

IN THE UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF NEBRASKA

SUSAN M. GRANT and REX BECK,)	
husband and wife,)	
)	
Plaintiffs,)	8:05CV66
)	
v.)	
)	
PHARMAVITE, LLC, a California)	MEMORANDUM OPINION
Limited Liability Company,)	
and NUTRACEUTICAL CORP.,)	
d/b/a SOLARAY, a foreign)	
corporation,)	
)	
Defendants.)	
)	

This matter is before the Court on motions to exclude the expert testimony of Michael Corbett, Ph.D. ("Dr. Corbett") filed by defendants Pharmavite, LLC and Nutraceutical Corp. (cumulatively "defendants") (Filing Nos. 82 and 93), defendants' motions to exclude the expert testimony of Michael Sorrell, M.D. ("Dr. Sorrell") (Filing Nos. 81 and 84) and defendants' motions for summary judgment (Filing Nos. 133 and 140). After examination of the evidentiary submissions, the briefs of the parties and the oral arguments presented at the September 6, 2006, *Daubert* hearing, the Court will grant the motion to exclude the testimony of Dr. Corbett and will grant the motion to exclude Dr. Sorrell's testimony as to causation. Without expert testimony, plaintiffs are unable to make a prima facie case. Therefore, defendants' motions for summary judgment will also be granted.

I. Summary Judgment Standard

Summary judgment is appropriate if the pleadings, depositions, answers to interrogatories and admissions on file, together with any affidavits, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56©). The party moving for summary judgment must always bear "the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986); see NELR 56.1(a). When the party seeking summary judgment carries its burden, the opposing party "must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1996); see NELR 56.1(b).

At the summary judgment stage, the evidence is viewed in a light most favorable to the nonmoving party, with all inferences drawn in that party's favor. See *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). In making this review, the Court does not "weigh the evidence and determine the truth of the matter" but instead determines "whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 249. "Where the record taken as a whole could not lead a

rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.'" *Matsushita*, 475 U.S. at 587.

II. Law Governing Admission of Expert Testimony

Because plaintiffs' claim involves complex issues of toxicology and pharmacology that a lay person could not be expected to understand, Nebraska law requires that plaintiffs prove it through expert testimony. *Marmo v. IBP, Inc.*, 360 F. Supp. 2d 1019, 1021-1022 (D. Neb. 2005). Under *Daubert* and Federal Rule of Evidence 702, the Court acts as a "gatekeeper," ensuring that only scientifically reliable and relevant expert evidence is presented to the jury. *Daubert v. Merrell-Dow Pharmaceuticals*, 509 U.S. 579, 589 (1993). 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 by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

The trial court's gatekeeping function requires more than simply "taking the expert's word for it." Fed. R. Evid. 702 (Advisory Committee Notes to 2000 Amendments). As *Daubert* explains, Rule 702 requires that an expert be qualified to render testimony on the subject, and that his testimony be reliable and

relevant. *Daubert*, 509 U.S. at 588, 590-95. Plaintiffs have the burden to prove by a preponderance of the evidence that Dr. Corbett's methodology is sound, and that his conclusions are based on scientifically reliable evidence under the *Daubert* standards. *Gilmore v. Woodmen Accident & Life Co.*, 2006 WL 1041719 at *1 (D. Neb. April 17, 2006) (citing *Daubert*, 509 U.S. at 592).

III. Discussion

This is a product liability action filed by the plaintiffs, Susan Grant and Rex Beck, who are husband and wife. Plaintiffs allege that Susan Grant ("Grant") took the herbal supplement black cohosh manufactured by the defendants beginning in 2002. Grant was diagnosed with autoimmune hepatitis in February, 2003, and subsequently underwent a liver transplant in March, 2003. The plaintiffs allege that Grant's liver disease was caused by her ingestion of black cohosh.

Dr. Corbett is a toxicologist who plaintiffs have retained as an expert witness. He opines that sufficient chemical evidence exists to implicate black cohosh as a general cause of liver toxicity which makes it biologically possible for Grant's liver disease to be a direct result of her ingestion of black cohosh over a number of months. He goes even further in opining as to specific causation that Grant's liver disease is more likely than not a direct result of her use of black cohosh as an herbal remedy.

Dr. Sorrell was one of Grant's treating physicians. Dr. Sorrell is a gastroenterologist, not a pharmacologist or a toxicologist. He admits that prior to treating Grant, he had never heard of black cohosh (Sorrell Dep. 13:10-11). Plaintiffs retained Dr. Sorrell as an expert witness in November, 2003.

A. General Causation

To establish their claim, plaintiffs must prove general causation as well as specific causation. "General causation is whether a substance is capable of causing a particular injury or condition in the general population." *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005). Here, plaintiffs could prove general causation with expert testimony finding black cohosh hepatotoxic, i.e. that it causes liver disease. Plaintiffs seek to introduce Dr. Corbett's testimony to establish general causation.

Dr. Corbett began with an opinion, which he termed a working hypothesis, that black cohosh was hepatotoxic. Dr. Corbett did not test this working hypothesis in reaching his opinion as to black cohosh's potential as a cause of liver disease. While Dr. Corbett acknowledged that his hypothesis could be tested by controlled animal and human testing he did no such testing (Corbett Dep. 200:7-9). Testing done by other scientists has failed to determine that black cohosh is hepatotoxic to humans. In fact, the scientific research has consistently held to the contrary -- that black cohosh is not hepatotoxic.

The Tenth Circuit Court of Appeals recently ruled inadmissible an expert witness' opinion which, at best was an untested hypothesis and, at worst was a hypothesis which has been tested and proven to be untenable. *Norris*, 397 F.3d at 887. Like the inadmissible opinion in *Norris*, Dr. Corbett's working hypothesis flies in the face of all of the research that has been conducted. While it is not necessary that an opinion be backed by scientific research, it is necessary that an expert's testimony, which contradicts all of the research, at minimum address and distinguish the contradictory research in order to support the expressed opinion.

Here, Dr. Corbett's untested hypothesis contradicts the body of research regarding black cohosh and liver disease. Dr. Corbett's response is simply to declare the research "wrong." Just saying that the research is wrong is insufficient to support an opinion that expresses exactly the opposite of what the research has concluded. *Id.* at 886.

Dr. Corbett skeptically examined the experiments done by others rather than conduct his own black cohosh research. He acknowledged that criticism and skepticism is only a starting point because, even if his skepticism "proves to be valid . . . you know, there's -- simply, the data is lacking. Then additional stuff has to be done. So, until that additional stuff is done, I can't really make a decision." (Corbett Dep. 59:5-60:22). Dr. Corbett then acknowledged that the "additional stuff" has not been done in this case (Corbett Dep. 59:5-60:22).

Not only does Dr. Corbett acknowledge that he lacked the information necessary to make a decision, he also acknowledged that all of the randomized, case controlled, placebo controlled studies that have been done on the issue of black cohosh and liver toxicity have demonstrated no liver toxicity (Corbett Dep. 74:12-76:6). Further, his greatest criticism of a paper by Professor Tieraona Low Dog ("Low Dog"), which was the first paper to review all published literature pertaining to preclinical and clinical safety of various forms of black cohosh, was that the paper relied in part on a study by Korn which Corbett could not find (Corbett Dep. 51:3-7). The Low Dog paper concluded that there is strong evidence for the safety of black cohosh in humans (Corbett Dep. Ex. 20, p. 132).

This is not a case where there is no epidemiology. Instead, it is a case where the body of epidemiology finds no association between black cohosh and liver disease. The Tenth Circuit Court of Appeals has excluded expert testimony because the testimony was unreliable where the expert ignored or discounted epidemiological studies which conflicted with the expert's opinion. *Norris*, 397 F.3d at 882. The Eighth Circuit has acknowledged that epidemiological studies are not always necessary in a toxic tort case. *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 992 (8th Cir. 2001). However, where there is a large body of contrary epidemiological evidence, it is necessary to at least address it with evidence that is based on medically reliable and scientifically valid methodology. *Norris*,

397 F.3d at 882. Dr. Corbett's failure to adequately address the body of contrary epidemiological evidence weighs heavily against admission of his testimony.

Another *Daubert* factor considered in evaluating the admissibility of an expert's opinion is whether or not the opinion is based on research conducted independent of litigation. *Lauzon v. Senco Prods.*, 270 F.3d 681, 692 (8th Cir. 2001) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995)). Expert opinions generated as a result of litigation have less credibility than opinions generated outside of litigation. See *Daubert*, 509 U.S. at 593. It is undisputed that Dr. Corbett's theory that black cohosh is hepatotoxic was developed solely in connection with this litigation. Dr. Corbett's opinion was not developed in a lab in the course of research; instead it was developed only after being contacted by plaintiffs' attorneys in connection with this litigation. This factor also weighs against admission of Dr. Corbett's testimony.

The next applicable *Daubert* factor is general acceptance. "Widespread acceptance can be an important factor in ruling particular evidence admissible." *Id.* at 594. Dr. Corbett has failed to demonstrate that his opinion has been accepted, let alone widely accepted. In fact, there is no evidence that Dr. Corbett has shared his working hypothesis with any other scientists, much less that any other scientists have accepted his untested working hypothesis as true. Thus, this factor also weighs against admission of Corbett's testimony.

Under *Daubert* and Rule 702 the Court will exclude as unreliable the testimony of Dr. Corbett regarding general causation because his opinion was based on a review of the errant report by Dr. Sorrell, was not based upon independent clinical research, stands in sharp contrast to the vast body of research, was only reached after being contacted in regard to this litigation, and is not widely accepted.

In addition to Dr. Corbett, plaintiffs also seek to use the testimony of Dr. Sorrell to establish general causation. But, Dr. Sorrell's opinion is also insufficient to establish general causation.

Dr. Sorrell is a physician, not a pharmacologist or a toxicologist. He was Grant's treating gastroenterologist and admits that prior to treating Grant, he knew nothing about black cohosh. Plaintiffs retained Dr. Sorrell as an expert witness in November, 2003. Only after plaintiffs retained him did Dr. Sorrell submit a report on Grant's case for publication in which he linked her liver disease to black cohosh. Unfortunately, Dr. Sorrell's study contained several serious factual errors including a statement that Grant "did not drink alcohol or use illicit drugs, and was not taking any medications, including other herbal medications, acetaminophen [and] nonsteroidal anti-inflammatory drugs." (Sorrell Dep., Ex. 4, p. 1). In fact, Grant did drink alcohol on a regular basis and was using, or had

used, several medications that are known or potential hepatotoxins.¹

The gold standard for determining whether a substance causes adverse reactions in the population is with a case-controlled, randomized, double blind study. Such a study has been conducted for black cohosh by Ruediger Osmers, but Dr. Sorrell was not aware of the study (Sorrell Dep. 65:7-66:25). In fact, considerable research has been conducted on black cohosh but Dr. Sorrell was unaware of the scientific community's studies which have consistently failed to demonstrate that black cohosh is hepatotoxic (Sorrell Dep. 65:7-66:25; Corbett Dep. 74:12-75:4). Dr. Sorrell acknowledged that ten to fifteen percent of liver disease is ideopathic, that is that there is no known cause (Sorrell Dep. 89:10-90:1).

Dr. Sorrell has acknowledged that you cannot prove causation with a single case report (Sorrell Dep. 62:17-63:1). He also acknowledges that there is no evidence-based medicine establishing that black cohosh causes liver failure (Sorrell Dep. 67:17-25). Further, at oral argument, plaintiffs' counsel also admitted that he was unaware of any direct studies demonstrating that black cohosh is a liver toxin. (Grant v. Pharmavite, Daubert Hearing, Sept. 6, 2006). With no evidence that black

¹ Plaintiff was presently taking Valtrex, Sudafed and Advil at the time of her liver transplant. She had taken Erythromycin for 2½ years ending just four months before her liver transplant. She also took such large doses of Ibuprofen in the 1990s that she developed anemia. All of these medications have warnings related to possible liver abnormalities or are contraindicated for people with liver disease.

cohosh is hepatotoxic, Dr. Sorrell's testimony cannot be used to establish general causation.

B. Specific Causation

Specific causation refers to whether a substance caused a particular person's injury. *Norris*, 397 F.3d at 881. Dr. Corbett's opinion as to specific causation will be excluded because he never examined Grant or her medical records but instead based his review solely upon a draft copy of Dr. Sorrell's case note which failed to consider or even mention that the plaintiff had used alcohol and several medications that are known to be or suspected of being hepatotoxic.² Dr. Corbett acknowledges the importance of having a full and complete history of what a patient may have been exposed to in attempting to analyze what may or may not have caused a patient's liver damage (Corbett Dep. 10:17). Dr. Corbett will not be allowed to testify as to whether or not black cohosh was the specific cause of Grant's liver disease because he never examined Grant and never even reviewed Grant's medical records.

Plaintiffs also seek to introduce the testimony of Dr. Sorrell to establish specific causation. Dr. Sorrell attempts to prove specific causation with a differential diagnosis. A "[d]ifferential diagnosis assumes that general causation has been proven." *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1413 (D. Or. 1996). The Eighth Circuit has held that the district court may properly exclude a differential diagnosis that

² See *supra* note 1.

is scientifically invalid. *Turner v. Iowa Farm Equip. Co.*, 229 F.3d 1202, 1208 (8th Cir. 2000). Here, Dr. Sorrell's differential diagnosis is scientifically invalid because general causation has not been proved. Thus, the differential diagnosis cannot be used to establish specific causation. Therefore, Dr. Sorrell's testimony as to specific causation will be excluded.

C. Summary Judgment

Without evidence to establish both general and specific causation, plaintiffs cannot survive defendants' motions for summary judgment. Plaintiffs' counsel acknowledged at oral argument that the case fails without expert testimony as to causation. Having excluded the testimony of Dr. Corbett and the testimony of Dr. Sorrell as to causation, plaintiffs have no evidence to establish either general or specific causation. Therefore, the Court will grant defendants' motions for summary judgment. A separate order will be entered this date in accordance with this opinion.

DATED this 8th day of September, 2006.

BY THE COURT:

/s/ Lyle E. Strom

LYLE E. STROM, Senior Judge
United States District Court

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PHARMAVITE, LLC, a California)	ORDER AND JUDGMENT
Limited Liability Company,)	
and NUTRACEUTICAL CORP.,)	
d/b/a SOLARAY, a foreign)	
corporation,)	
)	
Defendants.)	
_____)	

Pursuant to the memorandum opinion entered herein this date,

IT IS ORDERED:

1) Defendant Pharmavite, LLC's motion to exclude the expert testimony of Michael Corbett, Ph.D. (Filing No. 82 and 93) is granted;

2) Motions by defendants Pharmavite, LLC and Nutraceutical Corp. to exclude the expert testimony of Michael Sorrell, M.D. (Filing Nos. 81 and 84) are granted;

3) Defendants' motions for summary judgment (Filing Nos. 133 and 140) are granted; and

4) Plaintiffs' complaint is dismissed.

DATED this 8th day of September, 2006.

BY THE COURT:

/s/ Lyle E. Strom

LYLE E. STROM, Senior Judge
United States District Court