

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS**

KENNETH HALE and VIKI HALE,)	
)	
Plaintiffs,)	
)	
vs.)	Case No. 15-cv-00745-JPG-SCW
)	
BAYER CORPORATION, <i>et al.</i> ,)	
)	
Defendants.)	

MEMORANDUM AND ORDER

This matter comes before the Court on Defendants’ Motion [Doc. 30] to Exclude Plaintiffs’ Experts’ Opinions; Defendants’ Motion [Doc. 32] for Summary Judgment; and Plaintiffs’ Motion [Doc. 34] for partial Summary Judgment. All motions having been fully briefed, the Court heard oral arguments on January 26, 2017.

1. Background.

The Plaintiffs previously filed a complaint in this Court (*Hale v. Bayer Corporation*, 3:14-cv-00481-MJR-SCW) which was voluntarily dismissed on April 29, 2015. The plaintiffs then filed suit in the Circuit Court, Third Judicial Circuit, Madison County, Illinois on June 4, 2015, and the defendants removed the matter back to this court on July 9, 2015.

The Complaint alleges that plaintiff Kenneth Hale took Aleve® in early June 2013, as directed, and suffered permanent kidney injury. Aleve® is an over-the-counter form of a non-steroidal anti-inflammatory drug (“NSAID”) and Mr. Hale has been diagnosed with Minimal Change Disease (“MCD”). The complaint puts forth claims of strict product liability, negligence, breach of warranty, willful and wanton conduct, and on behalf of plaintiff Viki Hale, loss of consortium.

Defendants Walgreens Co. and Walgreens Business Services, LLC filed a motion to dismiss for failure to state a claim upon which relief could be granted and the Court granted their motion on September 16, 2015. [Doc. 16.] As such, Bayer Corporation and Bayer Healthcare LLC (collectively “Bayer”) are the remaining defendants in this matter.

2. Defendant’s Motion to Exclude Plaintiffs’ Expert Opinions.

The Defendants move to exclude the testimony of plaintiffs’ expert witnesses: Dr. Gourang Patel, Dr. Erik Daniels, and Dr. John Hoelscher pursuant to Federal Rule of Evidence 702. Defendants argue that these doctors’ opinions are “not properly founded in or based upon sufficient reliable medical, scientific, or other specialized knowledge” as required for admissibility set forth in *Daubert v. Merrell Dow Pharma., Inc.*, 509 U.S. 579 (1993) and *Kumho Tire Co., Ltd., v. Carmichael*, 526 U.S. 137 (1999). [Doc. 30.]

Federal Rule of Evidence 702 provides that:

“A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.”

Admissibility of expert testimony is also governed by *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its progeny. In *Daubert*, the Supreme Court held that Federal Rule of Evidence 702 did not incorporate the “general acceptance” test set forth in *Frye v. United States*, 54 App. D.C. 46 (D.C. Cir. 1923). Instead, the Court held that Rule 702 required district judges to be “gatekeepers” for proposed scientific evidence. *Daubert*, 509 U.S. at 589; *see also General Elec. v. Joiner*, 522 U.S. 136, 142 (1997). For scientific evidence to be

admissible, the Court found that a district court must find it both relevant and reliable; it must be scientific knowledge grounded “in the methods and procedures of science” and consist of more than “subjective belief or unsupported speculation.” *Daubert*, 509 U.S. at 589-90.

“The objective of [the gatekeeping] requirement is to ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

When dealing with scientific evidence, the preliminary question is “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.” *Daubert*, 509 U.S. at 592-93.

Considerations pertinent to this inquiry from *Daubert* include:

- (1) whether a theory or technique is capable of being or has been tested;
- (2) whether it has been subjected to peer review and publication;
- (3) the known or potential rate of error when applied;
- (4) the existence and maintenance of standards and controls; and
- (5) whether it has gained general acceptance.

Rule 702’s advisory committee’s notes suggest that courts also consider:

- (1) Whether 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;”
- (2) Whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion;

- (3) Whether the expert has adequately accounted for obvious alternative explanations;
 - (4) Whether the expert “is being as careful as he would be in his regular professional work outside his paid litigation consulting;” and
 - (5) Whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give.
- (2000 Amendments, Advisory Committee Notes)(*internal citations omitted*).

Expert testimony can consist of scientific, technical, or other specialized knowledge and *Daubert* still applies; however, the court is not required to apply all of the factors in *Daubert*. “We conclude that *Daubert's* general holding—setting forth the trial judge's general “gatekeeping” obligation—applies not only to testimony based on “scientific” knowledge, but also to testimony based on “technical” and “other specialized” knowledge. See Fed. Rule Evid. 702. We also conclude that a trial court *may* consider one or more of the more specific factors that *Daubert* mentioned when doing so will help determine that testimony's reliability. But, as the Court stated in *Daubert*, the test of reliability is “flexible,” and *Daubert's* list of specific factors neither necessarily nor exclusively applies to all experts or in every case. Rather, the law grants a district court the same broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination.”

Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 141–42 (1999).

Under Rule 702, “the proponent has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence.” (2000 Amendments, Advisory Committee Notes). To determine if an expert is qualified to testify on a particular matter, a court should “consider a proposed expert's full range of practical experience as well as academic or technical training.” *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000). However, generalized knowledge within an area is not necessarily enough to qualify an expert:

[A]n expert's qualifications must be within the same technical area as the subject matter of the expert's testimony; in other words, a person with expertise may only

testify as to matters within that person's expertise. Generalized knowledge of a particular subject will not necessarily enable an expert to testify as to a specific subset of the general field of the expert's knowledge.

Martinez v. Sakurai Graphic Sys. Corp., No. 04 C 1274, 2007 WL 2570362, at * 2 (N.D. Ill. Aug. 30, 2007) (citing *O'Conner v. Commonwealth Edison Co.*, 807 F. Supp. 1376, 1390 (C.D. Ill. 1992), *aff'd*, 13 F.3d 1090 (7th Cir. 1994)).

Dr. John Hoelscher

Dr. Hoelscher is the plaintiff Kenneth Hale's primary care physician. The defendants argue that Dr. Hoelscher is not a nephrologist and that he is not qualified as a general physician to issue causation opinions in this matter. Dr. Hoelscher refers his patients with kidney problems to a nephrologist and Dr. Hoelscher has never studied whether NSAIDs may cause particular kidney injuries. Instead, defendants argue that Dr. Hoelscher relied on the "opinion and diagnoses of Dr. Daniels to offer his opinion that plaintiff's MCD was caused by Aleve." [Doc. 30 at 9 & 10.]

The plaintiffs state in their written response that they "will not proffer Dr. Hoelscher to testify that Aleve® caused Mr. Hale's kidney injury." Dr. Hoelscher will be testifying about, "his care and treatment of Mr. Hale and Dr. Daniels' diagnosis guided that care and treatment." [Doc. 42 at 13.] At oral arguments, plaintiff again conceded that Dr. Hoelscher would not testify that Aleve® caused Mr. Hale's kidney injury. [Hearing TR. at 61.]

Therefore, the parties and the Court agree that Dr. Hoelscher is permitted to testify with regard to his care and treatment of the plaintiff Kenneth Hale, but that he is not qualified to testify with regard to causation.

Dr. Erik Daniels

Dr. Daniels is plaintiff Kenneth Hale's treating nephrologist and the physician that diagnosed Mr. Hale with NSAID-induced MCD. Defendants argue that Dr. Daniels' opinions

regarding causation are, “insufficiently supported by medical science” and that he, “is not able to definitively establish by any medical or laboratory test that plaintiff’s consumption of Aleve® was the cause of his [Mr. Hale’s] MCD.” Further, defendants argue that Dr. Daniels reached his diagnosis by a differential diagnosis – that is “ruling out” other potential causes until he was “left with the most likely one” – based on insufficient scientific data. [Doc. 30 at 6.]

The plaintiffs counter with the argument that Dr. Daniels is a practicing nephrologist and has been for over 20 years. He treated and restored plaintiff Mr. Hale’s kidney function and has medically managed Mr. Hale’s kidney injury. The plaintiffs cite to portions of Dr. Daniels’ deposition testimony on how he arrived at Mr. Hale’s diagnosis and the literature he relied upon in making the diagnosis. [Doc. 42 at 7.]

Defendants cite to *Ervin v. Johnson & Johnson*, in which the Seventh Circuit held that, “[t]he mere existence of a temporal relationship between taking a medication and the onset of symptoms does not show a sufficient causal relationship.” 492 F.3d 901, 904–05 (7th Cir. 2007). However, plaintiffs argue that *Ervin* is inapplicable since, “the *Ervin* court clearly states a differential diagnosis satisfies *Daubert* if the expert uses reliable methods.” [Doc. 42 at 7.]

The *Ervin* Court stated that:

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.’ Determining the reliability of an expert’s differential diagnosis is a case-by-case determination. *Id.* at 904.

Therefore, the Court must look at the methodology and epidemiological data supporting Dr. Daniels’ differential diagnosis to determine whether it went beyond “[t]he mere existence of a temporal relationship” between Mr. Hale consuming the Aleve® and the on-set of Mr. Hale’s symptoms.

First, Dr. Daniels established that Mr. Hale's kidney injury was acute and not chronic - meaning that it developed within a short period of time rather than over the course of months or years. He performed blood tests to rule out various multiple myelomas. Blood tests also showed no evidence of lupus and a biopsy of Mr. Hale's kidney showed no evidence of diabetic kidney. However, the biopsy did confirm MCD. Dr. Daniels also ruled out disorders that presented with chronic renal failure, but would not present with acute renal failure. Finally, Dr. Daniels considered and ruled out anything that Mr. Hale may have ingested that could have resulted in food poisoning and/or certain E. coli infections based on Mr. Hale's normal platelet counts. [Doc. 35-2 at 13, 17-22.]

Dr. Daniels admits that the majority of MCD is idiopathic, but testified that MCD is rarely accompanied by acute renal failure - only in about 10 to 15 percent of adult patients - which was one reason why he attributed the MCD to the Aleve®. However, he could not rule out that Mr. Hale's MCD was idiopathic. [Doc. 35-2 at 103-105.] He further testified that the clinical findings and the lab findings between idiopathic cause and NSAID-induced minimal change disease was identical - but that there was a temporal association of NSAIDs. [Doc. 35-2 at 106.]

Dr. Daniels testified that he determined the cause of Mr. Hale's kidney injury, "based on a combination of personal experience, the medical literature of which I brought a couple of - - of broad examples, and again, the clinical circumstances." However, he further testified that, "[t]his is not a condition whereby I can perform a test, a blood test, a urine test, a biopsy which will answer the question this is the nature of his condition and its cause." [Doc. 35-2 at 19- 22.]

The medical literature Dr. Daniels brought to his deposition included review articles that looked at, "non-steroidal anti-inflammatory drugs like Aleve, Motrin, Ibuprofen in particular."

Id. at 22-23. However, he stated that he went back and located these articles for his deposition as he, “thought it would make it easier to describe Mr. Hale’s case.” *Id.* at 24. He testified that he did not rely on the articles in determining his opinion while treating Mr. Hale as, “it’s something that’s well-understood” and “not difficult to come across articles that confirm the well-understood concept that non-steroidal anti-inflammatory drugs can both cause acute, chronic kidney – acute and chronic kidney injuries as well as heavy proteinuria.” *Id.* at 25. He testified that amongst medical professional, it has been generally known for at least the last 25 years that NSAIDs can cause renal injury or renal malfunctions.

However, the medical data that Dr. Daniels referred to concerned studies involving prescription strength NSAIDs. Dr. Daniels could not cite to any supporting literature involving over-the-counter NSAIDs or any studies with regard to dose-specific NSAIDs necessary to cause kidney disease. In fact, Dr. Daniels stated “that the last time I did a complete literature search on this particular topic was probably in the early 2000’s, maybe as long ago as the late ‘90’s, and so I’m fairly certain that at that time, prescription strength medications is what we were talking about. We were talking Ibuprofen 800’s and the like.” *Id.* at 57. He further stated that, “there’s not a lot in the medical literature in the last 10 to 15 years, frankly, with new studies.[T]here aren’t much in the way of studies looking at over-the-counter strength NSAIDs.” *Id.*

The primary action ingredient of Aleve® is naproxen sodium¹ and Dr. Daniels testified that he has never read any article that related naproxen sodium to renal injury. *Id.* at 60. Dr. Daniels has not conducted any research on NSAIDs, minimal change disease, or naproxen sodium. *Id.* at 53. In his practice, Dr. Daniels treats “less than a case a year” of minimal change

¹ “**Naproxen** ...is a nonsteroidal anti-inflammatory drug (NSAID) of the propionic acid class (the same class as ibuprofen) that relieves pain, fever, swelling, and stiffness. It is a nonselective COX inhibitor, usually sold as the sodium salt.” Wikipedia, <https://en.wikipedia.org/wiki/Naproxen>. (last visited 3.21.2017).

disease. *Id.* at 112. As such, Dr. Daniels cannot provide any scientific and/or medical data with regard to the relationship of over-the-counter NSAIDs and kidney disease – let alone any data that indicates a causal link between naproxen sodium consumption and minimal change disease.

Therefore, the Court finds Dr. Daniels' causation opinions are unreliable based on the lack of supporting medical science as required by Federal Rule of Evidence 702(b). Although Dr. Daniels has generalized knowledge of the diagnosis and treatment of kidney diseases, he does not possess expert knowledge with the specific subset of the over-the-counter NSAIDs and minimal change disease. As such, Dr. Daniels may testify with regard to his care and treatment of the Mr. Hale, but he is not qualified to testify with regard to causation.

Dr. Gourang Patel

The last expert that the defendants move to bar is Dr. Patel. Defendants argue that Dr. Patel, “is a pharmacist and not a medical physician.” Specifically, the defendants state that Dr. Patel:

[H]as never been employed by the United States Food and Drug Administration. He has never been employed in the area of pharmacovigilance. He has never participated in any clinical trials involving naproxen sodium, the primary action ingredient of Aleve®. He has never been involved with any clinical studies involving Aleve® or any other NSAID. He has never analyzed the chemical makeup of naproxen sodium. He admittedly is not qualified to discuss whether the ‘design has any impact on a particular patients.’ Dr. Patel has never been involved in any type of analysis regarding prescription drug or non-prescription drug labels. He does not know the FDA’s requirements for over-the-counter drug approval. He is not a marketing expert, nor has he ever studied the impact of drug marketing on consumer. His only opinions are reflective of ‘his profession and interactions with patients.’ However, Dr. Patel does not medically treat patients.” [Doc. 30 at 4. (*internal citations omitted*).]

Defendants further claim that Dr. Patel, “relied upon 203 adverse event reports in coming to his conclusion that plaintiff’s injury was foreseeable. Not a single one of those reports, however, dealt with MCD, and in any event experts cannot rely on adverse event reports for such opinions.” [Doc. 30 at 5 (*internal citations omitted*).]

The plaintiffs argues that Dr. Patel is “well-qualified” and “is being tendered for very specific opinions to include: Mr. Hale’s type of kidney injury was foreseeable to the defendants and, based on many years of educating and working with healthcare providers and providing healthcare services to patients, the danger of kidney injury/failure goes beyond that which would be contemplated by the ordinary patient with ordinary knowledge common to the community.” [Doc. 42 at 9.] Plaintiffs also argue that, “Dr. Patel has spent his entire career studying, educating, and counselling about the effects of prescription and over-the-counter drugs.” [Doc. 42 at 11.]

The Court will first address Dr. Patel’s qualification to render the opinion that Mr. Hale’s type of kidney injury was foreseeable to the defendants.

A foreseeability test, however, is not intended to bring within the scope of the defendant's liability every injury that might possibly occur. ‘In a sense, in retrospect almost nothing is entirely unforeseeable.’ (*Mieher v. Brown*, 54 Ill.2d 539, 544, 301 N.E.2d 307, 309.) Foreseeability means that which it is Objectively reasonable to expect, not merely what might conceivably occur. *Winnett v. Winnett*, 57 Ill.2d 7, 12-13, 310 N.E.2d 1, 4-5 (Ill. 1974).

Dr. Patel is a clinical pharmacist. [Doc. 30-1 at 27.] He is not a physician and he has never participated in clinical trials involving naproxen or any type of NSAID. *Id.* at 32, 33. Dr. Patel is not aware of any cases of minimal change disease associated with over-the-counter use of naproxen products. *Id.* at 56. Of the 203 adverse event reports that he reviewed in this case, none involved minimal change disease. *Id.* at 56. Dr. Patel testified that his “opinions are

reflective of my profession and my interaction with patients.” *Id.* at 37. He is not aware of the incident rate for MCD caused, or believed to be caused, by over-the-counter NSAIDs. He could not cite a single study linking naproxen sodium with minimal change disease.

Dr. Patel testified:

Q. . . . My question is, in your mind, what makes an event foreseeable? Is just one adverse event reported enough to make something foreseeable?

A. I guess I think of it as a pharmacist and a clinician and also a consumer. It’s not so much what’s reported that you see foreseeable, sir. It’s the mechanism of the drug and can the injury happen, and the answer is yes, it has been reported.

Q. And how many reports do you have to have to make it foreseeable? Just one?

A. Oh, I don’t know if there is answer to that, sir.

. . . .

Q. . . . Can you point me to something mathematically or statistically or based upon some sort of actual analysis that defines for me what you mean by “foreseeable”?

A. No sir. I don’t have an analysis of what foreseeable is. It’s my profession as a pharmacist and experience.

[Doc. 30-1 at 119-121.]

If 10,000 individuals were consuming over-the-counter Aleve® today, if asked, Dr. Patel could not opine that it is likely that X individuals would develop a kidney injury based on Y studies. If an expert is unaware of how likely an injury could occur – even in a general category of injuries – then there is no scientific basis for an opinion that it is “objectively reasonable to expect” that a particular injury is foreseeable. Dr. Patel has offered only speculation as the basis for his opinion.

As previously quoted, “[g]eneralized knowledge of a particular subject will not necessarily enable an expert to testify as to a specific subset of the general field of the expert’s knowledge.” *Martinez* at *2. Here, there is no indication that Dr. Patel has any expert knowledge beyond a general pharmaceutical knowledge with regard to NSAIDs and more specifically, naproxen sodium. Dr. Patel also does not appear to have any expertise with regard to drug induced kidney related diseases. As such, he is not qualified to offer an expert opinion that Mr. Hale’s injury was foreseeable.

Dr. Patel is also being tendered to render the opinion that the danger resulting from Aleve is greater than would be contemplated by an ordinary consumer. He testified that, “[i]n fact, my years of experience as a pharmacist and my thousands of interactions with consumers/patients lead me to the opinion that ordinary consumer/patient does not contemplate any serious adverse event from taking OTC Aleve as directed on the label.” [Doc. 30-1 at 126.]

Dr. Patel clarified his statement by stating that a consumer would understand the serious adverse events listed on label if the consumer had read the label. *Id.* However, he testified that he is not aware of how the Food and Drug Administration determines what should be on a label for over-the-counter medications nor has he reviewed any type of analysis as to drug labeling. [Doc. 30-1 at 34.]

He states that his opinion is based on his experience as a retail pharmacist who, “regularly interacted with consumers/patients and understand their level of awareness regarding OTC medicine and serious injuries and NSAIDs and kidney injury.” [Doc. 30-2 at 13.] He admits he is not a marketing expert and has never conducted any studies regarding the expectations of consumers with regard to over-the-counter medications. [Doc. 30-1 at 46.]

The Court acknowledges Dr. Patel's years of experience as pharmacist, but again, that experience only translates to general pharmaceutical knowledge and experience with a limited number of consumers and/or patients in a specific geographical area. There is no support within his report or deposition testimony that Dr. Patel has specific expert knowledge with regard to consumer expectations with regard to over-the-counter medications.

How many consumers read the warning labels prior to purchasing over-the-counter NSAIDs? Do they expect only the potential side effects listed on the product's label? Do consumers in large cities read warning labels more than consumers in rural areas? What effect does reading the warning have on the consumption of the product? What risks do consumers associate with over-the-counter NSAIDs? Basically, what do consumers expect when purchasing over-the-counter NSAIDs? If Dr. Patel cannot cite to any studies that indicate what consumers expect with regard to NSAIDs – or with any over-the-counter medication for that matter- then how can he opine, “that ordinary consumer/patient does not contemplate any serious adverse event from taking OTC Aleve as directed on the label.” He may be able to opine that the patients/consumers he has worked with do not expect any serious adverse effects from over-the-counter drugs, but there is no indication that he sought that type of information for each of the individuals he had contact with. There is simply too great an analytical gap between the data and the opinion offered.

Finally, Dr. Patel clearly does not have the necessary background to offer an opinion on whether the risk and danger of Aleve® outweighs its benefits. His entire opinion is based on the fact that there are alternative topical analgesics that may achieve the same relief benefit. That is like saying an individual could safely ride the train to work and thus have avoided a car accident. There are risks/benefits associated with a train and there are risk/benefits associated with car.

Dr. Patel's own testimony indicates that the determination of whether an alternative medication would have been beneficial to Mr. Hale would have needed to be done by his treating physician. Further, the only risk Dr. Patel references is the risk of kidney injury without discussing any other potential risk. The only benefit of Aleve® that Dr. Patel discussed was the generally known benefit of pain relief. There is no indication of a complete risk/benefit analysis being conducted by Dr. Patel and/or that Dr. Patel relied on any studies with regard to a risk/benefit analysis of Aleve®.

In his report, Dr. Patel states that, “[i]n forming the opinions expressed in this report I have considered medical records for Mr. Kenneth Hale, Deposition transcripts (Dr. Erik Daniels, Mr. Kenneth Hale), and several CDs which contain the flowing [sic]: Bayer APR, FDA AERs, Labeling information of Aleve, FDA Med Watch reports for Aleve, and package insert information for the products of Aleve and Naproxen sodium.” [Doc. 30-2, pg 14.]

Because of their limitations, case reports have been repeatedly rejected as a scientific basis for a conclusion regarding causation. Such case reports are not reliable scientific evidence of causation, because they simply describe reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group ... [T]hey do not isolate and exclude potentially alternative causes ... and do not investigate or explain the mechanism of causation.

Hollander v. Sandoz Pharm. Corp., 95 F. Supp. 2d 1230, 1237 (W.D. Okla. 2000), *aff'd in part and remanded*, 289 F.3d 1193 (10th Cir. 2002).

This Court has previously rejected experts' opinions inasmuch as they rely on case reports. *See Caraker v. Sandoz Pharm. Corp.*, 96-cv-04114, SDIL (Doc. 318, 2002)(case reports ‘make little attempt to isolate or exclude possible alternative causes, lack adequate controls and analysis.’). That leaves Dr. Patel's opinion to be based upon his review Mr. Hale's medical

records, depositions testimonies, labeling information, and package inserts. Again, this is simply too great an analytical leap between the data and the opinion offered since there is no evidence of any risk/benefit analysis being conducted.

As discussed above, expert opinions must be based a theory or technique that is capable of being or has been tested; subjected to peer review and publication; and/or be within the field of expertise claimed by the expert known to reach reliable results for the type of opinion the expert would give. Dr. Patel has provided no support – other than his general experience – of the opinions he has tendered in this matter. As such, the Court finds that Dr. Patel’s opinions are unreliable based on the lack of supporting data as required by Federal Rule of Evidence 702(b).

3. Defendants’ Motion for Summary Judgment.

The initial summary judgment burden of production is on the moving party to show the Court that there is no reason to have a trial. *Celotex*, 477 U.S. at 323; *Modrowski v. Pigatto*, 712 F.3d 1166, 1168 (7th Cir. 2013). Where the non-moving party carries the burden of proof at trial, the moving party may satisfy its burden of production in one of two ways. It may present evidence that affirmatively negates an essential element of the non-moving party’s case, *see* Fed. R. Civ. P. 56(c)(1)(A), or it may point to an absence of evidence to support an essential element of the non-moving party’s case without actually submitting any evidence, *see* Fed. R. Civ. P. 56(c)(1)(B). *Celotex*, 477 U.S. at 322-25; *Modrowski*, 712 F.3d at 1169. Where the moving party fails to meet its strict burden, a court cannot enter summary judgment for the moving party even if the opposing party fails to present relevant evidence in response to the motion. *Cooper v. Lane*, 969 F.2d 368, 371 (7th Cir. 1992).

In responding to a summary judgment motion, the nonmoving party may not simply rest upon the allegations contained in the pleadings but must present specific facts to show that a

genuine issue of material fact exists. *Celotex*, 477 U.S. at 322-26; *Anderson*, 477 U.S. at 256-57; *Modrowski*, 712 F.3d at 1168. A genuine issue of material fact is not demonstrated by the mere existence of “some alleged factual dispute between the parties,” *Anderson*, 477 U.S. at 247, or by “some metaphysical doubt as to the material facts,” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Rather, a genuine issue of material fact exists only if “a fair-minded jury could return a verdict for the [nonmoving party] on the evidence presented.” *Anderson*, 477 U.S. at 252.

As the Seventh Circuit Court of Appeals has repeatedly stated, “summary judgment is the ‘put up or shut up’ moment in the life of a case.” *AA Sales & Assocs. v. Coni-Seal, Inc.*, 550 F.3d 605, 612 (7th Cir. 2008).

Defendants’ motion for summary judgment argues that there is no competent evidence that Aleve® caused plaintiff Kenneth Hale’s alleged kidney injury. First, the defendants state that, “[a]s a matter of law, without sufficient admissible expert testimony, plaintiff cannot establish causation.” [Doc. 33 at 10.] They argue that there are, “no tests that can be given by a physician that can tell whether NSAIDs caused a given patient’s MCD.” As such, the defendants argue that the plaintiffs can “rule in” Aleve® as possible cause for Mr. Hale’s kidney injury, but that the plaintiffs cannot “rule out” that the majority of MCD is idiopathic. Defendants state that expert testimony, “must not only establish a credible basis for a reasonable inference that the drug proximately caused the injury, it must also eliminate reasonable secondary causes.” [Doc. 33 at 10 (*citations omitted*).]

In products liability cases in which the plaintiff alleges a design defect, Illinois (whose law supplies the substantive rules) permits the claim to be established “in either of two ways. First, the plaintiff may introduce ‘evidence that the product failed to perform as safely as an ordinary consumer would expect when used in an

intended or reasonably foreseeable manner.’ This has come to be known as the consumer-expectation test. Second, the plaintiff may introduce ‘evidence that the product's design proximately caused his injury.’ If the defendant thereafter ‘fails to prove that on balance the benefits of the challenged design outweigh the risk of danger inherent in such designs,’ the plaintiff will prevail. This test, which added the balancing of risks and benefits to the alternative design and feasibility inquiries ..., has come to be known as the risk-utility or risk-benefit test.”

Show v. Ford Motor Co., 659 F.3d 584, 585 (7th Cir. 2011)(*internal citations omitted*).

Language in *Mikolajczyk* raises the question whether Illinois treats the risk-utility and consumer-expectations approaches as distinct legal doctrines, or as aspects of a more general theory of liability: that a product is unreasonably dangerous. After an extended discussion of its cases, the Supreme Court of Illinois wrote: “In [an earlier decision], we stated that a plaintiff ‘may demonstrate that a product is defective in design, so as to subject a retailer and a manufacturer to strict liability for resulting injuries, in one of two ways.’ We then set out the consumer-expectation test and the risk-utility test. These two tests, therefore, are not *theories of liability*; they are *methods of proof* by which a plaintiff ‘may demonstrate’ that the element of unreasonable dangerousness is met.”

Id. at 585–86 (citing 231 Ill.2d at 548, 327 Ill.Dec. 1, 901 N.E.2d 329 (emphasis in original; citations omitted).

In this case, the plaintiffs cannot demonstrate – at least not through expert testimony – that Aleve® “failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner” or “that the product's design proximately caused his injury.” *Id.* Dr. Patel’s opinions with regard to “foreseeable” and “consumer expectations” have been barred along with the causation opinions of Dr. Daniels and Dr. Hoelscher.

Plaintiffs argue that, “[b]ecause Dr. Morrison² testified the Aleve label should warn of potential kidney injury, the strict product liability summary judgment is improper.” [Doc. 41 at 7.] However, Dr. Morrison’s testimony with regard to the Aleve® label is not sufficient evidence that “the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.” Nor is it sufficient evidence that the design of Aleve® caused Mr. Hale’s injury. It is only an opinion that potential kidney injury should be added to the label, but as with Dr. Patel, Dr. Morrison is not an expert on warning labels – he is physician with a subspecialty in nephrology. As such, it fails under both the consumer-expectation and the risk-utility test methods of proof.

At oral arguments, Plaintiff cited to *Milolajczyk v. Ford Motor Co.*, 231 Ill.2d 516, and argued that no expert testimony is required. The *Milolajczyk* court stated that:

The consumer-expectation test is a single-factor test and, therefore, narrow in scope. The jury is asked to make a single determination: whether the product is unsafe when put to a use that is reasonably foreseeable considering its nature and function. No evidence of ordinary consumer expectations is required, because the members of the jury may rely on their own experiences to determine what an ordinary consumer would expect.

The risk-utility test, in contrast, is a multifactor analysis and, therefore, much broader in scope. Under an “integrated” test, as envisioned by the *Mele* and *Besse* courts, consumer expectations are but one of the factors to be considered.

Id., 901 N.E.2d 329, 352 (Ill. 2008), *opinion modified on denial of reh'g* (Dec. 18, 2008).

The plaintiffs argued that the, “Plaintiff can choose which one [method of proof] to go forward on” and that “[w]e have chosen to go forward on the consumer expectation test.” Hearing TR at 7. Plaintiffs then acknowledged that the defendants could then, “bring forward a

² Dr. Aubrey Morrison, M.D. is defendants’ retained expert.

positive risk utility test.” Once a risk utility test is brought forward, the consumer expectation test becomes one of several factors under the risk utility test. “Each party is entitled to choose its own method of proof, to present relevant evidence, and to request a corresponding jury instruction. If the evidence is sufficient to implicate the risk-utility test, the broader test, which incorporates the factor of consumer expectations, is to be applied by the finder of fact.” *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 352–53 (Ill. 2008), *opinion modified on denial of reh'g* (Dec. 18, 2008). As such, it is not solely the determination of the plaintiffs on what manner of proof would be required.

The plaintiffs further cited to *Show* for the proposition that expert testimony is not required. *Show* indicates that the Supreme Court of Illinois “has not considered any design-defect suit involving a complex product, such as a car, in which the plaintiff declined to produce expert evidence, so they have not definitively held that such testimony is essential.” *Id.* at 585. However, the *Show* court notes that, “[m]any federal civil cases are resolved by six-person juries, and none by more than twelve. That is too few to reveal what expectations consumers as a whole may have. Professional surveys of consumers’ beliefs entail carefully designed questions put to hundreds of persons. If federal courts require expert evidence, in trademark and credit suits, why not in product-design-defect cases? Jurors know less about product design than they know about what confuses people who buy toothpaste or borrow \$10,000.” *Show v. Ford Motor Co.*, 659 F.3d 584, 586 (7th Cir. 2011)(*internal citations omitted*). The Court went on to note that, “Federal law often requires expert evidence about consumers’ knowledge and behavior, because jurors are supposed to decide on the basis of the record rather than their own intuitions and assumptions.” *Id.* at 586. The *Show* court further stated, “[i]f, as plaintiffs concede, it takes expert evidence to establish a complex product’s unreasonable dangerousness through a

risk-utility approach, it also takes expert evidence to establish a complex product's unreasonable dangerousness through a consumer-expectations approach." *Id.* at 587. Finally, the *Show* court pointed out that, "[b]ecause consumer expectations are just one factor in the inquiry whether a product is unreasonably dangerous, a jury unassisted by expert testimony would have to rely on speculation." *Id.* at 588. Therefore, although not mandated, *Show* strongly suggests that consumer-expectation method of proof requires expert testimony when the product is complex.

Aleve® is a NSAIDs drug. Drugs, by their very nature and design, are complex. To bring an over-the-counter drug to market involves – well, the Court is not certain. After thoroughly reviewing all documents in this matter, the Court still isn't aware of what the FDA requires on a drug label; or how it would be determined whether potential kidney injury should be included in a warning label; or whether that determination is based on clinical studies or reported incidents of the injury. If such a warning was included, would the average consumer read the label? Would the consumer reading a label not take the over-the-counter drug?

The Court agrees with plaintiff that *Show* does not mandate expert testimony in the consumer-expectation method of proof and that the *Poulter*³ court addressed *Show* and clarified that the Court should apply the, "accepting state law as controlling questions of what evidence is required to prove a case." *Poulter v. Cottrell, Inc.*, 2016 WL 7451630 * 2 (NDIL December 28, 2016). However, even assuming that the jury may rely on their own experiences to determine what an ordinary consumer would expect, plaintiffs have not demonstrated that Aleve® is unsafe. As stated above, the consumer-expectation test asks the jury to make a single determination: whether the product is unsafe when put to a use that is reasonably foreseeable considering its nature and function. In this case, every expert deposed stated that they believe

³ *Poulter v. Cottrell, Inc.*, 2016 WL 7451630 (N.D. IL December 28, 2016) was cited by plaintiffs at oral arguments.

Aleve® to be safe and effective when used as directed.⁴

The complaint also alleges negligence; breach of warranty; willful and wanton conduct; and on behalf of plaintiff Viki Hale, loss of consortium. All these claims require, among other elements, that Aleve® caused the plaintiffs' injuries. The element of causation is essential to these claims and renders all other elements immaterial.

Plaintiffs have not produced any admissible evidence from which a reasonable fact-finder could infer that Aleve® was cause of Mr. Hale's MCD. The plaintiffs – with or without the experts addressed above - have only established a temporal relationship between Mr. Hale's consumption of Aleve® and his MCD. Such a temporal relationship is not enough to survive summary judgment. Plaintiff Viki Hale's claim is derivative of Kenneth Hale's claims and as such, also cannot survive summary judgment.

4. Plaintiffs' Motion for Partial Summary Judgment.

Plaintiffs' Motion for Partial Summary Judgment is moot based upon the granting of Defendants' Motion for Summary Judgment.

5. Conclusion

Based on the above, Defendants' Motion [Doc. 30] to Exclude Plaintiffs' Experts' Opinions is **GRANTED** in part and **DENIED** in part; Defendants' Motion [Doc. 32] for Summary Judgment is **GRANTED**; and Plaintiffs' Motion [Doc. 34] for partial Summary Judgment is **MOOT**. This matter is **DISMISSED** without prejudice.

⁴ Dr. Daniels testified Aleve® safe and effective depending on the patient population. Doc. 33-4 at 9. Dr. Patel testified "over-the-counter product approved by the Food and Drug Administration considered to be safe and effective when taken as directed." Doc. 33-5 at. 54. Dr. Ho testified that in his experience, naproxen sodium was a safe drug. Doc. 33-2 at 42.

The Clerk of Court is **DIRECTED** to enter judgment accordingly.

IT IS SO ORDERED.

DATED: 4/20/2017

s/J. Phil Gilbert

J. PHIL GILBERT
U.S. DISTRICT JUDGE