Order Form (01/2005)

## **United States District Court, Northern District of Illinois**

Name of Assigned Judge or Magistrate Judge	Matthew F. Kennelly	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	09 C 3908	DATE	5/5/2011
CASE TITLE	Smith, et al. vs. I-Flow Corp.		

## DOCKET ENTRY TEXT

For the reasons stated below, the Court grants plaintiff's motion to strike certain opinions in part and denies it in part [# 130].

For further details see text below.]

Docketing to mail notices.

## **STATEMENT**

Amanda Smith and James Smith have sued I-Flow Corporation, alleging that Mrs. Smith suffered a disabling injury after using a pain pump manufactured by I-Flow. The Smiths have moved to strike certain opinions of two of I-Flow's designated expert witnesses. For the reasons stated below, the Court denies the motion as to Dr. Wayne Burkhead and grants the motion in part and denies it in part as to Timothy Budacki.

When considering the admissibility of expert witness testimony under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), a courts "must determine whether the witness is qualified; whether the expert's methodology is scientifically reliable; and whether the testimony will assist the trier of fact to understand the evidence or to determine a fact in issue." In making this determination, courts may consider a number of factors, such as (1) whether the scientific knowledge has been, or can be, tested; (2) whether the proffered theory or technique has been subjected to peer review or published; (3) the known or potential rate of error; and (4) whether the theory or technique has gained general acceptance in the relevant field. *Id.* at 592-94.

The Smiths challenge several opinions of Dr. Burkhead, who offers testimony on general and specific causation. They contend that Dr. Burkhead did not have a reliable scientific foundation for opining that (1) intra-articular use of pain pumps does not cause chondrolysis, (2) studies have shown an association between intra-articular infusion of anesthetic in combination with epinephrine, (3) younger people have an increased risk of suffering from chondrolysis because their shoulder plates are not completely fused, and (4) Mrs. Smith's chondrolysis was caused by bioabsorbable anchors. The Court disagrees. Dr. Burkhead's expert report provides a detailed discussion of peer-reviewed studies from the medical literature supporting each of these opinions. The Smiths object to Dr. Burkhead's extrapolations from this evidence, but these objections go to the weight of his testimony, not its admissibility. The Smiths will have an opportunity to challenge these conclusions at trial via cross-examination. *See Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000) ("The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact").

## **STATEMENT**

The Smiths also seek to bar expert testimony from Mr. Budacki, whose testimony I-Flow offers on the issue of whether the warnings it placed on its pain pumps were adequate. Specifically, they seek to exclude his opinions that (1) at the relevant time, there was no known association between intra-articular use of pain pumps and chondrolysis; (2) information concerning the risk of chondrolysis was not known or understood when I-Flow's the product was sold; (3) the warnings and instructions provided on the pain pumps were adequate; and (4) inadequate warnings did not cause or contribute to Mrs. Smith's injuries.

Mr. Budacki is a product safety and human factors consultant. He is not a medical doctor or a medical researcher and does not appear to have significant training in those fields. I-Flow does not contend otherwise; it says that Mr. Budacki has expertise "in the context of the manufacture and sale of medical devices." Def.'s Resp. to Pls.' Mot. to Strike at 12. I-Flow makes no effort to show that Mr. Budacki has the qualifications required to render an expert opinion on what the medical literature and research showed at the relevant time. *See id.* at 13 (arguing only, in conclusory terms, that he has "extensive experience in the human factors field, specifically relating to warnings and risk management."). The Court sustains the Smiths' motion as to points (1) and (2) above for this reason. *See Gayton v. McCoy*, 593 F.3d 610, 617 (7th Cir. 2010) ("The question we must ask is not whether an expert witness is qualified in general, but whether his qualifications provide a foundation for him to answer a specific question") (internal quotation marks omitted); *Mihailovich v. Laatsch*, 359 F.3d 892, 918 (7th Cir. 2004) ("Rule 702 permits a witness whose knowledge, skill, experience, or training has granted him expertise *in a particular field* to testify in the form of an opinion regarding one or more issues in the case") (emphasis added).

The Court overrules, however, the Smiths' argument that Mr. Budacki cannot properly testify regarding the adequacy of I-Flow's warnings. His expert report reflects that he has the necessary expertise in this field. In light of the Court's ruling barring Mr. Budacki from rendering opinions regarding the state of medical or scientific knowledge at the relevant time, it is not entirely clear how I-Flow will lay the predicate for Mr. Budacki to testify on this topic. It is likely, however, that I-Flow will be able to do so by, for example, hypothetical questions that ask him to assume certain facts (so long as those assumptions are supported by other evidence) or by reference to the testimony of other experts.

Finally, in his expert report, Mr. Budacki also offers an opinion on the cause of Amanda Smith's injury. *See* Pls.' Mot. to Strike, Ex. 23 at 12 ("The harm that occurred to Amanda Smith was not the result of a device malfunction, design flaw or defectively or inadequately designed warnings on I-Flow's part"). There is no indication in the parties' submissions or in Mr. Budacki's report that he has any experience in determining the cause of a medical condition. Without such expertise, he cannot properly testify regarding on specific causation or non-causation.