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SUPERIOR COURT OF NEW JERSEY

COUNTIES OF
ATLANTIC AND CAPE MAY

CAROL E. HIGBEE, P.J.Cv.

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MEMORANDUM OF DECISION ON MOTION
Pursuant to Rule 1:6-2(f)

CASE: **McCarrell v. Hoffmann-La Roche, Inc. and Roche Laboratories, Inc.**

DOCKET #: **ATL-L-1951-03**

DATE: **September 12, 2011**

MOTION: **New Trial, Judgment Notwithstanding the Verdict, or Remittitur**

ATTORNEYS: **David Buchanan, Esq. – Plaintiff**
Michelle Bufano, Esq. - Defendant

Having carefully reviewed the papers submitted and any response received, I have ruled on the above Motion as follows:

Nature of Motion

Following a five week trial in which Andrew McCarrell was awarded $25,159,540.19 for the injuries he sustained after ingesting Accutane, defendants now bring this motion for a new trial, judgment notwithstanding the verdict, or remittitur. Plaintiff opposes the motion.

Factual and Procedural History

Plaintiff Andrew McCarrell took Accutane from June 22, 1995 through October 19, 1995, for treatment of his acne. In August of 1996, while on vacation in Panama City, McCarrell began to experience stomach pain and diarrhea, which appeared to have resolved themselves while on vacation. On September 3, 1996, McCarrell visited Dr. James Allen, a general practitioner, for his flu-like symptoms and tests revealed that Plaintiff was anemic. McCarrell decided to go back to Dr. Allen after he continued to have intermittent diarrhea throughout September and October of 1996. At that visit, Dr. Allen put McCarrell on Pepto-Bismol, Tetracycline and Flagyl.

McCarrell's condition continued to deteriorate. Dr. Allen referred him to Dr. Mark Janich, a gastroenterologist. On November 26, 1996, Dr. Janich performed a colonoscopy and diagnosed McCarrell with inflammatory bowel disease ("IBD"). In December 1996, McCarrell underwent a total colectomy, which removed his colon and rectum, and the surgeon created a "j-pouch" out of Plaintiff's small intestine. McCarrell's second surgery occurred in January 1998 when a rectal abscess was surgically removed from his anus. By April 1998, McCarrell had to have a third surgery, an ileostomy, to cure his pouchitis in his j-pouch. Plaintiff lived with a colostomy bag for the next four and half years. On November 5, 2002, McCarrell underwent his fourth surgery to reattach his small intestine to the j-pouch. He continues to suffer from severe abdominal cramping and multiple bowel movements every day with episodes of incontinence. He will never have a normal bowel movement. The primary function of the colon is to remove water from the fecal waste and he no longer has his colon.

In July 2003, McCarrell filed his complaint against Hoffman-La Roche ("Roche"). His first trial began on April 30, 2007 and proceeded through May 29, 2007, when the jury returned a

verdict in favor of McCarrell for $2,619,000. On February 8, 2008, this court denied Roche's motion for judgment notwithstanding the verdict or in the alternative for a new trial.

Roche appealed this court's denial of its motion to the Appellate Division. The Appellate Division issued a 113-page decision on March 12, 2009, affirming the trial court on all but one point, reversing on a single evidentiary ruling, and remanded the matter for a new trial. The Appellate Division found this court erred when it precluded Roche from placing the number of adverse events reported by Accutane users "into a larger quantitative context" by allowing the defense to enter testimony on the number of users of Accutane during the time the adverse events were reported.

The opening statements for the retrial of this matter took place on January 13, 2010. At the close of plaintiff's case, Roche moved for a directed verdict, which was denied. The motion was renewed and again denied at the close of the case. Closing arguments took place on February 9, 2010 and the jury returned on February 16, 2010 to deliberate. The jury returned a verdict for McCarrell in the unanimous total amount of $25,159,530.19, which was broken down into $159,540.19 for compensatory damages and $25 million for disability, impairment, loss of enjoyment of life, pain and suffering. This court had dismissed plaintiff's claim for punitive damages before the first trial.

Standard of Review

Pursuant to R. 4:49-1(a), a motion for a new trial shall be granted "if, having given due regard to the opportunity of the jury to pass upon the credibility of the witnesses, it clearly and convincingly appears that there was a miscarriage of justice under the law." When deciding a motion for a new trial, the evidence should be viewed in the light most favorable to the non-moving party. Lanzet v. Greenberg, 126 N.J. 168, 174 (1991). The trial court's function on a motion for a new trial is to consider both the tangible and credibility factors and the feel of the

case to determine if the jury's verdict was a clear error or mistake. Kita v. Borough of Lindenwold, 305 N.J. Super. 43, 49 (App. Div. 1997). A jury verdict should only be set aside sparingly in favor of a new trial and only in cases of clear injustice. Boryszewski v. Burke, 380 N.J. Super. 361, 391 (App. Div. 2005), certif. den. 186 N.J. 242 (2006).

A motion for judgment notwithstanding the verdict must be granted if reasonable minds could not differ as to the conclusions to be drawn from the proofs. When deciding such a motion, the court must "accept as true all of the evidence that supports the position of the opposing party and must accord that party the benefit of all the legitimate inferences that can be deducted therefrom," and if reasonable minds could differ, the motion must be denied.

Discussion

Verdict Form and Inconsistent Verdicts

Defendant's first argument for a new trial is based on the jury verdict form. Defense argues the verdict sheet failed to ask the central question "Did Accutane cause Plaintiff's IBD?" and furthermore that the verdict sheet was inconsistent with the proximate cause instructions contained in the jury charge and as required by Alabama law.

In charging the jury, this court explained the second element Plaintiff must prove in a failure to warn claim as follows: "Two, that Accutane was a proximate cause of Mr. McCarrell's injury and damages. And I will describe what proximate cause is in a moment." (Feb. 16, 2010 Tr. 22:8-10). This court then proceeded to explain proximate cause:

> If you find that Roche failed to provide an adequate warning then you must consider first whether a stronger warning would have resulted in plaintiff not being prescribed and/or plaintiff not taking the drug. To prove proximate cause the **plaintiff must also prove that Accutane was a cause of his IBD**, but he need not prove that Accutane was the only cause. The cause of harm is that cause that naturally and probably brings about the harm.
>
> [Feb. 16, 2010 Tr. 22:11-19.]

The verdict sheet contained the following question with regard to causation: "Was Roche's failure to warn a proximate cause of Plaintiff's inflammatory bowel disease?"

This court finds no error with the jury verdict form. As Roche acknowledged, this court provided a two-pronged inquiry with respect to proximate cause during the jury charge. Roche's contention is that this court then erred by failing to break down the proximate cause question on the verdict sheet into two subparts. This court does not find this argument persuasive. The jury was adequately and appropriately charged with respect to proximate cause. They were told to consider whether McCarrell would not have been prescribed Accutane, or whether he would not have taken Accutane, if there had been a stronger warning. They were also told to consider whether Accutane caused McCarrell's IBD. In fact, the defense argued to the jury that the Flagyl, tetracycline and Pepto-Bismol caused his IBD. This was hotly contested during the trial. There was ample evidence to support the jury's finding that plaintiff's IBD was caused by Accutane.

Additionally, a jury verdict form is read in conjunction with the jury charge. "An accurate and thorough jury charge often can cure the potential for confusion that may be present in an interrogatory." Sons of Thunder v. Borden, Inc., 148 N.J. 396, 491 (1997). Therefore, if there was any confusion with the jury verdict form, which this court does not find, then the clear and thorough jury charge would have cured any confusion by providing the two-step inquiry that Roche argues is vital to the case.

Defendant next argues that Juror #10 gave inconsistent responses to the verdict sheet questions which cannot stand as a matter of law. Juror 10 found in question one of the jury verdict form that Roche did not fail to provide an adequate warning and then found in response to question two that Roche's failure to warn was the proximate cause of McCarrell's IBD.

Roche argues these are inconsistent responses that demonstrate this one juror was confused and therefore the verdict cannot stand.

When the jury was charged, this court instructed the jury on deliberating and voting as follows:

> All nine jurors must deliberate fully and fairly on each and every question, and all nine jurors must determine and vote upon each question. It is not necessary that the same seven of nine agree upon the answers to all questions. Whenever at least seven of nine jurors have agreed to any answer that question has been decided, and you may move on to consider the remaining questions in the case if it is appropriate to do so. All nine jurors should participate fully in deliberating on the remaining question, and a juror who has been outvoted on any question shall continue to deliberate with the other jurors fairly, impartially, honestly, and conscientiously to decide the remaining questions.
>
> [Feb. 16, 2010 Tr. 28:7-20.]

Therefore, the jurors were instructed they were to deliberate and vote on each question. After the verdict was rendered, this court polled the jury.

> The Court: Okay. Well, I want to thank you for your time. Just to poll the jury, were the same two nos for one and two?
>
> The Foreperson: Yes.
>
> The Court: They were the same two. And could you raise your hand if you voted no for one and two?
>
> The Foreperson: No. I don't think anybody voted the same.
>
> The Court: I want to know who voted no to question number one. Juror No. Five and 10. Okay. Was that the same for question two.
>
> The Juror: I think so.
>
> The Court: Yes?
>
> The Juror: Mine was yes.
>
> The Court: Juror 10, did you vote no for one and two?

The Juror: No.

The Court: It is not that big a deal. It is not going to make a difference. It is more for counsel's benefit because sometimes they want to know, and it is not required, but Juror No. 10, you voted no for one and two?

The Juror: I voted yes on the second one.

The Court: Okay.

The Foreperseon: I voted no on two.

The Court: You voted no on two, correct. So it was a different two. That's fine. That's perfectly appropriate. Just as I said in the instructions.

[Feb. 16, 2010 Tr. 39:6-40:10.]

Roche relies on Roland v. Brunswick, Corp., 215 N.J. Super. 240 (App. Div. 1987), for the position that a trial court has to reinstruct the jury when faced with an inconsistent verdict. In that case, the jury found that the plaintiff's comparative negligence was not a proximate cause of his injuries but then went on to find that plaintiff's fault had proximately contributed to his injuries to the extent of five percent. That was a case of clear jury confusion as evidenced by the incongruent findings. However, that case is easily distinguishable from this case. Roland involved a facially unanimous incongruent jury verdict. This case involves one juror who, as Roche argues, voted inconsistently, but his vote was not inconsistent under the circumstances and neither was juror #5's vote. Juror #5 found that the warning was inadequate. Juror #5 then did not find proximate cause. Juror #10 found the plaintiff did not prove the warning was inadequate, but did find when he considered the next question that a stronger warning would have resulted in plaintiff not taking Accutane and that Accutane caused plaintiff's injury so there was proximate cause. To be adequate a warning doesn't have to be the best or strongest warning. Based on what the defendant knew at the time, juror #10 could easily find the plaintiff

did not prevail on the proofs on this issue and still have found a stronger warning would have prevented plaintiff from being prescribed or taking Accutane and that Accutane caused his illness. The verdict is not inconsistent. In fact, the jury is told to accept the verdict on prior questions and continue to deliberate. If one juror finds no negligence on one of two defendants, he can still vote to uphold a 90/10 split of comparative negligence. In a case where a juror finds no permanent injury, for example, in an auto threshold case, he can still vote to award damages in a set amount. Each question has to be looked at separately and this is what jurors are always instructed. This is very different from a case where the jury votes in favor of no negligence and reaches a verdict on that question and then votes to award damages. The jury has no right to consider damages if there is no negligence verdict. They cannot compare negligence where the verdict on the prior question was that only defendant was negligent. In this type of scenario the Judge must question the jury and possibly order re-deliberation, but that did not occur here. This is not a case where the entire jury panel voted inconsistently.

Additionally, the jury was instructed that they were to deliberate and vote on each question. Juror 10 had an obligation to vote on question two after the majority of the jurors determined Roche failed to provide an adequate warning to McCarrell's prescribing physician. Juror 10 could have determined, even if he thought the warning was adequate, that Accutane caused McCarrell's IBD or McCarrell would not have taken Accutane if there was a stronger warning. Thus, he could have voted in the affirmative to question two without it being inconsistent with his vote on the adequacy of the warning.

Roche also argued this court was required to reinstruct the jury once it was faced with this incongruity. However, as this court stated during oral argument on this motion, there was no confusion when the jury verdict was read, and therefore no reason to reinstruct the jury. "The only person who was confused was the jury foreman, she didn't know who voted for what. The

jury foreman didn't know – hadn't kept track of who voted for what. But there was no confusion amongst the jurors. They knew what they voted." (May 6, 2010 Tr. 24:10-15). Even defense counsel who was present at the time the jury came back acknowledged that at the time he did not think there was confusion. (May 6, 2010 Tr. 26:24-27:1). There was no inconsistent verdict and therefore no basis for a new trial.

Hanauer Testimony

Defendant also argues a new trial should be granted because the admission of Dr. Stephen Hanauer's ("Hanauer") testimony tainted the trial. Roche argues Hanauer was improperly allowed to give expert opinion testimony, his testimony falsely imputed bad conduct to Roche, and the admission of the testimony confused the jury. Roche filed a motion in limine to preclude the testimony of Hanauer. After oral argument both before and during the trial, this court issued a thorough written decision on February 4, 2010 denying the motion and allowing Plaintiff to play the video taped deposition of Hanauer.

This court will rely on its February 4, 2010 memorandum of decision. After a thorough analysis of the applicable rules of law, the decision permits the testimony of Hanauer to be played at trial. In brief, this court determined the testimony was relevant and more probative than prejudicial. It was also determined that Hanauer's testimony was not admitted to show a potential bias in the Reddy article authors and not as an expert opinion. For further detail, this court directs the attention to its earlier memorandum of decision.

Limitation on Defense Experts

Roche next argues this court unduly prejudiced the defense by improperly limiting the number of Roche experts permitted to testify with respect to the Berstein Article and Crockett Abstract. Roche contends this court not only erred by limiting the number of Roche experts but further erred in forcing defendants to choose an expert on the issue when one was already

testifying. Roche also argues this limitation was more egregious because this court allowed Plaintiff to use duplicative and repetitive testimony from Dr. Bess. This is an apples to oranges argument as Dr. Bess was defendant's former corporate head of drug safety, not an expert.

During the pre-trial conference, this court addressed and denied plaintiff's motion in limine to exclude duplicative and unfounded expert testimony. In denying the motion, this court stated: "The duplicative testimony is going to be denied in advance but - - I'm not going to allow duplicative testimony. We are not going to have three causation experts." (Jan 12 Tr. 111:1-4). This court continued, "There is going to be one general causation expert, one case specific expert, one warning, and we're not going to overlap. There may be tiny overlap in the testimony but it's not going to be duplicative." (Jan 12. Tr. 111:6-10). Roche was aware before the trial even started that there was going to be no duplicative testimony, from either side.

Throughout the trial, this court continued to affirm its decision to not allow duplicative testimony. During the Plaintiff's case, this court reaffirmed its earlier ruling:

> I can say that I do not intend to allow either side to produce two experts on the same issues, so on causation, and if you're - - and even the studies, I mean if Crockett and Bernstein are addressed by Dr. Sachar then I don't really think they have to be addressed by Dr. Blume. The same would apply to defense witnesses. If those two articles are addressed by one of their experts I don't think it has to be addressed by two experts or three experts.
>
> [Jan. 25 Tr. 22:3-11.]

In fact, during Plaintiff's case there was an issue over Dr. Blume's qualifications and her ability to testify about the Crockett and Bernstein articles. Roche argued Blume should not be able to testify about what she considered the major flaws in these studies in epidemiology and this court responded, "Okay. She is not going to be able to do that at trial...Because that would be duplicative. I'm not going to let you have one causation expert, one epidemiologist and one warnings expert, and they're all going to talk about what's right about Bernstein and wrong

about Crockett. You can pick your one to discuss Bernstein in detail, and that will be it." (Jan. 25 Tr. 27:19-28:3). This court then told Plaintiff that Sachar was their expert on the studies since he had already testified extensively on them and furthermore that this court is "not going to let them have a second expert on it." (Jan 25. Tr. 28:16-17).

While dealing with the Defense experts, this court held them to the same limitation on expert testimony. During the same argument on January 25, this court addressed the testimony of defense experts Dr. Mayer and Dr. Harrington.

> Mr. Imbroscio: What we plan to do currently is have our epidemiologist, Dr. Harrington, be the witness. She is going to come in and talk solely about those two studies and the pros and cons. Obviously, Dr. Mayer is going to rely on the existence or nonexistence, but he is not going to get into any of the details and the substance, and I assume that's -
>
> The Court: He shouldn't mention it. We're not going to have two witnesses talking about the same thing.
>
> ...
>
> The Court: If you want to ask him did you rely on the Crockett article and the Bernstein article, and he can say yes. You start asking him did Bernstein show this, this, and this then no. If you want to use your epidemiologist, use your epidemiologist. If you want to use Mayer to do that, use Mayer ... I said from the very beginning, you can hire whoever you want, but they're not going to testify about the same thing.
>
> Mr. Imbroscio: Understood, Your Honor.
>
> The Court: And that goes for the Bernstein and Crockett. Use whichever one you want, but you're not using both.
>
> Mr. Imbroscio: Understood, Your Honor.
>
> ...
>
> The Court: I'm not going to hear his analysis of Bernstein and Crockett and the epidemiologist analysis of Bernstein and Crockett.
>
> [Jan 25 Tr. 34:12-22; Jan 25 Tr. 34:25-35:20; Jan 25 Tr. 41:3-19.]

The issue of duplicative testimony was again raised during the testimony of Dr. Mayer. During a side bar, this court went into the following colloquy with counsel:

> The Court: But we said we're not doing it repetitive, so we're not going to go through the studies with this witness and then go through the studies with an epidemiologist.
>
> Ms. Hennessey: **Understood.**
>
> The Court: So you're going to have to make the choice is all I'm telling you.
>
> Ms. Hennessey: **Understood.**
>
> The Court: And you haven't gone so far yet that I would bar an epidemiologist. And I don't mind having an epidemiologist to discuss the studies and what they mean, statistically, how they came to the results and what their conclusions were and why they are valid. But I'm not going to let this witness testify to it and then if he doesn't do a great job in the end, you call in the epidemiologist to say the same thing.
>
> Ms. Hennessey: **Absolutely understood. No duplicative topics. Absolutely understood.**
>
> [Feb. 2 Tr. 89:20-90:13.]

Roche then continued to question Mayer on the studies and chose to have Mayer be their expert on these studies.

Roche cannot argue the limitation on experts was a surprise. This court consistently and emphatically told both plaintiff and defendant that they were not going to be allowed to have multiple experts testify in-depth on the studies. Roche cannot now claim it was a surprise or this court waited until its expert started to testify to make this ruling. This was a ruling before the trial started and was maintained consistently throughout the testimony.

Roche further argues that this court's limitation was more egregious because Plaintiff was allowed to play some lines from Dr. Bess's testimony three times, once on direct and twice on cross-examination. The use of Dr. Bess's testimony however had nothing to do with the limitation of the experts. The testimony was used for cross-examination and not to present expert testimony. Therefore, the limitation on experts was not implicated with the playing of

Bess's testimony. Bess made certain statements as a former executive of the defendant. Other company witnesses and experts could be asked on cross-examination if they agreed with Dr. Bess. A trial judge has the authority to control the scope of cross-examination and such authority will not be interfered with unless clear error and prejudice is shown. State v. Messino, 378 N.J. Super. 559, 583 (App. Div. 2005). There was no error for this court to allow the testimony to be used for cross-examination and it did not have an impact on the limitation of experts.

Underreporting

Roche's next argument is that this court erred by permitting Dr. Blume to speculate as to underreporting. Roche contends Blume's testimony fails all three prongs of N.J.R.E. 702 because it was without basis and speculative. Plaintiff argues Dr. Blume's background in pharmacovigilance and drug safety qualify her to opine on the issue of underreporting and further that Roche's own experts testified to the same rate of underreporting.

Dr. Blume gave the following testimony on direct examination regarding underreporting rates:

> Q: Now, in the 1980's in this window of time, what were the accepted ranges generally understood in the pharmacovigilance community for the reporting rates of adverse events?
> A: It was generally considered a company would receive anywhere from 1 percent to 10 percent of the actual number of events experienced in the field.
> Q: And have you seen, in fact, that Roche said internally that's what they were using, between 1 and 10 percent?
> A: Yes.
>
> [Trial. Tr. Jan 28 132:17-25; 134:1-2.]

No objection was made to this line of questioning at the trial. In fact, in the beginning of the trial, the testimony of Dr. Alan Bess, former director of Drug Safety at Hoffman-La Roche was played to the jury. Dr. Bess testified regarding underreporting as follows:

A: There's theories in which there is underreporting. Roughly 10 percent of reports that occur are actually being reported to the FDA, or to a pharmaceutical company.
Q: Okay. And that's something that is well-known and was well-known within Roche when you were the head of U.S. Drug Safety, the concept of underreporting?
A: It's - - it's well-known. It's widely discussed. You have people like David Graham from FDA who talk about this all the time.

[Video Dep. Tr. Jan.13, 2010 294:9-17, 294:20-23.]

There was no error in permitting Dr. Blume to testify on the issue of underreporting. It was something within her knowledge as an expert in pharmacovigilance. The rate is also something that defense expert testified similarly about. In fact, theses same reporting rates are consistently used by experts and cited in published studies.

Dr. Sachar

Roche makes several arguments in its motion regarding the admissibility of Dr. Sachar's testimony. Each issue is taken up separately below.

Limited cross-examination

Roche's first argument is this court erred in limiting its cross-examination of Sachar which caused severe and unfair harm to Roche because it could not present the defense it had planned. When Roche had cross-examined Sachar for the same length of time as he testified on direct examination, this court called the parties to sidebar and had the following exchange.

The Court: We have just reached the point where the direct was four hours and 45 minutes and the cross is four hours and 45 minutes. The witness has been on the stand and I'm going to get him off the stand by the end of the day, if possible. I'm going to give you 15 more minutes, and he's going to have redirect, and then we will - - we have - - it should be close to a half hour, 40 minutes, and then we are done...

...

Mr. See: I just have to say for the record that my objection is because it's - - it isn't just because it won't give the jury about Mr. McCarrell's treatment and Dr. Sachar's view but not to be able to question him about it, so I, just for the record, just object.

The Court: Well, how much time do you need?

Mr. See: All I want is time enough to go through the pertinent facts of the case. I'm going to do my very best. I will go as fast as I can.

The Court: You have had as much time as he had on direct, and I'm offering you another 15 minutes plus recross. And you can't do it in 15 minutes? You need a half hour? Or you need an hour?

Mr. See: I will do my best. I won't be able to get what I want done in either of those times but -

...

The Court: Well, what he told me was he was going to pass him at noon. That's what you said yesterday. I said to you, how long do you think you're going to be with the witness, and you said until noon.
Mr. See: Your Honor, I'll do my best.
The Court: And it's now 3:15.

[Jan 26 Tr. 159:11-161:2; Jan 26 Tr. 161:9-14.]

Roche then continued to do the cross-examination of Sachar. Plaintiff later notified this court that Sachar could make it back to testify another day. This court then informed Roche it could take as much as it wanted for cross-examination and Roche withdrew its objection.

Mr. See: This is my last question.

Mr. Hook: Last question?

The Court: Is this the last question that you wanted to ask?

Mr. See: It is not.

The Court: Well then, ask every question you want to ask. Go ahead. 4:30.

Mr. See: No, I will ask this question.

The Court: You can ask it.

Mr. See: I need to have five minutes of redirect and that's all I want.

The Court: What?

Mr. See: I would like to have five minutes on redirect, depending on what Mr. Hook raises, and that's all.

> The Court: And you are withdrawing your objection? Because I'm not going to leave it that I restricted you. I have decided to let you go ahead and ask what you want to ask. Go ahead.
>
> Mr. See: **I withdraw it.**
>
> The Court: Withdraw what? The objection?
>
> Mr. See: Yes.
>
> The Court: Okay. Go ahead.
>
> [Jan 26. Tr. 176:10-177:7.]

The transcript makes it clear that Roche withdrew its objection to any time limitations this court imposed (which were actually subsequently removed).

Sachar was able to return the following day, and Roche was able to conduct a recross at that point. During one of the sidebars, Roche's counsel tried to argue its cross examination was abbreviated.

> Mr. See: As Your Honor knows, the cross-examination that I did yesterday was highly abbreviated.
>
> The Court: Not necessarily. Not by anything I ordered because I gave you three opportunities. At first, I said we were going to abbreviate it. Then I said take whatever time you need.
>
> Mr. See: I fully acknowledge that, Your Honor.
>
> [Jan 27 Tr. 4:13-22.]

After this court allowed Roche to take as much time as it wanted during the cross-examination of Sachar, it did limit Roche during its recross. This court refused to allow Roche to introduce any article not used on direct or cross because these were outside the scope of the re-direct examination.

Roche argues this court should not have strictly limited the recross to issues raised on redirect. However, it is well settled that matters concerning the scope of cross-examination are

left in the sound discretion of the trial judge. Further, the general rule is that re-cross is limited to things raised on redirect. This court did not restrict Roche's ability to cross-examine Sachar and any objection to the original limitation was withdrawn. Furthermore, this court acted within its discretion by not allowing Roche to introduce articles not previously raised in direct or cross.

Crockett

Roche's second argument is that this court erred in permitting Sachar to rely on two unpublished abstracts as a basis for his general causation opinion. Defense argues these articles are unpublished, have not undergone peer-review and are unreliable on their face. This court denied both the motion in limine to exclude the admission of the abstracts as well as the motion for reconsideration filed by defense.

During the pre-trial argument, Roche sought to prevent Sachar from testifying about the Crockett Abstracts. At that time, this court deferred ruling on the admissibility of the abstracts until an expert was on the stand and able to lay a foundation. Specifically, this court ruled:

> I am not ruling that it's admissible until I hear a witness on the stand tell me that it's a document that the witness and other scientific people would rely on and explain why. And when I hear that testimony, which is the foundation that I will need both to admit the Bernstein article, and to admit the Crockett article, I may reject either one of them, but I'm certainly not going to bar them in advance.
>
> [Jan 7 Tr. 203:12-21.]

On direct examination, Plaintiff's counsel asked Sachar if "experts such as you in the field of gastroenterology rely upon abstracts." Sachar responded as follows:

> Oh, tremendously you rely upon abstracts. Thousands, tens of thousands of gastroenterologists, as I say, come . . . to hear the first presentations of the results of important studies. They come from all over, they attend, they immediately start incorporating it into their practices. . . . M]eanwhile, the full manuscript of these studies, of these abstracts, are – are submitted for peer-reviewed publication, which is a long process. . . . It doesn't have the good housekeeping seal of approval in its final form until

> it's in peer-reviewed publication. But in the interim, it's very much relied upon, discussed, used and paid a lot of attention.
>
> [Jan 21. Tr. 182:18-183:22.]

Dr. Sachar then continued to testify regarding his use of abstracts prior to peer-reviewed publication when he was the chair of the FDA advisory committee for gastroenterology.

> Oh, my gosh, we would not only rely on abstracts, we would rely - - you have to rely on studies that had been done that hadn't even been presented as abstracts yet. It's fact, it's data, it's information. You have to have it. You can't wait until it comes out in the - - you know, published in the literature two years later. You've gotta act on the information when you have it.
>
> [Jan. 21. Tr. 184:2-9.]

After Dr. Sachar testified about the abstracts and before they were shown to the jury, the following took place at side bar:

> The bottom line is this: It doesn't have to be peer reviewed. It doesn't have to be accepted for publication. It has to be the type of document that scientists in the community would rely on. He has testified that it is. If you want to voir dire him on that particular issue right now, you can. If not, it will be admitted.
>
> [Jan 21. Tr. 186:11-17.]

New Jersey Court Rule 703 provides that the bases of opinion testimony by experts must be "of a type reasonably relied upon by experts in the particular field." The proponent of the expert must demonstrate that the data or information used were soundly and reliably generated and are of a type reasonably relied on by comparable experts in the particular field. Rubanick v. Witco Chemical Corp., 125 N.J. 421, 447 (1991). In Rubanick, the court held that a "scientific theory of causation that has not yet reached general acceptance may be found to be sufficiently reliable if it is based on a sound, adequately-founded scientific methodology involving the data and information of the type reasonably relied on by experts in the scientific field. Id. at 449. In

this case, Dr. Sachar testified clearly and emphatically that abstracts are the type of information and data that is reasonably relied upon by experts in his field.

Additionally, the abstract does not need to be peer reviewed or published in order for it to be the type of document that scientists would rely on. Publication and peer-review are factors, but are not dispositive. The Court in Hisenaj v. Kuehner, stated "publication itself, although not necessarily dispositive of general acceptance in the scientific community, does provide additional evidence of acceptance." 194 N.J. 6, 22 (2008). There was no error admitting the Crockett abstracts because they were not peer-reviewed and unpublished. Dr. Sachar testified the abstract is something reasonably relied upon and the fact it was unpublished and not peer reviewed does not change his testimony. In fact, the abstracts were the summary of a study conducted by the authors. They were presented to a large conference gastroenterologists. Subsequently after the trial, the studies were published.

Allowed unsupported general causation opinion

Roche's final argument is this court erred in allowing Dr. Sachar to give expert testimony because he failed the Kemp methodological standards for giving an expert opinion. Specifically, Roche makes five arguments, each of which will be addressed below.

Bernstein

Roche first argues Sachar's testimony on the Bernstein study is a net opinion, which should have been precluded. Roche contends Dr. Sachar rejected the Bernstein study out of hand because it did not support his personal beliefs but he did, according to Roche, agree with the design of the study, the use of a particular database, and the methodology, just not the conclusion. Plaintiff contends the Bernstein study does not undermine Sachar's opinions and Sachar's testimony on the study is far from a net opinion.

There was no error in allowing Dr. Sachar to give testimony on the Bernstein study. Dr. Sachar testified that there were four specific flaws in the Bernstein study which diminished the significance of the findings. These flaws were: (1) the study was smaller than the Crockett study; (2) the recommended dose of Accutane in Canada is smaller than the recommended dose of Accutane in the United States; (3) the recommended duration of treatment is shorter in Canada than the US; and (4) the background rate in Manitoba is higher than the overall rate in the US. (Jan. 22 Tr. 27:10-28:14). Dr. Sachar gave specific criticisms of the Bernstein study that supported his reasoning on why the study was flawed. As Roche noted, Dr. Sachar did also testify that Dr. Bernstein is "a real expert in this" but that does not mean that he cannot critique his study. (Jan. 22 Tr. 25:10). The jury was free to do what they wanted with the testimony but there was no error in permitting Dr. Sachar to testify about the study.

Crockett

Roche's next argument is this court should not have allowed Dr. Sachar to testify about the Crockett abstracts and Sachar's reliance on these abstracts reveal his opinion is unreliable and improper. Plaintiff argues Sachar properly relied on Crockett. This issue was previously addressed in a separate argument above and this court finds no error in allowing Sachar to testify regarding the Crockett studies.

Causality Assessments

Next Roche argues Sachar used causality assessments to prove general causation despite factual evidence that these assessments are used to monitor adverse events and not to prove causation.

The Appellate Division in McCarrell I dealt with Roche's argument that Dr. Sachar's testimony should have been excluded because he improperly considered Roche's causality assessments as part of his opinion. The Appellate Court stated, "We agree with Roche that

causality assessments, standing alone, are not sufficient to support an admissible scientific opinion on causation. In this case, however, the assessments were just one part of Dr. Sachar's analysis. We are persuaded that the trial judge did not abuse her discretion or violate the reliability tenets of *N.J.R.E. 702* in finding that causality assessments have been accepted in medical or scientific fields as potential indicia of causation, and could, when combined with other evidence, be rationally used to support Dr. Sachar's opinion on causation." McCarrell v. Hoffman-La Roche, Inc., 2009 N.J. Super. Unpub. LEXIS 558, at page 83 (2009). There was no error to allow Sachar to testify about the causality assessments. They were one part of his causation opinion and, as a part of the opinion, it was not error to allow Sachar to rely and testify about these assessments. These causality assessments were part of Roche's own internal documents done by their own scientists and doctors.

Retinoids

Roche's fourth argument is that Sachar acknowledged that retinoids sometimes can be anti-inflammatory yet this court permitted him to testify that Accutane causes IBD. The specific testimony Roche is referring to is as follows:

> Q: "Given that the etiology of IBD is largely unknown it is difficult to assess the plausibility of isotretinoin as a trigger of IBD. In fact, the mechanistic studies that are available in the published literature could support a beneficial effect of Vitamin A derivatives in regard to the development and perpetuation of IBD." Have I read that correctly?
>
> A: So far.
>
> Q: And it referred to Vitamin A derivatives, and, in fact isotretinoin or Accutane would be considered in that group, right?
>
> A: Would be considered a what?
>
> Q: They talk about Vitamin A derivatives.
>
> A: Yes, well, it is a form of Vitamin A, yes.

[Tr. Jan 22 142:8-22.]

This was cross-examination and the jury could consider the statements from a published article read by counsel to the plaintiff's expert but that does not in any way prevent him from his giving his opinion. Roche also refers to a hamster study done by Roche, in which the study abstract stated "And then, going down under the results, it states, RA, which we see is isotretinoin...also afforded significant protection." (Tr. Jan 26 143:11-14). However, Roche failed to point out Sachar's previous testimony that "retinoids may stimulate Th17 and its inflammatory effects, as well as reduce it." Sachar also testified that the opinion in the hamster abstract was "garbage" and gave his reasons for his opinion.

Besides the two points Roche cites to, Sachar was also questioned about evidence that non-steroidal anti-inflammatory drugs cause IBD. This line of questioning brought about by Roche contravenes the point that retinoids cannot cause IBD because they are anti-inflammatory.

Additionally, Sachar testified about the gastrointestinal bleeding reported in the Vesanoid label, which is a metabolite that transforms into Accutane when it is ingested. There was no error in allowing Sachar to testify regarding other retinoid evidence and class effect. Following the first McCarrell trial, the Appellate Division found Sachar's methodology to involve "data and information of the type that may be reasonably relied on by experts in the scientific field, including...class effects." McCarrell v. Hoffman-La Roche, Inc., 2009 N.J. Super. Unpub. LEXIS 558, at page 95-96 (2009). There was ample evidence for Plaintiff to advocate that Accutane and Vesinoid and similar drugs and produce similar side effects.

Scientific Support

Roche's final argument regarding Dr. Sachar is that there is no scientific support for Sachar's general causation opinion because not a single piece of scientific literature advocates what Sachar advocated to the jury. To again reiterate what the Appellate Division stated,

Sachar's "methodology involved data and information of the type reasonably relied on by experts in the scientific field, including animal studies, human clinical studies, dechallenge/rechallenge reports, class effects, causality assessments, published scientific literature, plaintiff's medical history and biological plausibility." McCarrell v. Hoffman-La Roche, Inc., 2009 N.J. Super. Unpub. LEXIS 558, at page 95-96 (2009). Sachar provided ample evidence in support of his opinion. Additionally, there is scientific evidence that supports his opinion, including the Crockett Abstracts, which is now peer-reviewed, published and concludes there is a causal link between Accutane and UC. The fact that IBD is considered a trigger for IBD is now included in textbooks and in other literature. There was no error in admitting his opinion and there is ample scientific support for his opinion although there is certainly contradictory evidence that also exists.

Marketing Trumped Safety

Roche next contends that Plaintiffs were permitted to argue, without basis, that marketing trumped safety. Roche argues Dr. Bess's testimony that this was the case with Accutane when he was head of drug safety should have been excluded for the following five reasons: (1) the "disagreements" between marketing and drug safety occurred in 1997, two years after McCarrell took Accutane and thus could not have caused Roche to refrain from making label changes that would have impacted Plaintiff; (2) the conversation Dr. Bess testified to related to the psychiatric side effects of Accutane and is thus irrelevant; (3) the undisputed evidence showed that marketing concerns did not trump safety; (4) given the inflammatory nature of the allegation, this court should have excluded it because its prejudicial impact outweighed its probative value; and (5) the testimony confused the jury.

Plaintiff argues that Roche waived this issue because it was never addressed on appeal in the first trial where it was also played. Next plaintiff argues there was no prejudice in admitting

the testimony because the details of the specific dispute were played for the jury and that included the part that the dispute was about psychiatric issues and when it occurred. Plaintiff contends this testimony is important to demonstrate the general culture within Roche and its argument was a fair characterization of the evidence. Finally, Plaintiff argues the testimony is not unduly prejudicial merely because it is harmful to defense.

There was no error in admitting Dr. Bess's testimony. Roche was not unduly prejudiced through the testimony of Dr. Bess. Dr. Bess was asked whether there were differences of opinion between Drug Safety and any other departments in the defendant company related to Accutane, and he responded that there were with Marketing. When asked to describe the specific instances, he stated "I was at meetings where Marketing felt that if certain label changes were made, it would impact the sales of the product. ... This dealt with the psychiatric label change of 1998." (Tr. Jan.13, 2010 134:1-3, 5-6). It was very clear that this conversation did not deal with IBD. However, the testimony did go to the overall culture within Roche and to the fact that the plaintiff was attempting to prove that Roche did not wish to put negative information about the side effects of Accutane in the label even when scientists did. Dr. Bess, as former head of Drug Safety, was properly allowed to give testimony regarding any disputes that occurred between his department and the marketing department. The nature of the disputes and the timing of the disputes were made clear to the jury. Since the defendant Roche argued they always acted in the best interest of the patient and had no reason for not giving an adequate warning, this testimony was properly admitted.

General Data Memo

Defense's next argument is that the Plaintiff lacked foundation to use the general data memo. Roche argues the entire General Data Memo is irrelevant because McCarrell did not have any GI or IBD symptoms prior to taking Accutane. Therefore, whether Accutane can

exacerbate a preexisting disease is irrelevant because McCarrell did not have any symptoms prior to taking the drug. Plaintiff argues the contraindication is relevant because it goes to whether or not Accutane causes IBD as well as the adequacy of the warning.

There was no error in allowing Plaintiff to introduce the General Data Memo, a Roche company document that is supposed to represent the defendant's core position on the science of the drug. The key portion of the document, and the part Roche takes offense to being used, states "in patients with ileitis, enteritis or colitis in the active phase of the disease [Accutane] is basically contraindicated." Even though McCarrell did not have any of the pre-existing conditions, the contraindication was still relevant to the issue of causation. As this court noted during oral argument on the motion in limine to preclude this evidence, "their [defense] expert admitted that that means that there is usually a causal link." (Tr. Jan 12. 2010, 108:11-12). During his cross-examination, Dr. Mayer, Roche's expert, acknowledged his previous testimony which he stated "contraindication means that there's hard evidence that suggests that if you give Agent A, it will cause B." (Tr. Feb. 4, 2010 167:4-6, 9-10). The contraindication language of the General Data Memo is relevant for causation, as acknowledged by Dr. Mayer.

Additionally, the General Data Memo is relevant for the adequacy of the warnings. Dr. Blume testified that "contraindications are such a critical component of any label." (Tr. Jan. 28, 2010, 181:5-6). Roche was given the opportunity to cross-examine Dr. Blume about her use of the contraindication language in the Memo. This testimony is relevant and properly admissible.

Failure to Test Reversed Burden of Proof

Next, Roche argues it is entitled to a new trial because this court erred in improperly allowing Plaintiff to suggest to the jury that Roche violated a nonexistent duty to test for IBD and thereby revered the burden of proof. Defense filed a motion in limine to exclude failure-to-test arguments, which was denied as overbroad on January 8, 2010. Roche argued plaintiff's

counsel used a failure-to-test argument during opening statements, when plaintiff's counsel said: "How many clinical trials with IBD as an endpoint was Roche doing while they were selling this drug? Zero. How many case control studies regarding IBD? All this information coming in? Zero. ... Not a single Accutane IBD trial or study. Nothing. Nothing." (Feb. 9 Tr. 220:1-13).

Counsel's remarks during opening statements did not shift the burden of proof. This court never shifted the burden of proof. This court charged the jury based on the standard jury charge, which was used in McCarrell I. The charge contained the following statements about the burden of proof:

> Now the burden of proof is on the plaintiff to establish his claims because if a person makes an allegation then that person must prove the allegation.
>
> In this action, the plaintiff has the burden of proof. Plaintiff's claims have to be proven by a preponderance of the evidence. This means that plaintiff must prove each element of his claim is more likely true than not. If you were to picture a scale and put on one side of the scale all the credible evidence that favors the plaintiff's on a question and all the credible evidence that favors the defense on the other side, plaintiff has to tip the scales ever so slightly in order to prevail. If the scales tip in favor of the defense or even if they are absolutely equal then the plaintiff hasn't prevailed, and you must find for the defendant.
>
> [Feb. 16 Tr 17:16-18:7.]

When describing to the jury what an adequate warning entails, this court again never shifted the burden onto defense. This court charged the jury as follows:

> Let's talk about what a warning is. Warnings may be in the form of words, symbols, or pictures. They must be in a form which will effectively convey the information. A manufacturer has the duty to warn prescribing physicians about potential serious risks of a drug if those risks are known or should be known by the manufacturer.
>
> To be adequate, the warning must be the kind of warning which a reasonably prudent manufacturer in the same or similar circumstances would have provided to the prescribing physician. In the case of a prescription drug an adequate warning must be given to the doctors who will prescribe the drug. This is true because it is the prescribing doctor who has to decide whether to prescribe a prescription drug to a patient.

> An adequate warning will communicate sufficient information on the risks of the drug that are known or should be known by the manufacturer. When you consider what is known or should be known you should understand that a reasonably prudent drug manufacturer should be deemed to know of reasonably obtainable and available reliable information. The manufacturer of a drug has a duty to take reasonable steps to find out information about the risks of their product, including doing such monitoring, investigation, and testing as may be reasonable under the circumstances. This duty continues even after the drug is approved and on the market.
>
> In evaluating this defense of Roche you may consider evidence relating to Roche's knowledge of potential IBD risks relating to Roche's knowledge of potential IBD risks of Accutane. A duty to warn arises if the manufacturer, in this case Roche, actually knew of should have known of the need to issue a particular warning. In determining what Roche should have known, you must understand that the law requires a manufacturer to keep reasonably familiar with and to know reliable information generally available or reasonably obtainable in the scientific community. In that regard Roche is deemed to be an expert in its field. And this information may come from its own scientists and studies from outside experts and/or literature in the field.
>
> [Feb. 16 Tr. 20:10-22). (Feb. 16 Tr. 21:23-22:11.]

The instruction given to the jury is consistent with products liability law in New Jersey and nationally. When liability is premised upon an inadequate warning, the issue becomes whether the manufacturer knew or could have known about side effects. Feldman v. Lederle Lab., 125 N.J. 117, 144 (1991). It is undisputed that pharmaceutical companies have a duty to warn of dangers which it knows or should know. See Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87 (2nd Cir. 1980). That duty includes a continuing obligation to "keep abreast of knowledge of its product as gained through research, adverse reaction reports, scientific literature and other available methods." Baker v. St. Agnes Hospital, 70 A.D.2d. 400, 406 (N.Y. App. Div. 1979).

The jury was properly charged with the appropriate burdens of proof and legal elements under the products liability law. Roche had a duty to warn of the risks that are known or should be known, and that was what was charged to the jury. Additionally, this court instructed that the

burden of proof is on the plaintiff. The burden of proof was not reversed and the jury was properly instructed.

Unduly Prejudicial Evidence

Defendant posits several arguments that this court's evidentiary rulings resulted in undue prejudice to the defense and therefore a new trial is warranted. Each of these arguments is addressed below. The overarching rules to bear in mind with the analysis below are Rule 401, Rule 402, and Rule 403. Rule 401 provides that "relevant evidence means evidence having a tendency in reason to prove or disprove any fact of consequence to the determination of the action." Rule 402 states "except as otherwise provided in these rules or by law, all relevant evidence is admissible." Finally, Rule 403 explains, "except as otherwise provided by these rules or other law, relevant evidence may be excluded if its probative value is substantially outweighed by the risk of (a) undue prejudice."

Causality Assessments

Defense argues the Plaintiff improperly, and repeatedly, argued that "causality assessments" evidenced that Roche knew that Accutane causes IBD, while Roche actually used the causality assessments to categorize adverse events. In this trial, as there has been in the previous Accutane trials, there was conflicting testimony over causality reports and what they are meant to identify. Roche's own employees testified that the causality assessments demonstrated causation. Dr. Alan Bess, former U.S. head of drug safety for Roche, defined a causality assessment as follows: "Well, a causality assessment is a - - is a term used in the world of Drug Safety trying to demonstrate a relationship, a cause-and-effect relationship between the drug and an adverse event." (Bess Script at 118:1-118:4). Dr. Reschef, former Roche medical safety evaluator was asked, "And, of course, you're making these causality assessments on a regular basis in connection with Accutane for - - to make a scientific evaluation as the relatedness of the

causality of the event, correct, sir?" and he answered, "Yes." (Reschef Script 148:12-17). It was not improper for Plaintiff to point out that Roche employees admitted causality assessments, in their mind, were used to signify causation. Further, the causality assessments were relevant to the knowledge Roche had and whether the warning was adequate based on that knowledge.

Additionally, the Appellate Division considered argument on causality assessments after McCarrell I. That Court noted:

> In a similar fashion, we reject Roche's related contention that it was unfairly prejudiced by plaintiff's counsel in the manner in which they questioned witnesses about the causality assessments and in the manner in which they described them in closing arguments. Roche described them in closing arguments. Roche presented its own competing proofs and arguments about the limited significance of causality assessments. The jury heard competing experts on the causation issues as a whole. Given the context, we do not think that plaintiff's attorneys exceeded the bounds of fair advocacy.
>
> [McCarrell v. Hoffman-La Roche, 2009 N.J. Super. Unpub. LEXIS 558, at *84 (March 12, 2009)].

There was no error in admitting the causality assessments and allowing Plaintiff to make the argument that these assessments can be used to prove causation because Roche's own employees describe them this way. The defense had ample opportunity to present conflicting testimony that causability reports were not really of value on the issue of causation. These are Roche's own documents and Roche's own former employees statements and the attempt to discredit them by the defense counsel creates a clear factual dispute that is clearly within the province of a jury.

Public Citizen Letter

Defense next argues this court mistakenly allowed plaintiff to use the Public Citizen letter to improperly bolster the expert testimony about inadequacy, rather than use it to show "notice." Roche argues plaintiff simply used Dr. Blume to introduce inadmissible opinion testimony, and even more egregiously used the letter to argue Roche should have warned patients about IBD.

This letter has been admitted in all previous trials. In McCarrell I, the letter was admitted in unredacted form. In subsequent trials, the letter has been redacted, but always admitted. In this trial, the letter was again the subject of pre-trial argument. Once again the letter was admitted, but this time in redacted form. In deciding to allow the letter with redactions this court stated, "I think the redactions make it more relevant to this case, so I'm going to allow it with the redactions." (Tr. Jan 28. 4:18-20). These were redactions requested by defense counsel.

Before plaintiff's counsel got into any details about the Public Citizen Letter, this court gave the following limiting instruction:

> This particular letter is being admitted not for the truth of what it says. In other words, it says this happened or their opinion is this scientifically. You can't consider that in deciding whether Accutane causes or triggers IBD. You can use it only for the purpose of determining what the company knew or should have known, what kind of notice the company had about the issue. So that's the limited purpose you can use it for.
>
> [Jan. 28 Tr. 84:8-16.]

The letter is relevant to notice. Any prejudice that Roche might have suffered was effectively limited through the redactions and limiting instructions.

Patient Brochure

Roche also argues this court improperly permitted Plaintiff to introduce evidence of patient warnings. Defense argues the Patient Brochure is entirely irrelevant for two reasons: (1) Roche has a duty to warn physicians, not patients, and (2) no warning in the patient brochure could have altered the result because Plaintiff admitted he did not read the warnings. In addition, Roche notes Plaintiff put forth no evidence that Dr. Gerald read or relied upon the Patient Brochure in deciding to prescribe Accutane.

Defense filed a motion in limine to exclude the Patient Brochure. This court denied the application, stating "I think it could very well go to the issue of warning, if nothing else, and

maybe, you know, depending on how big a role it plays in the trial and what happens maybe there should be an instruction to the jury that it doesn't go to the issue of would it have changed to proximate cause, but it does go to the issue of whether it is an adequate warning." (Jan 12 Tr. 147: 1-8). This court did advise defense counsel they could object to any particular question about the Patient Brochure during trial.

The Patient Brochure was relevant, and therefore admissible, because it went to the warning. Dr. Gerald testified it was her practice to hand patients the brochure, and it was one part of literature on Accutane that went to warning. Under FDA regulations patient brochures are part of "label" as the FDA defines it.

McLane

During the pre-trial conference, Roche objected to Plaintiff using the deposition of Jack McLane, as plaintiff's counsel had previously done in the earlier Accutane trials. On January 12, 2010, this court made an initial oral ruling that Plaintiff could not use the deposition. The following day, this court had counsel submit any objections to the deposition. After reviewing the objections, the deposition excerpts, arguments of counsel, and the law, the court reversed its decision and advised counsel the deposition could be used at trial. This court issued a written decision on February 4, 2010. This court relies on that memorandum of decision, which thoroughly and adequately addresses all arguments made by Roche concerning admitting the testimony of McLane.

Inflammatory Statements

Roche argues this court erred in permitting Plaintiff's counsel to make inflammatory and unsupported statements at trial. Each allegation will be dealt with separately.

First, Roche argues Plaintiff's counsel made numerous inflammatory statements during his opening statement. These remarks included: improper statements that Roche should have

warned about information contained in post-ingestion MedWatch reports, causality assessments, challenge/dechallenge/rechallenge reports, and the like; improper statements that Roche had a duty to warn patients; Roche had a plan to keep information from physicians; and God created our GI tract. As Roche noted this court did instruct the jury that they are to judge the adequacy of the warning based upon what Roche knew in 1995, and the later evidence was used for causation. If counsel's remarks were inflammatory, then this court's instructions after openings cured any prejudice that might have resulted.

Second, Roche argues counsel was allowed to argue that the Patient Brochure misstated the risks of IBD even though the brochure was irrelevant. The issue with the Patient Brochure has been dealt with above. It was not inflammatory to allow counsel to make an argument regarding the Patient Brochure because the brochure was relevant. Plaintiff's counsel also argued Accutane might have acted in concert with the antibiotics in causing McCarrell's IBD Dr. Sachar testified that the three medications Flagyl, tetracycline and Pepto-Bismol are often prescribed to treat IBD and there never has been a single case report that these three meds together caused IBD. This was in response to cross-examination by defense attempting to blame these medications for the plaintiff's IBD. Counsel properly argued this point to the jury. Counsel is afforded broad latitude in summation. "Counsel may argue from the evidence any conclusion which a jury is free to reach. Indeed, counsel may draw conclusions even if the inferences that the jury is asked to make are improbable, perhaps illogical, erroneous or even absurd, unless they are couched in language transcending the bounds of legitimate argument, or there are no grounds for them in the evidence.

Third, Roche points to statements made during closing argument which it alleges were improper. The first statement is when counsel said he was going to pass "the awesome responsibility [of] representing Andy and his family" to the jury. The next statement was how he