hormone which causes it. With respect to circulation, the drug's primary effects on blood vessels are to cause vasodilation (widening of blood vessels) and to lower blood pressure. Seizure side effects are commonly associated with vasoconstrictors, which produce the opposite effect on blood vessels and raise blood pressure.

Defendant points to five studies (two of them epidemiological studies, which study the causal relationship between an agent and disease) which show no statistically significant relationship between Parlodel and seizure. In fact, defendant states that several of the studies suggest the opposite--that Parlodel, as a vasodilator, actually exerts a protective effect against postpartum stroke.

In his expert report, the challenged expert, Dr. Iffy, opines that he believes Parlodel has caused a chronic seizure condition in plaintiff. To support his opinions, he relies not on epidemiological studies but on anecdotal case reports and his theory that Parlodel can act as a

vasospastic agent instead of a vasodilator.

II. Legal Standard

Rulings on the admissibility of expert testimony under Fed.R.Evid. 702 are in the sound discretion of the trial court. General Elec. Co. v. Joiner, 522 U.S. 136, 118 S.Ct. 512, 517, 139 L.Ed.2d 508 (1997). Precluding plaintiff's expert directly impacts defendant's motion for summary judgment brought pursuant to Fed.R.Civ.P. 56(c). The Supreme Court holds that "the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case." Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986).

III. Discussion

The issue is whether the expected testimony of plaintiff's expert Dr. Iffy has sufficient scientific reliability to be admissible under the standards for expert testimony set out in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). Without Dr. Iffy's testimony, plaintiff will be unable to offer evidence on causation at trial so her claim fails as a matter of law without the proof.

The threshold questions for admissibility of expert scientific testimony are whether the proffered testimony reflects scientific knowledge and whether it will assist the trier of fact. Daubert, 509 U.S. at 592, 113 S.Ct. 2786. In exercising the "gate keeper" function of deciding whether to admit such testimony, a Court must make "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Id., at 592-593, 113 S.Ct. 2786.

A "key question" which courts must answer as they undertake their review is whether the technique or theory being advanced by the expert is testable or has been tested, the methodology of which is "what distinguishes science from other fields of human inquiry." Id., at 593, 113 S.Ct. 2786. None of the five studies cited by defendant and designed to analyze the causal relationship between Parlodel and hypertension, stroke, and seizure supports Dr. Iffy's theory that Parlodel generally causes seizure. The plaintiff criticizes certain aspects of these studies, but she produced no epidemiological study, or other reliable scientific proof that does make the causal link between Parlodel and her condition, or any related condition. Plaintiff's lawyers attack on defendant's studies does not meet the law's requirements. She must come forward with reliable scientific evidence of her own to defeat a summary judgment motion when her case is based on the expert's proof.

The predicate of Dr. Iffy's opinion is that Parlodel caused plaintiff's injury because it involved the temporal association between her prescription and her injury as well as his review of case reports and adverse drug events. The case reports were generated through other litigation with which Dr. Iffy was associated. Adverse drug events (ADE's) are temporal associations between a drug's administration and an unexpected physical reaction. In this case, Dr. Iffy admits that ADE's do not demonstrate a causal link but instead represent coincidence. Case reports and ADE's are compilations of occurrences, and have been rejected as reliable scientific evidence supporting expert opinion so as to meet the requirements set forth in Daubert. Jones v. United States, 933 F.Supp. 894, 899 (N.D.Cal.1996), aff'd 127 F.3d 1154 (9th Cir.1997), cert. denied 524 U.S. 946, 118 S.Ct. 2359, 141 L.Ed.2d 728 (1998) (anecdotal case reports are not derived through the scientific method and "fall short of the proven, cause and effect relationship that is necessary to satisfy the Daubert standard."). See also Sanderson v. International Flavors, 950 F.Supp. 981, 1000 (C.D.Cal.1996) (holding that temporal coincidence is not a "valid scientific connection" to satisfy Daubert.), Casey v. Ohio Medical Products, 877 F.Supp. 1380, 1385-1386 (N.D.Cal.1995) (case reports are not reliable scientific evidence of causation and not sufficiently based on scientific reliability and methodology to be admitted into evidence under Fed.R.Evid. 702 and 703).

Neither case reports nor adverse drug reaction reports contain scientific analysis with the safeguards of a controlled experiment. Their most significant analytical defect is that they don't isolate and investigate the effects of alternative causation agents. They are compilations of reported phenomena. Unlike epidemiological studies, they do not contain a testable and systematic inquiry into the mechanism of causation. As such, they reflect reported data, not scientific methodology. The Daubert court noted this phenomenon was the distinguishing characteristic of scientific evidence. Daubert, 509 U.S. at 593, 113 S.Ct. 2786.

Dr. Iffy recognizes the insufficiency of reliance on case reports or ADE's to establish causation when he states that controlled studies are necessary to show

that a particular drug causes an event or a particular reaction. Yet, he has developed a hypothesis that plaintiff's seizure and other seizures reported in ADE's and case * 1157 reports were caused by Parlodel-induced vasospasms. He admits that it is "simply a hypothesis" which has not been tested and may be impossible to test.

His hypothesis is that drugs similar to Parlodel are vasoconstrictors and not vasodilators, and some women "cannot distinguish" between them. No study of this lack of discrimination is put forward. Testimony extending general conclusions about similar drugs does not meet Daubert's requirement of reliability. Schudel v. General Electric Co., 120 F.3d 991, 996-997 (9th Cir. 1997). The Schudel court recognized that "small differences in molecular structure often have significant consequences." Id. Dr. Iffy's unsupported suspicion may be correct but it is not a reliable scientific opinion based on the record before me.

Consequently, Brumbaugh is left with anecdotal reports and an untested theory as evidence of causation. Correlation of two events in time does not necessarily establish causation. That is why anecdotal reports are not generally accepted as reliable scientific evidence to establish causation. Further, Dr. Iffy's opinions have not been analyzed with the safeguards of a controlled experiment to see if his causal mechanism theory is valid. Nonetheless, Brumbaugh argues that Dr. Iffy need not know the precise mechanism of injury for his testimony to be admissible under Daubert. She relies on Kennedy v. Collagen Corporation, 161 F.3d 1226, 1230 (9th Cir. 1998), quoting Daubert, 509 U.S. at 590, 113 S.Ct. 2786. While Daubert does not require absolute precision in identifying the medical mechanism of injury, there still must be "sufficiently compelling proof that the agent must have caused the damage somehow." Kennedy, 161 F.3d at 1230, quoting Daubert on remand, 43 F.3d 1311, 1314 (9th Cir.1995). No such proof was advanced in this case. Moreover, the expert in Kennedy was not merely relying on case reports or adverse drug reactions but on epidemiological studies as well.

IV. Conclusion

Dr. Iffy is, in essence, opining that plaintiff's seizures are due to Parlodel because he believes that. He admits that this causation opinion is "simply a hypothesis." Since they lack the rigor imposed by scientific methodology, Dr. Iffy's opinions do not have the evidentiary reliability to be admissible and are therefore excluded pursuant to Fed.R.Evid. 702 and 703.

If relevant and reliable, an expert's opinion must also be helpful to the jury if it is to be admitted in evidence. Here, the limited probative worth of Dr. Iffy's testimony is outweighed by the substantial probability of misleading the jury so the evidence is inadmissible pursuant to Fed.R.Evid. 403. Without the testimony of Dr. Iffy, plaintiff is unable to generate a genuine issue of material fact with respect to causation, an essential element of her claim. Accordingly, defendant Sandoz is entitled to judgment as a matter of law. [FN2]

Wherefore, IT IS HEREBY ORDERED that

1) defendant's motion for summary judgment on the issue of medical causation (docket # 161) is GRANTED;

2) the clerk is directed to enter judgment for the defendant by separate document;

3) the trial date of September 13, 1999 is VACATED.

With respect to the other pending motions, IT IS FURTHER ORDERED that

1) plaintiff's motion for the sanction of default judgment (docket # 118) is DENIED;

2) plaintiff's motion for sanctions (docket # 150) is DENIED;

3) defendant's motion for summary judgment on the learned intermediary doctrine (docket # 158) is DENIED;

4) all other pending motions are DENIED as moot.

Opinion Footnotes:

FN1. No evidence exists in her medical records that the plaintiff actually was given Parlodel during either stay in the hospital or that a prescription was filled in her name. Plaintiff stated in her deposition that she did not recall ever taking Parlodel, but in an affidavit filed on August 10, 1999 opposing defendant's summary judgment motion, she states that she now remembers being administered the prescription in the hospital and also taking it at home. The issue of specific causation is material, however, only if plaintiff can demonstrate general causation between Parlodel and her injury. Since I find that reliable medical testimony does not exist with respect to general causation, it is not necessary that I reach the question of specific causation.

FN2. My view is based on the record before me in this case. This is not to say Dr. Iffy is wrong. I do not opine that Parlodel is safe or without problems. My determination is that in the case before me, the Daubert standard has not been met.