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	6/15/2011
CASE TITLE	Smith, et al. vs. I-Flow Corp.		

DOCKET ENTRY TEXT

The Court rules on defendant's motions *in limine* [# 167] as stated below. The Court advises that it anticipates entering an order on the morning of 6/16/11 dealing with most, and perhaps all, of plaintiffs' motions *in limine*.

■[For further details see text below.] Docketing to mail notices.

STATEMENT

The Court has reviewed the parties' motions *in limine* and the written responses to those motions. Further argument will be required on the following defense motions: 4, 5, 6, 7, 9, 12, and 18. On most of these, the Court has specific questions that it will pose at the final pretrial conference.

The appropriate resolution of the remainder of the defense motions is clear enough that no further argument on those motions is required, except as set forth below. The Court makes the following rulings:

1. The Court denies I-Flow's motion to bar "inaccurate statements regarding I-Flow's regulatory compliance, regulatory decisions . . . and duties arising under applicable regulations." I-Flow's arguments may bear on the weight to be given the evidence in question, but they do not affect its admissibility. In any event, the Court does not perceive that the evidence in question amounts to a mischaracterization of historical events. The evidence is relevant regarding, among other things, the existence of a duty to warn and I-Flow's knowledge of alleged risks from its pain pump. It may be true, as I-Flow argues, that certain actions by the FDA did not, by themselves, trigger a duty to warn. But those events are evidence that, with other facts, a jury might find trigger a duty to warn. Finally, plaintiffs' introduction of evidence of regulatory non-compliance does not, contrary to I-Flow's argument, amount to an attempt to enforce the Food, Drug, and Cosmetic Act via a private suit.

2. Evidence of remedial actions that I-Flow took after the date of plaintiff Amanda Smith's surgery is, in general, inadmissible pursuant to Federal Rule of Evidence 407. The Court is unpersuaded by plaintiffs' argument that evidence regarding later changes in I-Flow's "directions for use" and technical bulletins regarding its pain pump is appropriately admissible to show the feasibility of issuing such precautions, as plaintiffs have not given the Court any reason to believe that feasibility is a disputed or otherwise material issue in the case. Nor is the Court persuaded by plaintiff's argument that such evidence is relevant on the

issues of motive, duty, or breach, as plaintiffs contend without much explanation.

All of that said, the Court is unable to impose a hard-and-fast rule that evidence postdating Ms. Smith's surgery is inadmissible for that reason alone. Some of the post-surgery evidence cited by plaintiffs is admissible, at least in part, because it sheds light on I-Flow's knowledge or conduct prior to the date of the surgery and is not precluded from admission under Federal Rule of Evidence 403. Examples include the October 2007 Rodriguez e-mail indicating that I-Flow had been award of chondrolysis issues regarding the pain pumps for "several years" and the statement in a November 2009 FDA bulletin that the agency had never cleared infusion devices with an indication for use in intra-articular infusion of local anesthetics (the Court hastens to add that this does not necessarily make the entirety of that bulletin admissible). On the issue of hearsay, the Court is persuaded that the FDA bulletins meet the requirements of Federal Rule of Evidence 803(8).

The Court cautions that if I-Flow argues or introduces evidence suggesting that the FDA "never" voiced safety concerns at any time (as opposed to arguing that the FDA voiced no such concerns prior to Ms. Smith's surgery), that may open the door to the admission of evidence regarding concerns the FDA expressed after the date of Ms. Smith's surgery. Absent that, however, the FDA's December 2008 warning letter expressing such concerns is inadmissible as irrelevant and under Federal Rule of Evidence 403 due to the potential for unfair prejudice that far outweighs any limited probative value the letter might have regarding the issues the jury will be called upon to decide.

The Court is unpersuaded that Mr. Earhart's stock transactions are relevant to any disputed issue relating to liability for compensatory damages. The Court will entertain, at an appropriate point during the trial, further argument regarding whether this evidence is relevant and admissible on the issue of punitive damages, an issue the Court assumes it will bifurcate when presented with a request to do so (see further discussion below).

Finally, though the Court agrees with I-Flow that medical literature post-dating the relevant events is inadmissible to show notice, it may be relevant and admissible for other purposes, such to prove causation. Because I-Flow has not identified the particular medical literature at issue in this part of its motion, the Court is not in a position to identify exactly what literature is appropriately admissible. The Court also notes that it will be up to I-Flow to propose an appropriate limiting instruction advising the jury that it may not consider such evidence for the purpose of showing notice to I-Flow.

3. The Court denies I-Flow's motion to exclude the deposition testimony of Irene Naveau, a reviewer with the FDA, and a memorandum that Naveau wrote in 1998. I-Flow appears to contend that the FDA granted clearance for use of its pain pump and that this authorized its use within the shoulder joint, which is what is at issue in this case. *See, e.g.,* Def.'s Mot. *In Limine* at 3. Naveau's memorandum and testimony are relevant and admissible (and are not unfairly prejudicial) because, among other things, they tend to refute this contention and clarify what the FDA approved and what it did not approve. The Court also rejects I-Flow's argument that the memorandum is inadmissible hearsay (or contains hearsay-within-hearsay) and finds that the memorandum, in its entirety, is admissible under Federal Rule of Evidence 803(8). In this regard, the Court agrees with Judge Ann Aiken's thorough analysis in *McClellan v. I-Flow Corp.*, Nos. 07-1309-AA, 07-1310-AA & 08-478AA, 2010 WL 3954092 (D. Or. Oct. 7, 2010).

10. The Court denies I-Flow's motion asking the Court to bar evidence of a "retrospective case series evaluation" performed by Dr. Frederick Matsen and Dr. Brett Winter. I-Flow's entire argument is that

another court precluded the study in a separate case and that this Court should do so as well. *See* Def.'s Mot. *In Limine* at 39-41. Specifically, I-Flow notes that the judge in *McClellan v. I-Flow Corp.* excluded the study on the ground that it was unreliable because, among other things, it was tainted by litigation bias due to the role of attorneys for plaintiffs in pain pump cases in conceiving and directing the study, and because it was unfinished. Plaintiffs argue in response that following the *McClellan* ruling, the study was published in a peer-reviewed medical journal even after disclosure that attorneys had financially supported the study. These changed circumstances make I-Flow's bare reliance on the *McClellan* ruling inappropriate (assuming that bare reliance on a non-binding ruling otherwise would have been appropriate, a proposition the Court does not accept). In short, given the circumstances, I-Flow's cursory argument is insufficiently developed to warrant excluding the study.

11. The Court denies I-Flow's motion to bar evidence regarding a 2004 e-mail from I-Flow sales representative Cheryle Pritchard to Alan Dine, I-Flow's director of clinical research. I-Flow's arguments regarding the e-mail go to the weight to be given to it, not its admissibility.

13. I-Flow asks the Court to exclude evidence and argument "relating to the manufacture and assembly" of its pain pumps. Defs.' Mot. *In Limine* at 44. Stated that way, the motion is overly broad. The title of this section of the motion, however, suggests that I-Flow's argument is limited to evidence regarding *where* the pumps were manufactured and assembled – namely, Mexico. Plaintiffs have offered no basis for a contention that the fact the pumps were manufactured and assembled in Mexico is relevant to any issue to be tried in the case. For this reason, and because such evidence would be unfairly prejudicial in a way that far outweighs any conceivable probative value of the evidence, the Court grants I-Flow's motion to that extent. If I-Flow seeks to bar evidence beyond this via this part of its motion, it should be prepared to advise the Court at the pretrial conference specifically what it seeks to preclude.

14. In a previous ruling, the Court indicated that it was open to bifurcating the issue of punitive damages from the other issues in the case. As far as the Court is aware, no formal motion seeking bifurcation has yet been filed. In section 14 of its motion *in limine*, I-Flow asks the Court to bar evidence relevant only to a claim for punitive damages until it determines there is a colorable claim for such damages. This is inappropriate as a motion *in limine*. Federal Rule of Civil Procedure 50(a) provides I-Flow with all the opportunity it needs to seek a ruling on the sufficiency of the evidence supporting the request for punitive damages once plaintiffs have been "fully heard" on that issue.

The Court notes that if any party makes a formal motion to bifurcate, both sides should be prepared to explain, given the overlap between liability for compensatory damages and liability for punitive damages, what evidence would be admissible only at the punitive damages phase of a bifurcated trial.

In addition, plaintiffs should be prepared to advise the Court how they contend (as they appear to do in their response to I-Flow's motion) that evidence regarding I-Flow's financial condition is relevant to any issue *other than* punitive damages. *See* Pls.' Resp. to Def.'s Mot. *In Limine* at 43-44.

The Court also notes that I-Flow appears to make an argument against punitive damages via a conclusory and unexplained sentence in a footnote (the second sentence of footnote 14). That is insufficient to preserve the issue, so it is forfeited for present purposes.

15. I-Flow seeks to bar evidence suggesting that its pain pumps were defective. It notes that plaintiffs advanced in their complaint an allegation of defective design and manufacturing. In response, plaintiffs argue

that under Michigan law, which governs liability for compensatory damages, a product is defective when distributed without sufficient warnings. The Court does not understand I-Flow to contend that plaintiffs should be precluded from advancing their failure to warn theory. Rather, the Court understands I-Flow to contend that plaintiffs should be precluded from arguing that the product's design was defective or that it was manufactured in a way that rendered it defective. Plaintiffs should be prepared to advise the Court at the hearing whether they intend to advance any such contentions at trial and if so, what evidence they have that supports such contentions.

16. I-Flow asks the Court to bar certain testimony by Ms. Smith's treating physician Dr. Julie Dodds. The title of section 16 of its motion, however, is worded in a way that appears to apply to all of Ms. Smith's treating physicians, not just Dr. Dodds. Plaintiffs respond that the Court has already ruled. That is partly correct and partly incorrect. The Court ruled on the admissibility of Dr. Jon Sekiya's testimony in its May 3, 2010 decision regarding I-Flow's motion to exclude certain opinions. The Court has not yet ruled, however, regarding Dr. Dodds or Dr. Michael Shingles. At the pretrial conference: 1) I-Flow should be prepared to advise the Court whether their motion concerns any treating physician other than Dr. Dodds; 2) if I-Flow's motion also concerns Dr. Sekiya, I-Flow should be prepared to state what appropriate basis it has for reconsideration; 3) to the extent I-Flow's motion concerns Dr. Dodds and Dr. Shingles, both sides should be prepared to address whether and to what extent the issues regarding these physicians are the same as or different from those the Court considered in connection with Dr. Sekiya's testimony.

17. The Court denies I-Flow's request to bar use in opening statement of excerpts from video deposition testimony. The Court will expect plaintiffs to disclose by no later than noon on the Friday before the start of trial any such excerpts they intend to use in opening statements and will expect defendants to make reciprocal disclosures by no later than 5:00 p.m. on the Saturday before the start of trial.