

FILED

OCT 28 2009



Carol E. Higbee, P.J.Cv.

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OPINIONS**

**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: **Mace/Sager/Speisman v. Hoffman LaRoche**

DOCKET #: **ATL-L-199-05, ATL-L-197-05, ATL-L-196-05**

DATE: **October 28, 2009**

MOTION: **Motion for Judgment Notwithstanding The Verdict or
In The Alternative For a New Trial**

ATTORNEYS: **Michele Bufano, Esq., for Defendant
David Buchanan, Esq., for Plaintiff**

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

Following a four week trial in which plaintiff Kelly Mace was awarded \$1.5 million for pain and suffering and \$128,000 for future medical expenses, plaintiff Lance Sager was awarded \$2.5 million for pain and suffering and \$125,000 for future medical expenses, and plaintiff Jordan Speisman was awarded \$8.5 million for pain and suffering and \$142,500 for future medical expenses for injury sustained from their use of the drug Accutane, manufactured by

Hoffman-LaRoche, Inc and Roche Laboratories, Inc. ("Roche"), defendant Roche now brings this motion for judgment notwithstanding the verdict or, in the alternative, a new trial. Plaintiffs oppose this motion.

STATEMENT OF THE FACTS

(1) Kelly Mace

Kelly Mace ("Mace") ingested Accutane for treatment of her acne from July 1999 to December 1999. In December 1999, she began developing symptoms of IBD – bloody, uncontrollable diarrhea. On February 22, 2000, she was diagnosed with ulcerative colitis. Subsequently, in January 2005, Mace brought suit against Roche arguing that Accutane was the cause of her IBD and that Roche failed to adequately warn her treating physician of the risks of IBD.

(2) Lance Sager

Lance Sager ("Sager") also took Accutane for the treatment of his acne between January 1998 and June 1998. He first experienced symptoms of IBD in February 1998 and was diagnosed with IBD in December 1998. Lance's symptoms continued and he suffered from severe diarrhea, rectal bleeding, stomach cramps, and anal abscesses and fistula that impaired his ability to walk straight up or sit down. He also filed suit against Roche on January 6, 2005, for failure to warn and claimed that Accutane caused his IBD.

(3) Jordan Speisman

Jordan Speisman ("Speisman") ingested Accutane from November 1999 through April 2000. He first experienced symptoms of IBD in January 2001 and was diagnosed with ulcerative colitis on February 2, 2001. Speisman has been prescribed over ten different medications for management of his IBD including the steroid prednisone, a drug that causes his face to swell, as well as Remicade, an IV medication he was being treated with at the time of the trial. Speisman

was scheduled for a surgical consult at the time of trial because of the severity of his condition. Removal of the colon or removal of part of the intestines is a common tradition for IBD when other options have failed. He filed suit against Roche on January 6, 2005, alleging that Accutane was the cause of his IBD and that Roche did not adequately warn his prescribing physician of the risk of Accutane causing IBD.

STANDARD

A judgment notwithstanding the verdict is given only if “upon accepting as true all the evidence that supports the opponent’s position, and upon providing the opponent with all reasonable inferences, reasonable minds could not differ.” Sun Coast Merchandise Corp. v. Myron Corp., 393 N.J. Super. 55, 70 (App. Div. 2007). This standard has been interpreted to require “the evidence and uncontradicted testimony [to be] plain and so complete that disbelief of the story could not reasonably arise in the rational process of an ordinary intelligent mind.” Id. citing Ferdinand v. Agricultural Ins. Co., 22 N.J. 482, 494 (1956) (internal quotations omitted).

The Court shall grant a new trial only 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.” R. 4:49-1(a) (emphasis added). Further, “[j]ury verdicts should be set aside in favor of new trials only with great reluctance, 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).

DISCUSSION

Exclusion of Numbers Evidence

First, relying on the recent Appellate Division decision McCarrell v. Hoffman-La Roche, the defendant argues that a new trial is merited based on the exclusion of the

"numbers" evidence. Defendant argues that it was prevented from introducing certain testimony about numbers and calculations on IBD background rates and the Accutane users who developed IBD. The defendant argues the exclusion of this evidence demands a new trial be granted. In fact since the defendant declined several opportunities to present this evidence to the Court outside the presence of the jury for a ruling, it is unclear as to exactly what evidence was actually planned to be offered, but is clear that this evidence was never ruled on by the Court because defendant chose not to offer it.

McCarrell v. Hoffman-La Roche

In McCarrell v. Hoffman-La Roche, the Appellate Division vacated and remanded a judgment against Roche because of the exclusion of some evidence of the number of background rate of Accutane users or of the rate of IBD in the general population. Throughout the McCarrell trial, the plaintiffs were allowed to introduce evidence of causality reports and adverse event reporting. Id. at 93-95. Plaintiffs were also permitted to bring out evidence of under-reporting to demonstrate that the numbers of reported IBD events were only a fraction of the actual incidence of IBD in the population using Accutane. Id. at 95.

The defense was allowed to introduce testimony that, by 1983, about 300,000 prescriptions for Accutane, and only seven or eight people reported IBD symptoms. Id. at 98. The defense was also allowed to introduce testimony that IBD affects a range of 26 to 200 people per 200,000 in the United States. Id. at 98.

The defense, however, was precluded from introducing expert testimony from Dr. J. Paul Waymack. Dr. Waymack's expert report provided that, based on a comparison of the background rate of IBD in the general population and to the numbers of patients who developed IBD while on Accutane, a causal relationship between Accutane and IBD is not likely. Id. at 97. The Court excluded this evidence at trial because I found this comparison was not valid since

there was no accurate measure of either the number of people who took Accutane or the number who developed IBD after taking Accutane.

The defense also attempted to introduce, through Dr. Huber, the lead clinical physician for Roche between 1996 and 1999, Roche's estimate of Accutane users between 1982 and 1995. Id. at 100. After the plaintiffs objected, the defense proffered that Dr. Huber would testify as to the rates of Accutane users between 1982 to 1995, and 1982 to 2005, and the number of adverse event report of IBD as of 1995. The purpose of this testimony was allegedly to demonstrate that Roche monitored the amount of adverse event reports, and demonstrated the notice Roche had of a relationship. This Court excluded this evidence because it concluded that the real purpose of these numbers was to demonstrate the risk of developing IBD from Accutane was insignificant when compared to the number in the general population who have IBD. I stated that "[t]o suggest that a reasonable company doesn't explore a rare risk is an unfair suggestion to the jury." Id. at 100.

The Appellate Division found this to be reversible error because it prevented the defense from putting in context the plaintiff's evidence on adverse event reporting. The Appellate Division stated that this evidence may have led the jury to be "more indulgent of Roche's delay in upgrading the risk information on Accutane's label and package insert," and "[a]t a minimum, the actual usage data for Accutane would go to 'safety signaling' concerns, i.e., whether Roche had received sufficiently frequent adverse 'signals' to take corrective action." Id. at 101. This evidence would offer to the jury "a fuller and more balanced picture of the data bearing upon the company's delay in changing its label." Id. at 102. The opinion also cautioned that the new trial should not be all about these numbers. Accordingly, McCarrell was remanded for a new trial which is presently scheduled before this court. This decision was not rendered by the Appellate Division until after the Mace/Sager/Speisman trial.

Mace v. Hoffman-La Roche

In the Mace trial, similar issues on numbers arose repeatedly, but this court's position was different. Plaintiffs initially filed a motion in limine to exclude the purported number of Accutane users in order to prevent the defense from comparing the incidence rates of IBD in the population as a whole to rates of IBD in the population of Accutane users. If the court decided to admit the evidence, the plaintiffs sought to limit the evidence to the purpose of "signal detection." Pl.'s Br. JNOV, 13.

This Court denied the motion to bar this evidence. The Court did exclude reference to evidence of the purported number of Accutane users in opening statements. This Court clearly reserved any further rulings and specifically stated that "the Court will rule on any testimony about the numbers at trial." Order Denying Mot. in Limine, Oct. 17, 2008, 2. Further, "[b]oth plaintiffs' and defendant's witnesses should be instructed not to mention the number of adverse events reported and/or the number of users or prescriptions without prior permission of the Court." Ibid. It was clear that the motion to bar the testimony was denied. The Court clearly advised counsel that these numbers could be used if a proper foundation was laid.

The issue arose first with testimony of Dr. Bess, who sought to testify as to the theory of under-reporting of adverse events. The defense stated their position again was that, if the court sought to exclude numbers of total Accutane users or incidence of IBD, then the court should also exclude testimony on under-reporting of adverse events. Mace Hr'g Tr. 211:12-212: 2, Oct. 17, 2008. I ultimately allowed numbers of under-reporting, stating

I think realistically you just can't take reports that list numbers without putting in the numbers, and that's what we mostly have, we have causality reports where there's number of gastrointestinal complaints, we have numbers of this and numbers of that, and in the end it is all part of the evidence and can't be parsed out. So, I'm going to allow them to play this with the understanding that probably most of the numbers are going to come in during the trial, but there may still be some points

where a number simply isn't appropriate or not relevant or doesn't have a proper foundation. So I'm going leave counsel to during the course of the trial, raising the issue as it comes up, and I think that it has become pretty clear that the – that in the end restricting the numbers makes it more difficult than allowing them in, and I don't think that it made much difference between when we allowed them and didn't allow them.

[Hr'g Tr. 220:2-20 (emphasis added).]

The Mace trial was before the McCarrell decision, but even before the McCarell decision, this Court had changed its mind about the evidence. I also stated that counsel could assume "that when it comes to numbers if they're basic to the case and they have some role I probably will be allowing them in during the trial." Hr'g Tr. 221:2-4. In fact, the Mace/Sager/Speisman trial was the third trial, and in the second Accutane trial after McCarrell the numbers came in with instructions to the jury as to how they could use them.

On the cross examination of the plaintiff's causation expert, the defense elicited testimony on the text of the Reddy article, which Dr. Sachar relied upon. Specifically, the defense asked: "[n]ow, in this study that you had looked at, did you notice that there were 20 million prescriptions of isotretinoin written in the U.S. between 1982 and 2000?" The expert answered the question, stating "Right. I certainly did. I knew that it wasn't 20 million people, but I knew it was 20 million prescriptions." Hr'g Tr. 1665:20-1666:1. the exact number of people who took the drug could only be estimated. At that point the plaintiffs objected to this evidence. After discussing the matter off the record, I stated on the record that:

since the defense counsel had brought out the number in the Reddy article that the plaintiffs could bring out the fact that in the article that the Reddy article refers to that cites the number of prescriptions, they also indicate that that means that through various estimates and assumptions that aren't very clear, but that they would estimate that between 4 to 5 million actual people who took the drug for the period of time.

[Hr'g Tr. 1673:5-13.]

Continuing to take it on a question by question basis, I allowed in the fact there were 20 million prescriptions, but I went on to say that I was:

very doubtful that there's sufficient evidence for background rate in the general population versus background rate in Accutane. I don't know where those numbers would come from. And there are a lot of problems with the other comparison of numbers, which is the numbers of people who took the drug compared to the reporting because of the nature of the uncertainty of both numbers. But I'm not precluding that from being testified to, and I'm not agreeing that it can be. I am making it very clear that no one is to reference other than the one reference – other than the short thing that plaintiffs are going to do now, no one should reference these numbers again during the trial or make those comparisons, unless first you approach the bench.

[Hr'g Tr. 1673:21-1674:11.]

Accordingly, the plaintiffs asked Dr. Sachar in their re-direct about the Reddy article reference to Accutane prescriptions over an 18-year period, and whether the article that the Reddy article cited was referring to 4 or 5 million people who took Accutane over that 18 year period. Hr'g Tr. 1701: 19-1702: 13. Dr. Sachar confirmed this was the case.

During the defense's case, many opportunities were made for the defense to introduce more numbers evidence. Prior to Dr. Huber, a defense witness, taking the stand, the court stated: "I have already said based on what I have seen so far I would need to hear a proffer of exactly what he is going to say, and, if necessary, the foundation for that outside the presence of the jury." Hr'g Tr. 2042:19-23. I continued by stated: "[t]he ruling has been, no, you can't ask about those two types of numbers ... or comparison of two sets of numbers, unless you have the witness explain to me off the record his basis for using them and how he is going to use them." Hr'g Tr. 2042:25-2043:1-6. By "off the record" it was meant out of jury's presence in a hearing. The defense attorney, Mr. Thames, responded by stating "That's a helpful reminder. We'll just leave it at that." Hr'g Tr. 2043:7-8. The Court stated in response: "If you do that I would prep him for that first thing in the morning with as quickly as possible as to what your questions are

going to be.” Hr’g Tr. 2043:9-11. The defense did not respond, and did not proffer this testimony the next day. Rather, the defense solicited testimony from Dr. Huber on signals, signal detection, monitoring safety data, and how Roche evaluated data for signals. Dr. Huber also testified about the need for placing the number of reports in context. The defense, therefore, chose not to take advantage of the chance to have a hearing on the use of any other numbers by Dr. Huber. The Court was somewhat surprised that defendants made no effort to proffer this evidence.

On cross-examination, Dr. Huber testified about the theory of underreporting of adverse events. Hr’g Tr. 2163:23-2164:16. The plaintiffs, on cross-examination, not the defendants asked Dr. Huber to multiply the number of adverse events by the under-reporting rate. Hr’g Tr. 2185:14-17. The defense objected to this line of questioning, stating that “if we’re not going to get in the numbers then we ought not to talk about under-reporting rates and under calculations, which is what we’re doing. I didn’t get into numbers at all.” [Emphasis added] Hr’g Tr. 2184:22-25. The court did not require Dr. Huber to perform the calculation, but did allow Dr. Huber to testify to the rate of under-reporting that was utilized by Roche. Hr’g Tr. 2187:3-22. Dr. Huber did not offer more calculations or “numbers” evidence, however, and the defense did not make an attempt to solicit this information, despite the court’s guidance on the issue.

In the plaintiff’s cross examination of the defendant’s causation expert, Dr. Mayer, the plaintiffs attempted to question Dr. Mayer on testimony given during his deposition on the expected rate of IBD in the population. The defense objected to this line of questioning. I stated at that time that

[i]t was my understanding that there were two issues that the plaintiffs were questioning the scientific validity of. One was comparing the number of instances, the number of adverse events reported with IBD versus the background rate, the number that you would expect amongst—number of people you expect to have IBD in the general population, number of people you would expect to

have—who do get IBD on Accutane. And the argument was that there was no scientific basis—no foundation for it, because it was really impossible to tell exactly how many people took Accutane or to tell what the adverse event rates were compared to the real adverse events. And all in all, those calculations couldn't be made.

[Hr'g Tr. 2435:10-23.]

Here again, it was the defendant who made it clear they objected to plaintiff's use of numbers because the defendant was not seeking to get in calculations evidence. The plaintiffs who had initially objected to this evidence by filing a motion in limine to exclude it, stated they were concerned that the defendants would introduce the evidence through a future defense witness, and argued that in that case the plaintiff should be entitled to introduce the evidence through their witness anticipatorily. Hr'g Tr. 2439:17-2440:3. Defense counsel objected to this proposition, stating the plaintiff would be able to cross-examine any witness who might introduce the evidence, and then stating "but that is not what this witness testified to on direct. *That is not what we have chosen to present thus far in our defense, and so, it is not at issue at this point.*" Hr'g Tr. 2440:4-9 (emphasis added). The defense had chosen not to proffer a foundation for any other evidence on numbers outside the jury's presence. The court was provided a copy of the deposition of the witness, which the court examined and after reading it, I stated to plaintiffs they could not elicit testimony about calculations that the defendant wouldn't introduce through their witness:

he goes on to say he doesn't think he has enough information to even make the calculation. And since that's case [sic], and that seems to be the rule here, the rule is going to be nobody is going to make this calculation, period. So, he is not going to make it, and the next expert for them is not going to make it. They're not going to be able to bring it on cross, they're not going to be able to bring it out on direct.

[Hr'g Tr. 2442:1-9.]

I continued to rebuff the plaintiffs' counsel's attempt to question the witness about calculations the defendant expert acknowledged in his deposition he could not do. Plaintiff wanted it clear that the defense would not produce such testimony.

PLAINTIFF: I think now is the time to have that conversation.

THE COURT: If it is legitimate, then it should be a hearing now before, you know. Does everybody agree? [Defense], is that your position?

DEFENDANT: Yes, ma'am.

THE COURT: The defense is willing to accept, at this point, as the plaintiffs are, that if nobody—if one side is not going to bring it in, the other side is not going to be able to bring it in.

DEFENDANT: And the "it" to which we are talking about are these calculations and numbers?

THE COURT: Calculations.

PLAINTIFF: Well, let's be specific.

THE COURT: There's no reason for you to ask him the background rate. There's no reason for them to ask the background rate. And Sachar's background rate doesn't really matter, because nobody is going to do a calculation from it, right?

[Hr'g Tr. 2442:11-2443:10.]

Since the defense wasn't going to present a witness to the Court for a foundation for any calculations, it was clear they were not going to be offered by the defendant. In fact, Dr. Huber could not support them. The matter was concluded when the Court stated: "All right. So, nobody is going to do the calculation. And everybody is shaking their head okay, all right."

Hr'g Tr. 2443:23-24.

Finally, after both sides rested before closings the defense objected to slides that were being used in the closing which pointed out the number of adverse events reported to the company among users of Accutane, a number that had been placed in evidence. Hr'g Tr. 3478:7-12. The court allowed the plaintiff's numbers of adverse events to come in, because the number "is not being used to show there were a huge number of reported events. That's not the purpose. [The plaintiff] is not going to use it for that. He said that, and as long as he is not using

it for that, it is a number that's in evidence and that can be used." Hr'g Tr. 3480:23-3481:3. Of course, defense could have also presented slides on the number of prescriptions that was also in evidence. These slides did not include calculations, only raw numbers.

Based in this record, the defendant argues that a new trial is merited because, as in McCarrell, calculations of background rate evidence was improperly excluded. The defendant's brief notes numerous instances in which plaintiff's witnesses described the number of adverse event reports and other "numbers" evidence, focusing on the testimony of Dr. Blume, the plaintiff's warnings expert, and Dr. Sachar, the causation expert, both of whom testified to the number of adverse event reports. As a result, the defendant argues that they were prevented from giving context to the number of adverse events entered into evidence by the plaintiff.

The record clearly speaks to the defendant, in fact, putting in evidence raw numbers and declining to have a hearing outside the presence of the jury on other calculations, despite the court's guidance on the issue. Defendants did not want a hearing on the background calculations to establish a basis for the admission of this evidence. The doctrine of invited error bars a "disappointed litigant from arguing on appeal that an adverse decision below was the product of error, when that party urged the lower court to adopt the proposition now alleged to be error." Brett v. Great American Recreation, 144 N.J. 479, 503 (1996). The doctrine promotes fairness in the litigation process by not allowing a disappointed litigant to take one course of action and then appeal that course of action if the outcome is unfavorable. The doctrine also promotes fairness to the court, because the litigant denied the trial court the opportunity to apply the correct law in the earlier litigation. "Elementary justice in reviewing the action of a trial court requires that that court should not be reversed for an error committed at the instance of a party alleging it." Ibid.

The court repeatedly made it clear that any numbers and calculations would be admissible provided the expert provided background or foundational evidence in advance of

presenting testimony on them. Roche never availed itself of the opportunity to present this evidence in a hearing before the Court despite the court's reminder that it could do so, and objected when plaintiffs attempted to cross-examine the expert on them.

The court's ruling on the evidence in Mace is quite dissimilar from the court's ruling in McCarrell, where the court ordered a blanket ban on the presentation of all calculations of background rates vs. rate of IBD in Accutane users. The court stated during the course of the Mace trial with regard to numbers evidence, "when it comes to numbers if they're basic to the case and they have some role I probably will be allowing them in during the trial." Hr'g Tr. 221:2-4. The court also said, "I'm not precluding that from being testified to, and I'm not agreeing that it can be. I am making it very clear that no one is to reference other than the one reference ... unless first you approach the bench." Hr'g Tr. 1673:21-1674:11. A reasonable interpretation of these statements is **not** that any defense evidence was excluded, but that the Court was open to allowing numbers and calculations as long as they were presented to the Court first so the Court could make an informed ruling.

Defense counsel repeatedly made the conscious decision not to lay a foundation for numbers evidence. Prior to Dr. Huber testifying, the court anticipated that defendant may want to enter numbers evidence and reminded defendant to first approach the bench to first lay a foundation. To this, defense counsel responded, "That's a helpful reminder. We'll just leave it at that." Hr'g Tr. 2042:25-2043:1-6. Similarly, defendant had an opportunity to bring in numbers evidence with Dr. Mayer, but again decided not to. The court said, "The defense is willing to accept, at this point, as the plaintiffs are, that if nobody—if one side is not going to bring it in, the other side is not going to be able to bring it in. All right. So, nobody is going to do the calculation." Hr'g Tr. 2442:11-2443:10. To this statement, both defendant's and plaintiffs' counsel nodded their heads in agreement.

The argument that defendant may consciously chose not to lay a foundation to introduce certain number evidence at trial, outside the presence of the jury so the Court could evaluate it, and then later claim that the court prohibited it from introducing evidence at trial, is very disingenuous. Defendant articulated on the record that they understood the Court's offer for a hearing and chose not to pursue it. Accordingly, a new trial will not be granted based on the argument that the court excluded opinions on testimony that was never offered.

Admission of Dr. Sachar's Expert Opinion

The defense next takes issue with the admission of opinion of Dr. David Sachar, arguing that he fails to meet the standards in New Jersey for expert testimony. Specifically, the defendants allege that Dr. Sachar's opinion is merely a "hypothesis," for which there is no "general acceptance" among the medical or scientific community. In McCarrell v. Hoffman-La Roche, the Appellate Division considered at length the basis for Dr. Sachar's opinion, and found it admissible. The Appellate Division evaluated the basis for the opinion, including animal studies, case reports, causality assessments, the Lefrancq memorandum, the comparison to Vesanoïd, and biological theories. McCarrell v. Hoffman-La Roche, No. A-3280-07T13280-T1 (App. Div. March 12, 2009) (slip op. at 54). The Appellate Division found each of these to be a valid basis for an opinion on causation. Because the Appellate Division has affirmed the admission of the opinion of Dr. Sachar, this court will not again re-examine the basis for Dr. Sachar's general causation opinion. The court instead considers the basis for Dr. Sachar's specific causation opinion below.

Specific Causation Opinion

Dr. Sachar also testified that he found Accutane to be the specific cause of the IBD in the three plaintiffs. For plaintiff Lance Sager, Dr. Sachar testified that he examined the medical

records of Mr. Sager, the depositions of the Sagers and the treating physicians, and biopsies from Mr. Sager's colonoscopy in 1998 and 2003. He examined the biopsies looking for an antibiotic induced type of injury. Hr'g Tr. 1529:6. He testified that he took into account other risk factors and was able to rule them out. Hr'g Tr. 1529:22-25. On the basis of this review, Dr. Sachar testified that he was able to conclude that Mr. Sager's Crohn's disease was caused by Accutane. Hr'g Tr. 1527:22-23.

For plaintiff Kelly Mace, Dr. Sachar testified that he examined her medical records from her treating dermatologist and gastroenterologists, her pathology slides, reports of the pathologist. He testified he considered her history of antibiotics, her half-brother who was diagnosed with IBD. Hr'g Tr. at 1540:2-11. He considered the fact she began bleeding while on Accutane. Hr'g Tr. at 1540:14. He examined her pathology slides looking for "signs of a circulatory disturbance, of an inflammation of blood vessels, of an acute drug injury from an NSAID, of a superimposed virus in the tissues, or something like that, but those weren't there. It was pretty classic ulcerative colitis." Hr'g Tr. at 1538:3-8. He testified that her consumption of diet pills after her diagnosis would not have affected his conclusion. Hr'g Tr. at 1542:1. He concluded that Kelly Mace's ulcerative colitis was caused by Accutane. Hr'g Tr. at 1540:22-23

For plaintiff Jordan Speisman, Dr. Sachar testified that he examined his dermatology records, his pathology reports and slides. He considered the period of latency between Jordan's use of Accutane, ending in April 2000, and his first onset of symptoms, in January 2001. Hr'g Tr. 1553:20-23. He noted that Roche internal documents indicated latency periods around 1400 dates. Hr'g Tr. 1553:7-8. He testified that he examined the pathology slides for other factors, such as NSAIS and other antibiotics. Hr'g Tr. 1554:15-18.

Dr. Sachar's specific causation opinions demonstrate that he thoroughly examined plaintiff's medical histories. Dr. Sachar detailed how he could rule out other causes of the

plaintiffs IBD. He ultimately found that Accutane was the cause of each plaintiff's IBD.

Basically, he first opined that Accutane could cause IBD, and then found based on a differential diagnosis that the most likely cause was Accutane in each of plaintiffs' cases.

Preemption by Federal Law

During the pendency of this action, the United States Supreme Court rejected the argument that the FDCA preempts state law. Wyeth v. Levine, 129 S.Ct. 1187, 1190 (2009). A drug manufacturer has the ability to strengthen its label after the initial label approval and "bears responsibility for the content of the label at all times." Id. at 1198. "[A]bsent clear evidence that the FDA would not have approved a change to [the manufacturer's] label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements." Ibid. The Supreme Court further rejected the argument that state tort-law duties obstruct the purpose of the federal drug labeling laws, stating that "[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly," as well as serving "a distinct compensatory function that may motivate injured persons to come forward with information." Id. at 1201.

Subsequently, the Appellate Division remanded to this Court the McCarrell v. Hoffman-La Roche matter on the numbers issue, as described above. Specifically, the Appellate Division stated,

"[g]iven we are remanding this matter on other grounds because of independent trial errors, we also remand the preemption issues to the trial court, for further development of the record and evaluation in light of Wyeth. The trial court is free to permit additional discovery, motion practice and other proceedings as may be necessary to rule on these issues prior to any new trial."

[McCarrell, supra, No. A-3280-07T13280-T1 at 60.]

Roche has never, in the course of several Accutane trials here and across the country, presented any evidence that the FDA rejected a proposed change to the Accutane warning label

with regard to IBD or would have rejected one if it was offered. If there was evidence of such communications between Roche and the FDA, Roche would certainly have argued this point at trial. Additionally, the Appellate Division in McCarrell explicitly stated that, since McCarrell was *already* being remanded, the trial court should consider the preemption argument as well. The Appellate Division did not state that this point, alone, required a remand. Given the complete lack of evidence on the preemption argument, I do not find this issue requires a new trial.

Statute of Limitations

Next, this Court must address defendant's argument that plaintiffs' claims were barred by the statute of limitations. Defendant contends that plaintiffs reasonably learned or should have learned that their injuries could have been due to their ingestion of Accutane prior to two years of filing their lawsuits. Defendant emphasizes that each plaintiff punched Accutane pills daily from a blister pack beneath the following statement: "YOU SHOULD BE AWARE THAT ACCUTANE MAY CAUSE SOME LESS COMMON, BUT MORE SERIOUS SIDE EFFECTS. BE ALERT FOR ANY OF THE FOLLOWING: SEVERE STOMACH PAIN, DIARRHEA, RECTAL BLEEDING. IF YOU EXPERIENCE ANY OF THESE SYMPTOMS ... DISCONTINUE TAKING ACCUTANE AND CHECK WITH YOUR DOCTOR IMMEDIATELY." Defendant more specifically maintains that Speisman should have connected his injury with Accutane because he was informed of the gastrointestinal risk of abdominal pain when first prescribed Accutane. Finally, defendant argues plaintiffs' position that they only learned Accutane caused their injuries when they saw lawyer ads to be false, because plaintiffs do not remember the language or any specific details of the lawyer ads.

N.J.S.A. 2A:14-2 mandates that personal injury actions be brought within two years of accrual of the cause of action and reads, "Every action at law for an injury to the person caused

by the wrongful act, neglect or default of any person within this State shall be commenced within two years next after the cause of any such action shall have accrued." N.J.S.A. 2A:14-2. Courts have indicated that the statute of limitations should not be treated as a mere technicality and have adopted the discovery rule in response. The discovery rule ensures that the two-year statute of limitations for a personal injury action does not start until the plaintiff becomes aware of the wrong. In Lopez, the Court stated, "a cause of action will be held not to accrue until the injured party discovers, or by an exercise of reasonable diligence and intelligence should have discovered that he may have a basis for an actionable claim." Lopez v. Swyer, 62 N.J. 267, 272 (1973).

The discovery rule is an equitable doctrine designed to mitigate the harsh, unjust results that would flow from strict adherence to a rule, where an otherwise blameless injured person is unaware that he has a cause of action. Id. at 272-274. The interest of the injured plaintiff must be balanced against fairness to the defendant where significant time has passed since the incident and "memories have faded, witnesses have died and evidence has been lost." Ibid. The determination of when the statute of limitations begins, or Lopez inquiry, "requires more than a simple factual determination," and is one that should be made by a judge in a separate proceeding from that of the jury. Ibid.

The Lopez inquiry places an "emphasis upon the factual nature of an injured party's knowledge of a basis for a cause of action." Lynch v. Rubacky, 85 N.J. 65, 73 (1981). The inquiry looks to the operative facts as to injury and fault that were known or should have reasonably been known by the injured party. Ibid. It is emphasized that "a plaintiff must have an awareness of 'material facts' relating to the existence and origin of his injury rather than comprehension of the legal significance of such facts." Ibid.

Here, the court conducted a Lopez hearing to determine when Mace, Sager, and Speisman first associated their injuries to Accutane to resolve whether plaintiffs properly filed their lawsuits within two years in compliance with the discovery rule.

Speisman testified that he took Accutane from November 1999 to April 2000, and was diagnosed with ulcerative colitis in 2001, but did not put together that Accutane may have caused his ulcerative colitis until October 2003, when he saw a newspaper ad in the Gainesville Sun. When asked, “[h]ow did you first put together in your mind that there may be a connection between Accutane and IBD,” Speisman responded, “There was a newspaper ad that my mother and I saw that said to call a phone number.” Hr’g Tr. 174:8-14. Speisman testified that no doctor ever told him that Accutane caused his IBD prior to reading the newspaper ad. Hr’g Tr. 174:4-7. Speisman also testified that he remembered seeing writing on the blister pack, but did not remember reading it. When asked, “[a]nd you remember when you opened it it had all this writing on it,” Speisman responded, “Yes, I don’t remember reading it.” Hr’g Tr. 180:6-8. Even if he had read it, his symptoms occurred after he stopped the drug.

Sager testified that he started taking Accutane in January 1998 and began experiencing symptoms of IBD in February 1998, but continued with his prescription through June 1998. Hr’g Tr. 199:8-25. Sager testified that none of his doctors ever indicated that Accutane caused his IBD. Like Speisman, he remembered seeing the warning on the blister pack, but did not recall reading it. Hr’g Tr. 203:9-11. The language in the blister pack mentions IBD. Sager said that he first associated his IBD with Accutane in early 2004, when a friend told him about a television ad. Sager testified, “My friend told me there was a commercial about a law firm that said there was colitis or Crohn’s and Accutane call this number.” Hr’g Tr. 203:24-204:1.

Similarly, Mace testified that she took Accutane between July 1999 and December 1999 and first experienced GI symptoms in December 1999, but did not associate her ulcerative colitis

with Accutane until 2003, when her mother's friend saw a newspaper article that said that Accutane may cause IBD. Mace stated that she did not remember reading the warning on the blister package. Mace testified, "[t]he main thing I remember is the pregnancy, you know, the pictures and everything ... I don't recall if I read it." Hr'g Tr. 245:9-11. The most obvious warning which was that Accutane could cause birth defects if used during pregnancy dominated the blister pack. Mace also indicated that none of her doctors told her that her IBD was caused by Accutane.

The Court finds plaintiffs' testimony credible and believes that plaintiffs did not associate their IBD with Accutane until they saw an advertisement. The discovery rule applies and plaintiffs properly filed suit within two years of discovery. Defendants argue that the three plaintiffs should have associated Accutane with IBD when they read the warning on the blister pack. The Court accepts plaintiffs' testimony that they did not read the warning on the blister pack as true. However, even if plaintiffs did read the warning on the blister pack, the warning is not enough to connect their prior use of Accutane with their IBD. The warning advises the patient to stop taking Accutane if he or she develops certain gastrointestinal symptoms while taking the drug. The warning does not advise the patient that if he/she may develop IBD even a year or two after taking Accutane, or that if they develop IBD it will be too late as there is no cure for IBD. It is a permanent condition. In fact, the blister pack doesn't even mention IBD, which is a serious disease much different than a bout of diarrhea. None of their doctors told them about a link between Accutane and IBD.

Adequacy of Label & Proximate Cause

The defendant asserts that the plaintiffs failed to submit evidence that would cause a reasonable jury to conclude that either the warning was inadequate or that any inadequacy in the warning was the proximate cause of plaintiff's injuries.

Defendant first argues both that the “associated with” language sufficiently warned prescribing doctors of a possible causal relationship, and that the warning should have been evaluated under New Jersey law rather than Florida law. This court has previously examined the “associated with” language, found that it could not state the warning was adequate as a matter of law, and therefore left the adequacy determination to the jury. See In Re: Accutane Litigation, supra, No. 271, slip. op. at 6; Grier v. Cochran Western, 308 N.J. Super. 308, 317 (App. Div. 1998) (stating “questions of reasonableness in determining the adequacy of warnings are ordinarily left for the jury to resolve”). The Appellate Division considered the defendant’s arguments in McCarrell and affirmed this court’s determination both to apply the law of plaintiff’s home state, and to submit the question of adequacy of the warnings to the jury.

Therefore, the court will not reconsider the issue of whether the warning is adequate as a matter of law. Rather, the court will consider whether the plaintiff presented sufficient evidence that would lead a reasonable jury to conclude that the warning was inadequate. If, all inferences granted in favor of the plaintiffs, a reasonable jury could not find it inadequate, then judgment notwithstanding the verdict is required.

Plaintiff points to numerous pieces of evidence in support of its position that Hoffmann-LaRoche itself believed Accutane caused IBD in some patients and therefore the warning was inadequate. This evidence includes: MedWatch reports dated 1985 through 1997 (challenge/dechallenge/rechallenge reports), the 1986 Shifferdecker Report (P36), the 1987 Shifferdecker Report (P38), the 1997 Shifferdecker Report (P55), and the October 1999 Laflore Report, which support the fact that Accutane causes IBD. These are internal Roche records. They also presented conflicting testimony on the meaning of the actual words in the warning from Roche’s own scientists. This split by Roche scientists as to what the warning in the label actually meant certainly could support a finding the warning was not clear. The plaintiffs also

produced a warnings expert, Dr. Cheryl Blume who testified to the inadequacies in the product label. The evidence was sufficient to support a reasonable jury's determination of inadequacy.

It is not appropriate for the Court to overturn a finding of proximate cause where a jury had a basis for finding proximate cause existed, but defendant argues that any inadequacy in the warnings was not the proximate cause of the plaintiff's injury. This argument arises from the defendant's interpretation of the learned intermediary doctrine. A drug's warning is due to the prescribing physician under Florida law. Buckner v. Allergan Pharms., 400 So. 2d 820, 822 (Fl. Ct. App. 1981) (stating "we hold that this duty to warn is fulfilled by an adequate warning given to those members of the medical community lawfully authorized to prescribe ... prescription drugs"). Because the warning is due to the physician, the defendant argues that the plaintiff must show the physician *would not have prescribed* the drug as a result of the strengthened warning, and it doesn't matter if the doctor would warn the patient of the risk and the patient would have refused to take the drug.

The defendant's argument takes the learned intermediary doctrine too far. The learned intermediary doctrine is not a proximate cause principle, but rather only applies to the question of the adequacy of warnings. The manufacturer's warning is due to the physician, and the warning should be judged by whether it would be clear and adequate to the physician, but for proximate cause to exist, the patient plays a role. There are two separate issues, first whether the warning was adequate as addressed to physicians, and second whether a stronger warning would have made the physician give the patient a stronger warning and then the patient would choose not to take the drug. Florida law recognizes that a doctor's duty is to make a patient's choice "an intelligent one, based upon sufficient knowledge to enable him to balance the possible risks against the possible benefits." Buckner v. Allergan, 400 So. 2d 820, 823 (Fl. Ct. App. 1981). An adequate warning therefore provides the physician with the information that the physician

needs to communicate the risks and benefits to the patient. The patient is still a factor in the equation when it comes to whether an adequate warning would have stopped the patient from taking the drug, which is a proximate cause question.

All of patients prescribing physicians testified that they would take into consideration a heightened warning and that a heightened warning would be relevant either to their prescribing patterns or to the conversations they had with their patients regarding the drug. Each plaintiff testified that if they had known Accutane would cause IBD, they would not have taken the drug. Hr'g Tr. 243:16-19; 900:10-18; 350:8-10. This is sufficient evidence for a reasonable jury to have concluded that the inadequate warning was the proximate cause of the plaintiff's injury. There have been three jury trials in New Jersey and two in other states involving Accutane and IBD, and each jury has found the warning was inadequate and the plaintiffs' IBD was caused by Accutane use.

Causation Expert Limitation

Defendant also argues that it was unfairly limited to one causation expert and this inhibited Roche's ability to rebut plaintiffs' causation evidence.

The court addressed the issue of duplicative expert testimony in a pre-trial motion brought by plaintiffs. In its October 17, 2008 order, the court indicated that Roche was limited to one witness to speak on each issue; that is, one on general causation, one on warnings and one for each plaintiff on specific causation. The court continues to hold this position. These are long cases and overlapping witnesses on issues must be discouraged.

The court has the discretion to exclude relevant evidence where it will lead to prejudice, confusion, or waste of time. N.J.R.E. 403 reads, "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, confusion of issues, or misleading the jury or (b) undue delay,

waste of time, or needless presentation of cumulative evidence.” Here, allowing defendant to present numerous experts on general causation could be prejudicial because it would result in repetitive overlapping evidence and could have had the cumulative effect of improperly swaying the jury.

The court notes that it did not order that defendant was limited to testimony about general and specific causation from only one expert, but rather just that the same opinions could not be repeated by different experts. In fact, defendant did have more than one expert testify as to different issues related to causation. Defendant elicited some causation testimony from Dr. Mayer, Dr. Blumberg, and Dr. Gudas.

Finally, plaintiff’s use of scientific literature to question Dr. Gudas on causation was appropriate because Dr. Gudas testified on direct that there was evidence Accutane was actually beneficial to the intestine, and plaintiff’s counsel had a right to question her about this testimony. Essentially, defendant opened the door allowing plaintiff to enter this line of questioning, and the court properly overruled defendant’s objection. Hr’g Tr, 2891:3-20.

Failure-to-Test Argument Reversed Burden of Proof

Next, Defendant asserts that Roche is entitled to a new trial because plaintiffs reversed the burden of proof. Defendant maintains that plaintiffs used a “failure to test” theory in their opening statement, when plaintiffs’ counsel said, “How many studies did Roche conduct on GI symptoms, how many clinical trials were the endpoint ... Zero. Zero.” Hr’g Tr. 122:21-123:16. Defendant also argues that plaintiffs proceeded to elicit expert testimony from Dr. Sachar and Dr. Blume and that even plaintiff’s own witness, Dr. Blume, asserted that a clinical study isolating IBD is impossible.

The court never shifted the burden of proof. The Court charged the jury based on the standard charge:

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, studying and testing as may be reasonable under the circumstances. This duty continues even after the drug is approved and on the market.**

....

In determining what Roche should have known, 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.

[Hr'g Tr. 3660:18-3662:9 (emphasis added).]

The instructions given to the jury are consistent with the state of pharmaceutical products liability law in New Jersey and nationally. It is undisputed that pharmaceutical companies have a duty to warn of dangers which it knows or should know. See Lindsay v. Ortho Pharm. Corp. 637 F. 2d 87 (2nd Cir. 1980); Golod v. Hoffman-La Roche, Inc., 964 F. Supp. 841 (S.D.N.Y. 1997). And that duty encompasses 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). Further, other courts have upheld similar failure to warn jury instructions in drug liability cases where the charge stated that the jury could consider ongoing testing a part of ordinary care. See Young v. Key Pharmaceuticals, Inc., 922 P. 2d. 59, 68 (Wash. 1996). Thus, the jury instructions on failure to warn were proper and certainly the amount of testing done on Accutane is relevant to the jury in considering what the Roche should have known. In fact the same arguments by Roche were made in the McCarrell trial and the Appellate Division did not find fault with them.

Florida courts have permitted the jury to consider the amount of testing conducted in a failure to warn claim. In Adams v. G.D. Searle, 576 So. 2d 728 (Fl. App. Ct. 1991), the Florida Court of Appeals opined that it agreed with and would follow Kociemba v. G.D. Searle, 707 F. Supp. 1517 (M.N. Dist. Ct. 1989), where the Minnesota District Court concluded that failure to test is not a separate cause of action but that it is relevant for the jury to consider as, "a subpart of a manufacturer's duty to design a product with reasonable care ... subsumed in the plaintiffs' claims for ... failure to warn." The Minnesota District Court stated,

[R]ecognizing a continuing duty to test which is subsumed as a part of the continuing duty to warn is a consistent extension of existing law. Therefore, this Court holds that its instruction to the jury concerning a manufacturer's continuing duty to test is not erroneous. Of course, any continuing duty to test would also be limited to "special cases." If a manufacturer has no information concerning potential dangers associated with a product, it will be under no duty to continually test the product. Conversely, if a manufacturer does obtain sufficient credible information that a product already in use is potentially dangerous, the manufacturer should test that product to determine the extent of any danger, and then issue an appropriate warning or product recall.

[Id. at 1528-1529.]

Defendant also makes reference to Dr. Blume's testimony as evidence that even she believes that it is impossible for Roche to conduct a clinical study. Defendant's selective excerpt from the trial testimony is misleading. Dr. Blume testified,

It is always nice if you can do a prospective placebo-controlled study, but, in this case, we probably could not have. You would have needed 20 or 30 thousand patients to really do a good job for IBD ... but absent being able to do that, then you needed to be doing the type of database studies we talked about so frequently this morning."

[Hr'g Tr. 1309:8-20.]

Dr. Blume did not indicate that Roche could not have conducted any studies, but only that a placebo-controlled study might be too difficult and that Roche could still have conducted studies based on information in its databases.

It should be clear that the best type of studies on causation were lacking in this case. The “gold standard” that is considered the most scientifically reliable study is a controlled randomized clinical trial. It may be true that a randomized clinical trial cannot be conducted, as Dr. Blume testified, but Hoffmann-LaRoche conducted no studies to examine the causal relationship between Accutane and IBD despite numerous written records where their doctors found complaints of IBD were probably caused by Accutane. Usually it is the manufacturer who tests its product and organizes clinical trials on safety issues. In Barrow v. Bristol-Myers Squibb Co., 1998 U.S. Dist. LEXIS 23187 (M.D. Fla. Oct. 29, 1998), the Florida District Court referred to Professor Margaret A. Berger who wrote, “conditioning liability on plaintiff’s ability to prove that defendant’s product caused plaintiff’s illness is counterproductive; the insistence on causation creates incentives on the part of corporations not to know and not to disclose.” Barrow, quoting Margaret A. Berger, Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts, 97 Colum. L. Rev. 2117 (1997). The Florida Court recognized this can create a problem. There is something disturbing about defendants attacking plaintiff’s proof because they were unable to produce stronger evidence of certain types of trials and studies when the fact is it is the manufacturer who is expected to conduct studies but chose not to do any studies on IBD and Accutane despite reports from doctors that patients developed IBD from the drug. This argument must fail. The Court did not shift the burden or eliminate general causation. The jury was told the plaintiff must prove general causation.

Unduly Prejudicial Evidence

Defendant forwards several arguments that the Court’s evidentiary ruling resulted in undue prejudice to the defense, and therefore, a new trial is required. The Court examines each of these arguments below, bearing in mind the New Jersey Rules of Evidence states that

“relevant evidence may be excluded if its probative value is substantially outweighed by the risk of ... undue prejudice, confusion of issues, or misleading the jury....” N.J.R.E. 403.

Improper Use of Reddy Article

Defendants cite prejudicial error in both the manner in which Dr. Sachar utilized the Reddy article, and in the court allowing Dr. Sachar to rely on the Reddy article when the deposition of Dr. Reddy was denied by the court. As a result of this prejudice, the defendant asserts a new trial is required. The court rejects this argument.

The defense asserts that Dr. Sachar misconstrued the Reddy Article and improperly stretched its results to include his own opinion. This criticism of the Reddy Article is not one that would merit its exclusion. The Reddy Article is a study done in accordance with accepted scientific methodology, and it was accepted for publication in a peer-reviewed journal. The Reddy Article is the type of evidence relied on by experts in the field. The defense did address on cross examination their concerns about Dr. Sachar’s testimony.

Further, the deposition of Dr. Reddy was denied by the Court because of the impending trial which had been scheduled well in advance. To allow the deposition of Dr. Reddy to occur at that point in time would have resulted in delay of the trial date. Additionally, the Court notes that right before the Mace trial was the defendant’s first attempt to depose Dr. Reddy, despite the utilization of the article by Dr. Sachar in other Accutane trials before this Court. The defense had the opportunity to take her deposition for years, and did not request it until it was too late. It would not have been one deposition since, if Reddy was deposed, the plaintiffs wanted to depose the other authors of the Article.

The case law cited to by the defendants on this point is distinguishable. In Bender v. Adelson, the defense expert was excluded by the plaintiff’s motion, and the plaintiff, in closing remarks, asked the jury to draw an adverse inference from the defense’s failure to produce an

expert. 187 N.J. 411, 433 (2006). The situation in Bender is not comparable to the situation presented here. Dr. Sachar relied on a scientific journal article, which is an acceptable method of formulating an expert opinion. Dr. Reddy was not a required defense witness and no adverse inference can be drawn from the failure of the Dr. Reddy to appear, nor did the plaintiffs comment on the absence of Dr. Reddy. The defense has not asked to depose every author regarding every study or article relied on by Dr. Sachar and does not claim prejudice that Dr. Sachar relies on those forms of evidence without the defense being able to offer testimony from their creators.

The defense argues that the subsequent deposition of Dr. Reddy confirms that Dr. Sachar's testimony on the contents of the Reddy article were false and speculative, but the effect of Reddy's deposition testimony on the jury is very speculative. Reddy did state at her deposition there was no "journal speak" in the article, a term Dr. Sachar used to explain to the jury that authors in journals do not usually say x causes y, but are conservative in their language. While some of the Reddy testimony might have aided the defendants, other portions help plaintiffs. Plaintiff's counsel points out the causation language was stronger in the article originally and only because one of the other authors was asked to change the language that weaker language was used. The person the plaintiffs allege got the article changed was a defense consultant. During her deposition, it became known for the first time that original draft of the article did use the word "cause" and this, in fact may make the deposition more helpful to plaintiffs than defendants. At future Accutane trials, the parties may call Reddy to testify, but it is not grounds to remand this matter.

New Scientific Evidence

At the time of the trial there were animal studies, internal memorandums, causality reports, as well as scientific literature including case abstracts placed in various recognized

scientific journals, reference to the IBD/Accutane connection in an accepted medical textbook, and the Reddy article that described a study done by the authors linking IBD and Accutane by independent causation evaluation using the Naranjo scale to reported cases of IBD from persons on Accutane.

The defendant had not conducted any clinical trials or large epidemiology studies to explore the issue and there was only limited literature as described above. Recently, there have been some new studies and literature on the issue of the causal relationship between IBD and Accutane. The new evidence that now exists consists of depositions of the Reddy article authors which, as previously discussed, could be helpful to defendants or plaintiffs, and certainly it cannot be stated that these depositions would have clearly changed the outcome of the trial.

There are other pieces of literature that will undoubtedly be discussed by experts at future Accutane trials, but which were not relied upon (because they did not exist) by the experts in this trial. Although the defendant, Hoffmann La-Roche, has ceased to manufacture Accutane, it is still being manufactured and sold in a generic form by other companies. There is an interest in the relationship between Accutane and IBD which is demonstrated by recent publications describing studies. These papers suggest more studies should be done.

The Court has reviewed these papers. They present conflicting results and there are statements in them that could be useful to support the opinions of both defendant and plaintiffs experts.

In cases that turn on scientific evidence, the cases usually involve a "battle of the experts" and new findings, new studies and new opinions can and will evolve over time. Science is a search for truth, but it does not have a finish line. Scientists regularly look again, test again and find additional scientific evidence to support or disprove what is believed to be true by all or part

of the scientific community. In law, unlike in science, there must be a final decision based on the facts and opinions presented at trial.

In Quick Check Stores v. Twsp. of Springfield, 83 N.J. 438, the New Jersey Supreme Court sets forth the law that should be applied in this case:

When a motion for a new trial is made under R. 4:49-1 to produce additional evidence, such a motion should be granted when that evidence would probably alter the judgment and by due diligence could not have been discovered before the court announced its decision. See *Nieves v. Baran*, 164 N.J. Super. 86 (App.Div.1978). These are also among the prerequisites to relief from a final judgment within one year under R. 4:50-1. Under that rule it is well established that it must appear that the evidence would probably have changed the result, that it was unobtainable by the exercise of due diligence for use at the trial, and that the evidence was not merely cumulative. *State v. Speare*, 86 N.J. Super. 565, 581-582 (App.Div.1965), certif. den. 45 N.J. 589 (1965); *Minter v. Bendix Aviation Corp.*, 26 N.J. Super. 268, 271 (App.Div.1953), rev'd on other grounds, 24 N.J. 128 (1957); *State v. Hunter*, 4 N.J. Super. 531, 536 (App.Div.1949).
[Emphasis added]

The new literature was certainly not available at trial and is not cumulative but there is no certainty that it would have changed the result. The effect of this new evidence may or may not change the outcome of future motions and trials, but at this point, the Court cannot find there was a miscarriage of justice. It is likely before or after the Appellate Division decision in this case is rendered there may be more new studies. Before the hundreds of Accutane cases that are continuing to be tried now, it is very likely there will be new studies. This is the nature of scientific research. This principle was described by the District of Columbia Court of Appeals in Merrill Dow Pharmaceuticals v. Mary Virginia Oxendine, 649 A.2d 825, at 831.

Although science is a constantly evolving process, the law depends upon a high level of certainty once an outcome has been determined. A trial can be no more than a resolution of an immediate dispute on the basis of present knowledge; its outcome must turn upon the teachings of science as understood at the time of trial as best can be discerned through the presentations of the parties. Where scientific facts are at issue, it is not unexpected, given the nature of the process, that the passage of time will

bring forth further scientific data and inquiry relating to the ultimate scientific fact at issue. To reopen the trial's determination of scientific truth, however, runs squarely into the fundamental principle of certainty.

And further quoted:

"A fundamental principle of litigation that has been stressed in a variety of contexts is the importance of finality." *Id.* at 1218. Consistent with this approach, courts have generally held that part of the criteria for the grant of a motion on the basis of newly-discovered evidence is that the evidence "is material and controlling and clearly would have produced a different result if presented before the original judgment," *Brown v. Petrolite Corp.*, 965 F.2d 38, 50 (5th Cir. 1992)

One of the new studies defendant relies upon was authored in part by an expert consultant for one of the generic manufacturers of Accutane who are in litigation. The most recent study has language that is helpful to defense and other language helpful to plaintiffs. This study finds a statistically significant relationship between IBD and the use of Accutane but in an analysis of subgroups the statistics demonstrate a causal relationship between use of Accutane and ulcerative colitis but the study did not produce such evidence of a link between Accutane and Crohn's disease. All the recent literature calls for more studies. The battle of the experts outside the courtroom is continuing to unfold and it is impossible at this stage to know how these recent developments will influence a jury. Clearly defendants have not demonstrated that the new evidence clearly would have caused a different result.

Closing Remarks on Testimony of Dr. Alan Bess

The defendant next argues that plaintiffs counsel distorted the testimony of Dr. Alan Bess in their closing remarks, and that these remarks had a "clear implication that Roche was somehow a bad actor driven by greed." Generally, counsel is given "broad latitude" in making closing remarks. However, comments must be "restrained within the facts shown or reasonably suggested by the evidence adduced." *State v. Bogen*, 13 N.J. 137, 140 (1953); see *Tartaglia v.*

UBS Painewebber Inc., 197 N.J. 81 (2008). Counsel must not “misstate the evidence or distort the factual picture.” Condella v. Cumberland Farms, Inc., 298 N.J. Super. 531, 534 (Law Div. 1996). “To remedy the prejudice caused by untrue statements or inferences, trial courts may, depending on the severity of the prejudice, issue a curative instruction or grant a mistrial.” Bender, supra, 187 N.J. at 433. However, a failure to object to remarks at closing “speak[s] volumes about the accuracy of what was said.” Tartaglia, 197 N.J. at 128.

The comments made by Mr. Hook in closing were:

He said there were many disagreements between his department of drug safety and marketing on Accutane. Many disagreements. Roche marketing took precedence over safety. Unbelievable. Unbelievable. Marketing calling the shots. And why? They had another problem going on with another side effect for Accutane. Any label change would hurt U.S. sales. Any label change. So, if it was any label change would hurt sales on another side effect is that going to apply here? Here it is. This is the problem I had with their psych issue. Any label change would hurt – ‘Tell me what the disagreement was over?’ ‘The disagreement was, as I said earlier, Frank Condella felt very strongly that any label change’ – any label change ‘would hurt U.S. sales. Their philosophy was to protect the franchise, build the product, and he made it very clear that he wouldn’t tolerate any action that would hurt the product.’

[Hr’g Tr. 3637:15-25, 3638:1-9, Nov. 18, 2008.]

The comments made by Mr. Hook properly told the jury that the disagreement over the labeling change was not in relation to IBD, but another side effect. However, Dr. Bess did testify as to his frustration with marketing trumping safety and being told any label change would be negative for the company. Mr. Hook properly described the testimony of Dr. Bess. In fact, Mr. Hook quoted from the transcript, which was in evidence, directly. Any characterization that Mr. Hook made of Dr. Bess’s testimony did not misstate the factual picture, and was within the latitude counsel is granted in making closing remarks.

To the extent that the defendant argues this testimony of Dr. Bess should not have been admitted, the court rejects the argument. The disagreement between marketing and safety may

not have been based on the same side effect, but it was a disagreement over whether the labeling of side effects for the same drug Accutane should not be strengthened because any stronger warning would be detrimental to sales. The testimony was very relevant and was not unduly prejudicial.

Public Citizen Letter

The defendant argues that the Public Citizen letter was not necessary to notice, because the cooperation with the FDA on the IBD issue demonstrates that Roche had notice of the IBD issue, prior to the letter. However, the letter addresses whether Roche was aware of the *severity* of the IBD risk associated with the drug. Further, the admission of the letter was subject to a limiting instruction from the court, which further eliminated any possibility of prejudice.

This issue was the subject of a motion in limine which was ultimately denied by the court. The court allowed the Public Citizen letter to be admitted, specifically stating that "it is important to go to that issue of notice, what they were told, who told them, when it was told, and the FDA's response, and those are factual issues I think that are important." Hr'g Tr. 663:8-11. The Court then redacted several portions of the letter, thoroughly reviewing the letter to minimize any prejudicial effect. Hr'g Tr. 664:1-673:1. The Court further expounded the reasons for the admission of the letter, stating:

I do believe this is an important document to show that as early as 1983 the same things that are being said in this trial were being said to Roche, and they were being given the same concerns and put on alert about those concerns that early. ... It should not be used for causation, and I will give a curative instruction.

[Hr'g Tr. at 673:2-6, 17-18.]

Therefore, the prejudice that the letter could have caused was effectively minimized by the Court's redactions and limiting instruction.

Causality Assessments

The defendant argues that the causality reports were improperly admitted at trial and were utilized in a highly prejudicial manner. There has been conflicting testimony over the causality reports and what they identified. Although the defense contends the causality reports were never intended to conclude causation, Roche employees testified contrarily. Dr. Bess's testimony specifically provided that "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." Hr'g Tr. 118:1-4. Testimony was also presented from Dr. Reshef, a former Roche medical safety evaluator, regarding the process undertaken to produce the causality reports. When Dr. Reshef was asked if the purpose of the causality assessments was to make a "scientific evaluation as to the relatedness of the causality of that event," he responded "Yes." Hr'g Tr. 148:12-17. It was not improper for the plaintiffs to point out that former Roche employees considered the causality reports to signify causation. Further, the causality reports were very relevant to the internal knowledge of Roche and whether the warnings appropriately described the risk of IBD. The evidence was appropriately put before a jury.

The defense argues that plaintiff's use of a coding manual from 1978, four years before Accutane came on the market, was improper and prejudicial. However, the authenticity of the coding manual was not challenged at trial. The defendant supplies no evidence to demonstrate the existence of another coding manual or other evidence that would demonstrate this coding manual was not in effect. The document was not improperly admitted.

The defense also takes issue with the Naranjo scale testimony, in that the Court did not allow to be taken from defense's labeling expert. The defense states that this ruling enhanced the prejudice suffered from the causality reports, because the defense could not counter the plaintiffs Naranjo score testimony. However, the Court did not bar the defendant from discussing the Naranjo score with their causation expert, or from discussing the causality reports with their

warnings expert. Rather, the Court prevented the defense from attacking the Naranjo score with a warnings expert, Dr. Faich, when the Naranjo score was not used by Roche for warnings purposes until *after* the plaintiffs in this trial consumed the drug. The Naranjo score used by the scientists who authored the Reddy article could go to causation but could not possibly have altered the warnings given to these plaintiffs. Allowing the defense's warnings expert to testify as to the value of Naranjo scoring would have been misleading and confusing to the jury. The Court detailed this ruling at trial, stating that:

[Y]ou could use the Naranjo scale, could have, and could go through it in detail with your causation expert, but you didn't do that. You could, in fact, with this expert go through the causality reports. You can discuss the value of causality reports. You can discuss the subjectivity of them. You can attack them. But what you're doing here is simply attacking the Naranjo score, which is not part of the basis of what they knew or didn't know when they did the warnings, and this guy is a warnings expert, period. He is not a causation expert.

[Hr'g Tr. 3153:18-3154:3.]

These rulings did not result in prejudice to Roche, and again, the defendants chose not to offer this critique by the causation experts.

Testimony of Prescribing Physicians

The defendant argues that plaintiffs turned the prescribing physicians into labeling experts. Specifically, the defendant focuses on testimony from each of the prescribing physician that asked, in differing ways, if Roche had evidence that Accutane caused IBD, or evidence of positive challenge-challenge and positive rechallenge regarding Accutane and IBD, would you have wanted to know this information. Defendant argues these questions turned each prescribing physician into labeling experts, and confused or misled the jury.

The court rejects the argument that these comments were misleading or confused the jury. The questions were necessary to examine proximate causation: specifically, whether a different

warning would have changed the information communicated to the patient or the manner in which the physician prescribed the drug. The questions were appropriate for the prescribing physicians.

Use of Hearsay

The defense argues that Dr. Sachar improperly used hearsay to bolster his opinion and therefore violated the Rules of Evidence, by conveying the opinions of Dr. Reddy and her co-authors. First, as the plaintiffs note, to the extent that Dr. Sachar relied on any scientific literature, the learned treatise exception to hearsay would apply. The learned treatise exception to the hearsay rule allows “statements contained in published treatises, periodicals, or pamphlets...established as a reliable authority by testimony or by judicial notice” to be read into evidence “[t]o the extent called to the attention of an expert witness upon cross-examination or relied upon by the expert in direct examination.” N.J.R.E. 803(c)(18).

However, there is a limitation on the extent to which an expert may rely on a learned treatise. “An expert witness should not be allowed to relate the opinions of the non-testifying expert merely because those opinions are congruent with the ones he has reached.” Krohn v. New Jersey Full Insurance Underwriters Ass’n, 316 N.J. Super. 477, 486 (App. Div. 1998).

While the court recognizes this limitation, the defendant does not cite to a point in Dr. Sachar’s testimony where he utilized expert opinions to “bolster” his own instead of using them as a basis for his opinion. Dr. Sachar discussed the learned treatise and how he relied upon it and what it showed him. The defendant appears to only argue that the *plaintiffs counsel* utilized Reddy’s opinions improperly in their closing arguments. Specifically, plaintiff’s counsel used a closing slide that indicates Dr. Reddy and her co-authors agreed with Dr. Sachar’s causation opinion. Def.’s Brief at 20. However, as noted above, counsel is given “broad latitude” in making closing remarks and comments must only be “restrained within the facts shown or reasonably suggested

by the evidence adduced.” State v. Bogen, 13 N.J. 137, 140 (1953). Plaintiff’s closing remarks are suggested by the evidence adduced as trial and were not beyond the latitude granted for closings.

Impeachment Documents

The defendant objects to the plaintiffs use of undisclosed documents during their cross examination of Dr. Gerald Faich, who was introduced as a defense expert. Plaintiff utilized certain documents to impeach the credibility of Dr. Faich without producing the documents during the discovery process. The court rejects the defendants argument that the use of these documents caused them to suffer prejudice.

The New Jersey Court Rules have a very liberal standard for determining what evidence is discoverable. R. 4:10-2(a) provides that “[p]arties may obtain discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the pending action....” (emphasis added). The evidence purportedly not produced here relates to an entirely collateral issue, completely unrelated to the subject matter at hand. It is not required to be disclosed by the rules of discovery.

Further, the production of documents request that the defendant points to specifically states that the plaintiffs must produce all documents that the plaintiff “may attempt to exhibit or introduce into evidence at trial.” However, as these documents were used solely for impeachment purposes, they were not introduced into evidence nor did plaintiff seek to introduce the documents for that purpose. The documents were not required to be disclosed during the discovery process.

Consolidation of Claims

Defendant also argues that Sager, Mace, and Speisman should have had separate trials because their claims do not arise out of the “same transaction or series of transactions.”

Defendant asserts that each plaintiff had a different medical history and was prescribed different amounts of medications. More specifically, defendant submits that Speisman's case caused severe prejudice to Roche because he was a surgical candidate and the history of his treatment led the jury to conclude that Mace and Sager might also require surgery and consequently inflated their award.

The court previously considered whether plaintiff's cases should be tried separately in a pre-trial motion by defendant. The court denied defendant's motion there and affirms its position here.

R. 4:38-1 allows the court to consolidate cases and reads, "When actions involving a common question of law or fact arising out of the same transaction or series of transactions are pending in the Superior Court, the court on a party's or its own motion may order the actions consolidated." The purpose of consolidation is "to eliminate multiplicity of litigation and to enable the courts so to arrange pending causes that the same facts and transaction would not undergo the inconvenience of double litigation." Judson v. People's Bank, 17 N.J. Super. 143, 144 (Ch. Div. 1951). Cases should be consolidated to promote judicial economy where there are the "same witnesses, the same facts and the same testimony." Id. at 145. Consolidation is appropriate as long as "questions of law and fact are common to both cases." Robertson v. Biernacka, 9 N.J. Super. 591 (Ch. Div. 1950).

Consolidation is proper in pharmaceutical cases where the facts are not identical. In Batson, two sisters filed two separate cases claiming that they had suffered teeth staining after being prescribed different brands of tetracycline by the same doctor. Batson v. Lederle, 290 N.J. Super. 49 (App. Div. 1996). On appeal, the court commented, "we do not understand why these matters, which were to be tried sequentially, were not consolidated, since the proof in each case was practically identical." Ibid.

Here, consolidation was proper because plaintiffs' cases share common questions of law and fact, and trying the cases separately would have tripled the cost, time, and effort of preparing and trying plaintiffs' cases. All three plaintiffs' claims arise out of the same transaction because they all suffered IBD as a result of ingesting Accutane and asserted a failure to warn claim against Roche. Plaintiffs Mace, Sager, and Speisman relied upon the same documents, records, and expert testimony to support their cases. Florida law also applied to all three plaintiff's cases.

There are factual differences between plaintiff's cases, but as the court in Batson asserted, consolidation is proper even where all the facts are not identical. Defendant asserts that Speisman's case prejudices Mace's and Sager's case because Speisman is a potential surgical case. However, the testimony presented on the specific facts of each plaintiff's case ensured that the jury was able to distinguish Speisman's case from Mace's and Sager's case. The jury also returned a verdict with much higher award for Speisman, than for the other plaintiffs. A discussion of the damages awarded each plaintiff follows. In other pharmaceutical cases, this Court has had juries on more than one occasion decide proximate cause in favor of one plaintiff and deny the other plaintiff a verdict.

Remittitur

Defendant contends that the plaintiffs' verdicts were excessive and moves for a remittitur of damages. If the Court orders a remittitur, defendant is entitled to a new trial if plaintiffs do not consent to a reduced judgment. There is a high threshold where defendant seeks a remittitur for jury damages because the jury's judgment as the initial fact-finder is "entitled to considerable respect." Baxter v. Fairmont Food Co., 74 N.J. 588, 597 (1977). Justice Hall opined, "a trial judge should not interfere with the quantum of damages assessed by a jury unless it is so disproportionate to the injury and resulting disability shown as to shock his conscience and to convince him that to sustain the award would be manifestly unjust." Id. at 596. A jury award

should not be upset unless, "it clearly and convincingly appears that there was a miscarriage of justice under the law." Ibid. Similarly, Justice Johnson indicated that remittitur can only be ordered where there is a sense of "wrongness" and what "must exist in the reviewing mind is a definite conviction that the judge went so wide of the mark, a mistake must have been made." Id. (quoting State v. Johnson, 42 N.J. 146, 162 (1964)).

In determining whether the awarded damages are excessive and a remittitur should be ordered, the judge may not substitute his judgment for the jury. The judge "is not a thirteenth and decisive juror." Id. at 598. The judge must also evaluate the evidence in the light most favorable to the plaintiff. Id. at 599.

Here, the jury awarded Mace \$128,000 in economic damages and \$1.5 million for compensation of pain and suffering, disability and loss of enjoyment of life. The jury awarded Sager \$125,000 in economic damages and \$2.5 million for pain and suffering, disability and loss of enjoyment of life. Speisman was awarded \$142,500 in economic damages and \$8.5 million for pain and suffering, disability and loss of enjoyment of life.

The evidence on disability, pain, suffering and loss of enjoyment of life must be considered in a light favorable to plaintiffs. This Court must review each of the awards separately.

The evidence presented during the trial was that IBD is a permanent condition that has no cure. IBD, or Inflammatory Bowel Disease, consists of two distinct types of Crohn's Disease and Ulcerative Colitis. Both cause serious and recurring gastrointestinal problems. In both types of IBD, the patients have rectal bleeding, diarrhea, incontinence of bowel, fatigue and stomach and bowel cramping and pain. The embarrassment of losing control of bowels while in public creates emotional suffering that was testified to by all three plaintiffs. The disease is chronic but does go into periods of remission and then periods when the disease flares up. Patients should

have at least yearly colonoscopies according to the experts. As to each plaintiff there was specific evidence about their individual condition.

Jordan Speisman

Speisman testified that he has been diagnosed with Ulcerative Colitis. He has been treated with over ten (10) different medications including Asacol that he was on from 2001 up to the trial. He also took prednisone, which his mother described as making his face 'all bloated and distorted.' Hr'g Tr. 1051:9-10. In addition at the time of trial he had been placed on an IV medication Remicade which has numerous side effects.. His mother testified he is so disabled he often cannot get off the couch. Both he and his mother described him as so tired and in such pain from his condition that he can barely function.

His mother stated the following describing her son:

He comes out of the bathroom, and I say to him, "Are you okay?" And he is like, he doesn't want to talk about it, and you know, I'm a mom, and I say to him, "What's going on, what is wrong?" And he says, "Well, I have had blood in my stool and I have been going all day." And, you know, he is embarrassed to tell me, and then he will just like, you know, he will just go lay down on the couch and he takes a blanket. It's a routine.

And he goes on the couch, and he puts on the blanket because he is cold and he is pale and he is sweaty. And if he has been on prednisone his face is all distorted and round. And sometimes he is shaking. And he lays down on the couch, and I turn on the TV, and he lays there and he dozes.

[Hr'g Tr. 1038:1-15.]

Later his mother described in her testimony the emotional toll the bowel problems have had when she stated:

Q And can you tell the jury what you have observed about Jordan when he is having a flare and he is out in public?

A Just gets like really panicky. He gets like - - because he is afraid that he is not going to get to the bathroom, and he gets sweaty and anxious and hyped up, and I can just see it coming on when it is happening. And it is that whole stress of not being able to reach the bathroom in time.

And it is not even just in public places. He was in his house, and he was living with two roommates, and there's two bathrooms. He always had to make sure there's two

bathrooms at least wherever he is – wherever he lives. And he told me that he had to go to the bathroom really bad and that both of them were in the bathrooms, and he had to go so bad that he went out in the garage, and he had to go in in a box, and I just – I was horrified for him.

[Hr'g Tr. 1052:7-24.]

Jordan Speisman himself described ups and downs with the disease, but related to the jury descriptions of the numerous procedures he has had performed upon him and the physical pain as well as the emotional upset over never knowing when you will need to use a bathroom and the fear you won't make it to the bathroom. His testimony was his disease was getting worse and he was having constant flares of the disease. He testified he could not live in the condition he had been in during the months before trial. He was scheduled for a surgical consult at the time of trial. Speisman testified, "It is embarrassing. I mean, the last one I can remember, which wasn't very long ago ... just driving home and trying to make it home before I had to go the restroom, and I couldn't make it and I used the restroom in my truck, on myself, and had to do laundry and take a shower." Hr'g Tr. 917:9-14.

Speisman testified that he had been a very active person and that during one flare up that lasted a month, he did not get out of bed most days and had about fifteen bowel movements a day. Hr'g Tr. 929:5-25. He also testified that after graduating from college, he worked as an insurance salesperson, but can't go to work anymore and is on disability. Hr'g Tr. 889:5-10. He had been getting IV Remicade every six (6) weeks before the trial, and described constant medical treatments and procedures. He was and still is a young man and the testimony was that he has a serious disabling condition that he will have for the rest of his life.

Lance Sager

Sager testified to severe stomach cramping, rectal bleeding, and uncontrollable urgency to use the bathroom. Hr'g Tr. 251:5-6. He testified, "I usually crawl up in a ball and just wait there, and I really can't eat too much, and I feel I get the shivers, I get weak and sometimes get

sick because of that.” Hr’g Tr. 275:1-6. Sager said that he had painful anal abscesses and a fistula that would cause him such severe pain that he could not walk straight up or sit down. Hr’g Tr. 263:9-21. Sager also described constant treatments and medications which had dramatically changed his life.

Sager testified that he is often not able to go to work and as had to leave work when he has accidents on himself. Hr’g Tr. 272:1-10. His testimony described a life changing disease that caused him great physical and emotional pain.

Verdicts for Speisman & Sager

Both of these plaintiffs were young men at trial. They described horrible effects of IBD in their lives. The testimony supported the fact their conditions would be permanent.

The weight of the evidence supports the jury’s verdicts for both of them as reasonable. Clearly, there was evidence that IBD has caused a very painful, significant alteration of their lives. The Court does not find that there is a sense of “wrongness” in the juror’s award or that a mistake must have been made. The larger award for Speisman was justified by his description of his illness.

In addition, similar verdicts have been awarded in comparable cases. In McCarrell v. Hoffman-LaRoche, Andrew McCarrell obtained a \$2.5 million verdict against Roche by arguing that Accutane caused his IBD. In Kendall v. Hoffman-LaRoche, Kamie Kendall Rees was awarded a \$10.5 million verdict against Roche for IBD caused by Accutane. Also, in Mason v. Hoffman-La Roche, the jury awarded Adam Mason \$7 million in damages against Roche for IBD caused by Accutane. 2001 C.A. 002416 (Escambia Cir. Ct. 2007). Sager’s awards of \$2.5 million, and Speisman’s award of \$8.5 million respectfully are in line with their described disabilities, pain and suffering, and did not shock the Court.

Kelly Mace

There was testimony that as a result of IBD, Kelly Mace has suffered physical pain and embarrassment, and has been limited in her activities. Mace testified that IBD, "felt like a really intense pain in my stomach ... like someone was kicking me in the stomach." Hr'g Tr. 424:1-4. She also testified that she carries an extra pair of pants wherever she goes and said, "[y]ou're just kind of stuck with living in fear your whole life ... chained to the bathroom." Hr'g Tr. 446:15-16. She was young, had a long life expectancy, and according to all the medical testimony, IBD is a permanent condition. She described losing control of her bowels in a fitting room at a store while shopping and other similar occurrences.

However, this court also recognizes that unlike Sager and Speisman, who treated regularly with doctors, had repeated procedures done on them and took numerous medications to help them, Kelly Mace did not get this type of medical care. Mace testified that she had rectal bleeding between 2003 and 2006, and flares of her disease and obviously the jury believed her. However, Mace had a colonoscopy in 1999, but has not had any colonoscopies since that time. Between 2003 and 2006, Mace did not visit a gastroenterologist. Hr'g Tr. 471-472. Mace also testifies that she has not taken any prescription medications since 2003, and that she is currently taking over-the-counter medications and has tried probiotics. Hr'g Tr. 471:3-9. The evidence supporting significant disruption of her life and constant medical treatment for her disease such as endured by Speisman & Sager was simply not presented. Her verdict of \$1.5 million was the smallest of the three, but unlike the other two verdicts, the size of the verdict did shock and surprise this Court. This Court, therefore, orders that within twenty (20) days, plaintiff, Kelly Mace, must accept a remittitur of her verdict to the sum of \$450,000.00, or the court will order a new trial as to her damages only.

This is still a substantial sum because she did present evidence she has flares of her disease continuing up to and at trial. Her testimony was supported by mention of her problems

in various medical records. Her descriptions of her loss of control of her bowels on several occasions in public places was believable. The Court also recognizes she is young and has a permanent chronic disease although it does not appear to be so severe she required constant medical intervention. The defense suggests her lack of medical procedures and prescription medications means she does not have a significant injury, but the jury found her credible when she described repeated bouts of incontinence and bloody diarrhea that she was simply living with because she was told her condition has no cure and prescribed medications did not seem to help her. She and her mother basically testified she just put up with repeated flares of her condition because they believed the way to deal with adversity was to just accept it.

Verdict Form

Defendant also maintains that the verdict form provided to the jury was improper. First, defendant argues that that the second question directed to the jury, "Is the use of Accutane a cause of IBD in some people who take it?" presented a question of general causation with no context or connection to the plaintiffs' claims. Defendant also argues that the verdict form did not provide the jury with direction on the burden of proof, and that the verdict form allowed the jury to determine that plaintiffs would not have taken Accutane even if their doctors prescribed it.

The verdict form presented to the jury read:

- (1) Did Roche fail to provide an adequate warning to plaintiff [name] prescribing physician about the risks of IBD from Accutane that Roche either knew or should have known about prior to [time period]?
- (2) Is the use of Accutane a cause of IBD in some people who take it?
- (3) Would a stronger warning have prevented the plaintiff from taking Accutane?
- (4) Was Accutane a substantial factor in causing plaintiff to develop IBD?

The verdict form serves as a decision tree for the jurors to follow in reaching a verdict. The verdict form did provide factual context specific to each plaintiff's claim. The general causation question is a necessary step in the process, but it is a "general" issue. It is the testimony, arguments, and supporting documents presented during the trial that provide the jurors with context and connection specific to each plaintiff. The verdict form also need not advise the jury as to instructions on the law, because instructions on the law should be provided by the court during the jury charge. Thus, the verdict form should not have provided the jury with direction on the burden of proof. The court appropriately advised that the burden of proof was on the plaintiff during the jury charge as follows,

The burden of proof is on the plaintiffs to establish their claims because if a person makes an allegation then that person must prove the allegation. In this action the plaintiffs have the burden of proof. Plaintiffs claims have to be proven by a preponderance of the evidence. This means that plaintiffs must prove each element of their claims is more likely true than not. If you picture a scale, and you put on one side of the scale all the credible evidence that favors the plaintiff, and you put on the other side of the scale all the credible evidence that favors the defense on the other side plaintiffs have to tip the scales ever so slightly in their favor in order to prevail. If the scales tip in favor of the defense or if they're absolutely equal then plaintiffs haven't prevailed, and you must find for the defendant.

[Hr'g Tr. 3658:4-19, Nov. 18, 2008].

The verdict form properly asked the proximate cause question and the instructions followed the law. The court gave the following instruction on proximate cause during the jury charge:

"To prove proximate cause each of the plaintiffs must prove first whether a stronger warning would have resulted in he or she not being prescribed Accutane or he or she not taking the drug. To prove proximate cause each of the plaintiffs must also prove that he or she has inflammatory bowel disease and that Accutane was a cause of his or her IBD, but they need not prove that Accutane was the only cause."

[Hr'g Tr. 3663:11-18.]

Next, a more specific causation question in place of the second general causation question, such as, "Has Kelly Mace proven that Accutane was a cause of her IBD?" is unnecessary. The second question, "Is the use of Accutane a cause of IBD in some people?" more clearly separates general causation from specific causation, which is addressed in the third question. The second question does provide helpful information to the court and parties, but it does more than that. The second question serves as a gateway question because if the jury does not find that Accutane can cause IBD in some people, the jury does not need to deliberate any further.

For the foregoing reasons, defendant's motion is granted in part and denied in part. Defendant's motion for judgment notwithstanding the verdict, or in the alternative a new trial, on all issues is denied as to all three plaintiffs. However, defendant's motion for a remittitur, or new trial on damages, is granted with regard to Kelly Mace. The court will order a remittitur for Mace in amount of \$450,000 for pain and suffering, and gives her twenty (20) days to accept the remittitur, or the Court will schedule a new trial on damages only for Kelly Mace.


CAROL E. HIGBEE, P.J.Cv.