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SUPERIOR COURT OF NEW JERSEY
COUNTIES OF
ATLANTIC AND CAPE MAY

CAROL E. HIGBEE, P.J.Cv.

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

CASE: **In re Accutane Litigation**
In re Isotretinoin Litigation

DOCKET #: **Case No. 271**

DATE: **July 1, 2010**

MOTION: **Reconsideration of May 6, 2010 oral ruling denying Roche's motion to amend March 6, 2009 order regarding *ex parte* communication with treaters**

ATTORNEYS: **Michael Rosenberg, Esq. – Plaintiffs**
Michelle Bufano, Esq. – Defendants Hoffman-La Roche Inc. and Roche Laboratories Inc.
James Ferrelli, Esq. – Defendants Ranbaxy, Inc. Ranbaxy Laboratories, Inc., and Ranbaxy Pharmaceuticals, Inc.

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

FACTUAL AND PROCEDURAL BACKGROUND

On March 6, 2009, this Court issued an order which provided, "Defendants and their attorneys may not communicate with any physician-expert who has or is treating a patient

involved in this litigation." On March 3, 2010, defendants Hoffman-La Roche Inc. and Roche Laboratories Inc. ("Roche") filed a motion to amend this order. Roche argued the Court should amend its order so it reflects the Court's intent that neither party may contact treaters *ex parte*. Plaintiffs opposed this motion arguing the Court never intended to bar communications between plaintiffs' attorneys and plaintiffs' physicians and to do so would violate the fiduciary doctor-patient relationship. After the April Accutane trial was adjourned, oral argument on this motion was also adjourned. At the May 6, 2010 case management conference, this Court made an oral ruling denying Roche's motion. The Court informed counsel there would be a written memorandum issued on this matter. The Court based its decision on the belief that there is or should be a special relationship between a doctor and a patient.

Roche sent a letter to this Court on May 12, 2010 to illustrate "the fundamental prejudice and unfairness of allowing only one party unrestricted *ex parte* access to treating physicians." Roche specifically pointed to one case in which it claims it was prejudiced because plaintiffs' counsel has unrestricted access to treaters. First, Roche argued that Kimberly R. Wilson, Esq. ("Ms. Wilson"), counsel for plaintiffs, had a telephone conversation before his deposition with Dr. Sachdeva, a treating gastroenterologist, and Dr. Sachdeva requested "any" literature relevant to the lawsuit. Defense alleges Ms. Wilson only provided the Crockett article, which is a recent epidemiology study which in part supports a causal link between IBD and Accutane, and not the Bernstein article, which found in another epidemiological study there was no such link. The latter article was authored by one of the generic manufacturers of Accutane litigation expert. The second instance Roche points to concerns a pre-deposition conversation between Ms. Wilson and Kathleen Boykin, a prescribing nurse practitioner, in which Ms. Wilson allegedly stated she is representing Falco because "she feels that Accutane caused his IBD," and that "there are findings that people on Accutane have ulcerative colitis." The third instance involves

a conversation between Ms. Wilson and Julie Carson, a prescribing physician's assistant, in which Roche alleges Ms. Wilson told Ms. Carson that IBD "was buried very deeply" in the Accutane package insert. Roche argues these events demonstrate why allowing one party *ex parte* access to treating physicians creates an unfair and unlevel playing field and prejudices the defense.

On May 14, 2010, the Court informed all counsel it would be treating the May 12th letter as an informal motion for reconsideration of the May 6th oral ruling and gave counsel until Friday, May 21, 2010 to submit any additional briefs on the matter. In response, counsel for the generic defendants essentially joined in Roche's request for an order prohibiting all counsel from engaging in *ex parte* communications with treaters. Counsel for generics argued plaintiffs have utilized their own *ex parte* access to treaters to covert them into advocates for plaintiffs' legal positions.

In opposition plaintiffs' counsel filed a letter and affidavit of Ms. Wilson. Plaintiffs argue there was nothing improper with Ms. Wilson's contacts with the treating physicians and the Court should deny defense's motion for reconsideration. Plaintiffs responded to each individual incident alleged by defense. First, with regard to Dr. Sachdeva, plaintiffs argue the doctor asked Ms. Wilson if there are any articles linking Accutane with ulcerative colitis and not, as defense counsel alleged, for any literature relevant to the lawsuit. Based on that specific request, Ms. Wilson provided Dr. Sachdeva with the Crockett article, which strongly links Accutane to ulcerative colitis but not to Chron's disease, another form of IBD, by a statistically significant margin. She did not discuss the article and the article played no role in his deposition. With regards to Nurse Boykin, plaintiffs allege that twenty minutes prior to her deposition, Nurse Boykin met with Ms. Wilson and Nurse Boykin asked what the lawsuit was about and the types of questions she would be asked. In response, Ms. Wilson informed her that Falco was alleging

Accutane caused his ulcerative colitis and after more questions from Nurse Boykin Ms. Wilson informed her this was not the first lawsuit with these allegations and plaintiffs had previously won such lawsuits. Finally, concerning the allegations about Ms. Carson, plaintiffs argue that while walking to the conference room to take Ms. Carson's deposition, Ms. Carson told Ms. Wilson she had no idea that Accutane was linked to IBD and that she did not believe there was anything in the label. Ms. Wilson then corrected her by saying "well, it is in the label, but don't feel bad, it's buried." At her deposition, the nurse practitioner candidly revealed her lack of awareness of the warning. It should be noted that almost all prescribing doctors received almost all the information they got about drugs from the defendant manufacturers in their label, their Dear Doctor letters, and their sales representatives who regularly call on the doctors. In summation, plaintiffs' counsel argues there is no basis for the Court to amend its prior ruling, and the Court does not find this conduct was improper.

Defense counsel sent a reply letter to the Court on May 26, 2010. In this letter, the defendants argue that plaintiffs have an unique opportunity to influence treaters prior to their depositions since only the plaintiffs may have contact with them. Defendants further argue it is unfair that plaintiffs' counsel is able to develop a rapport with the treaters before the depositions while defense counsel does not have the same opportunity.

DISCUSSION

A. Stempler v. Speidell

In 1985, the New Jersey Supreme Court held that in personal injury litigation, a defendant's counsel could conduct informal interviews with a plaintiff's physician and that authorization for these interviews could be compelled from a plaintiff by a court order. Stempler, 100 N.J. at 382. Stempler involved a medical malpractice and wrongful death action

brought by a decedent's estate against one of the decedent's doctors who was the attending physician at the time the decedent died. Id. at 370-371.

The defendant sought to compel unrestricted authorizations that would permit the defendant's counsel to personally interview the decedent's treating physicians. The plaintiffs opposed the authorizations claiming that depositions were the only appropriate form of discovery to be used that wouldn't create an undue risk of disclosing confidential information that was not related to the litigation.

The Court weighed the interests in protecting the patient-physician privilege and the privacy interests of the plaintiffs in such cases against the defendant's right to interview a plaintiff's treating physicians instead of being restricted to formal, expensive, and inconvenient discovery methods, such as depositions and other procedures provided for by the Court Rules. Id. at 381. The Court concluded that these *ex parte* interviews, as well as other informal means of discovery that reduce the cost and time of trial preparation should be encouraged. Id. at 382. Consequently, the Court held that because a physician would not participate in such an interview without the consent of the plaintiff, the authorization could be compelled. Id. The Court made efforts to preserve the plaintiff's privacy interests and the patient-physician privilege by requiring defendants to provide reasonable notice of the time and place of the proposed interviews. Id. The authorizations also required defendant's counsel to "provide the physician with a description of the anticipated scope of the interview, and communicate with unmistakable clarity the fact that the physician's participation in an *ex parte* interview is voluntary." Id.

Further, the Court held that a plaintiff could seek and obtain a protective order, if an *ex parte* interview threatens to cause substantial prejudice to the plaintiff. Id. at 383. The protective order could either require that plaintiff's counsel be present during the interview or "in extreme cases," require that the defendant conduct a formal deposition. Id. The Court believed

that "the flexibility afforded by our decision will permit trial courts and counsel to fashion appropriate procedures in unusual cases without interfering unnecessarily with the use of personal interviews in routine cases." Id.

B. HIPAA, the Privacy Rule, and Smith v. American Home Products Corp. Wyeth-Ayerst Pharmaceutical

In 1996, Congress enacted the Health Insurance Portability and Accessibility Act, 42 U.S.C. § 1320d, *et seq*. The matter of whether the Stempler decision was preempted by HIPAA was directly addressed by the Honorable Judge Corodemus, J.S.C. in the case of Smith v. American Home Products Corp. Wyeth-Ayerst Pharmaceutical, 372 N.J. Super. 105 (Law Div. 2003) as an issue of first impression.

The Smith case involved a mass tort against manufacturers of the drug phenylpropanolamine ("PPA"). The plaintiffs in that case challenged the defendants' request for Stempler authorizations claiming that the informal discovery procedures were preempted by HIPAA. Smith, 372 N.J. Super. at 109. The Smith court ultimately found that HIPAA does not conflict with New Jersey's patient-physician privilege under N.J.S.A. 2A:84A-22.4 or with the informal discovery techniques permitted under Stempler. Id. at 110.

In rendering her decision, Judge Corodemus provided a detailed description of the history and purposes of HIPAA and the Privacy Rule. The Privacy Rule is a collection of regulations created by the Department of Health and Human Services that came effective in April of 2003 and sets forth the standards and procedures regarding the collection and disclosure of "protected health information" ("PHI"). Id. at 111. Judge Corodemus noted that a primary purpose of both HIPAA and the Privacy Rule is to control the dissemination of a patient's private medical information through electronic transmission. Id. at 123. The Judge also noted that both New Jersey law and HIPAA provide exceptions to the patient-physician privilege in the instance of

civil litigation. Id. at 125. Specifically, 40 C.F.R. § 164.512(e) allows for disclosure in the course of any judicial proceeding in response to a court order or in response to a subpoena, discovery request, or other lawful process, provided that certain requirements listed in the regulation are met. N.J.S.A. 2A:84A-22.4 provides:

> There is no privilege under this act in an action in which the condition of the patient is an element or factor of the claim or defense of the patient or of any party claiming through or under the patient or claiming as a beneficiary of the patient through a contract to which the patient is or was a party or under which the patient was insured.

HIPAA specifically provides that the Act supersedes any contrary provision of State law. 42 U.S.C. § 1320d-7(a)(1). State law is not preempted if it provides for additional protections beyond those afforded by federal regulations regarding patient health information. See 42 U.S.C.A. § 1320d-7(a)(1); 45 C.F.R. § 160.203. While HIPAA does not specifically authorize *ex parte* communications with plaintiffs' physicians, there is no explicit prohibition of such communications in the Act either. Law v. Zuckerman, 307 F.Supp.2d 705, 708 (D. Md. Feb. 27, 2004); see also Smith, 372 N.J. Super. at 132. After making this same observation, Judge Corodemus concluded that New Jersey law, should govern the courts and "*ex parte* interviews as a form of informal discovery may proceed as permitted under Stempler." Smith, 372 N.J. Super. at 132.

Although Judge Corodemus found that Stempler interviews were not prohibited by HIPAA, she also found that Stempler safeguards for disclosure authorizations were beneath the requirements set by HIPAA. Additionally, recognizing that mass tort cases may sometimes fall within the Stempler Court's meaning of "extreme cases," Judge Corodemus found that allowing *ex parte* interviews is not mandatory, but rather up to the court's discretion and in mass tort cases, formal discovery proceedings can be ordered. Id. at 131-133.

Ultimately, Judge Corodemus denied the use of *ex parte* interviews in the Smith case because of the large number of cases that had been filed and the very short period of time before trial was scheduled to begin. While the use of Stempler interviews was not allowed in Smith, Judge Corodemus specifically noted that they were not prohibited from future mass tort cases, "but rather, given the intricacy of such cases, special hearings early during case management for the design of HIPAA-compliant authorization forms may become the custom for conduct of Stempler interviews in future mass tort litigation." Smith, 372 N.J. Super. at 136.

C. Bonanno v. American Home Product

In a Case Management Conference on January 2, 2004, the Honorable Charles J. Walsh, J.S.C. determined that Stempler interviews would not be allowed in the New Jersey diet drug mass tort. Judge Walsh declined to say whether he believed Stempler interviews were preempted by HIPAA. Judge Walsh noted that it would be very difficult to control and administer cases by allowing Stempler interviews in that particular mass tort.

D. In re VIOXX

On November 17, 2004, this Court granted plaintiffs' motion to prohibit *ex parte* interviews of plaintiffs' doctors by defense counsel in the Vioxx litigation. The Court noted that trial courts were given discretion to forbid Stempler interviews in "extreme cases" and Vioxx was such a case. The Court also denied defense request to forbid plaintiffs' counsel from speaking to their client's doctors *ex parte*. The Court stated, "There is no decision known to this court where a Judge has restrained counsel from talking to their client's own doctors."

E. In re: Diet Drug Litigation

Judge Wilson, who succeeded Judge Walsh in managing the Diet Drug litigation, denied defendants' motion seeking *ex parte* interviews. Judge Wilson distinguished two decisions by Judge Walsh which permitted defendants to take Stempler interviews. In those decisions, there

were thirteen causes of action and the cases were headed for trial in less than two months. Additionally, it had recently been ruled that plaintiffs' were entitled to be relieved of their heeding presumption which created a switch in the burden of the evidence onto the defendant. After distinguishing the two decisions, Judge Wilson stated:

> In mass tort dockets, the alleged efficiency of allowing Stempler interviews does not outweigh the impracticality of doing so. The Court does not have unlimited judicial resources nor unlimited time. To permit these interviews opens a "Pandora's Box." Litigation over the litany of potential problems (ie: length of notification of plaintiffs' doctors, valid consent disputes, valid authorization submission on HIPAA, etc.) will severely limit the Court's ability to move these cases to trial. The Court finds it important to note that such disputes occurred over just the handful of Stempler interviews which Judge Walsh did allow.

In re: Diet Drug Litig. No. L-6016-04, p. 5 (N.J. Super. Law Div. Jan. 13, 2006).

Judge Walsh therefore attempted to do what Judge Cardemus had suggested might be done but found it caused not efficiency but more litigation, time, and expense.

E. Guas v. Novartis Pharmaceuticals Corp.

Defense main support for its motion is the 2009 memorandum of decision from the Honorable Jessica R. Mayer in Guas v. Novartis Pharmaceuticals Corp., Docket No. MID-L-7014-07MT. The court denied defendant's motion for an order permitting *ex parte* contacts with plaintiffs' treating physicians, finding that such a procedure fails to promote a simpler, cheaper, more efficient, and informal means of discovery. Id. at page 18. The court further held that "in the interest of fairness to all, no party – Plaintiffs nor Defendants – shall engage in *ex parte* contacts with Plaintiffs' treating physicians or influence the deposition or trial testimony of Plaintiffs' treating physicians. To hold otherwise would facilitate the potential for either counsel to influence Plaintiffs' treating physicians." Id.

F. Analysis

First this Court will address the ruling that defendants cannot communicate *ex parte* with plaintiffs' doctors even though defense counsel has not challenged this ruling. Defendants originally sought permission to conduct *ex parte* Stempler interviews, which was denied. Stempler is distinguishable from this Accutane litigation and such interviews are inappropriate for this type of mass tort. The purpose of Stempler was to take a simple personal injury case and allow the doctor to be interviewed without a formal deposition. That reasoning can not apply with this type of mass tort litigation.

The defendants in Stempler argued that "requiring the formality of depositions would impose unnecessarily cumbersome restrictions on his right to prepare for trial. He contends that an informal interview is the most appropriate way to ascertain whether any of plaintiff's physicians possess unprivileged information relevant to the defense of the litigation, arguing that in this context depositions are impractical, inefficient, and costly." Stempler, at 377. The court went on to state personal interviews "should be encouraged as should other informal means of discovery that reduce the cost and time of trial preparation." Id. at 382. Therefore, as this Court previously noted, Stempler interviews were designed to allow a simpler, cheaper, more efficient and informal means of discovery than depositions.

The purpose of Stempler does not hold up in the Accutane litigation. First, no defendant is likely to do an interview with a doctor instead of taking a deposition, which was the main intent of Stempler. Second, it would be difficult to control and administer Stempler interviews, particularly the potential problems that can arise if such interviews were allowed in the Accutane litigation, where there are approximately 973 active cases. The Court does not have unlimited resources nor unlimited time to deal with disputes over problems that arise from Stempler interviews. In particular, this Court takes note of the disputes that occurred over the handful of

Stempler interviews Judge Walsh did allow in the diet drug mass tort litigation. As Judge Wilson stated, "In mass tort dockets, the alleged efficiency of allowing Stempler interviews does not outweigh the impracticality of doing so." In re Diet Drug, at page 5. Such interviews will not make the litigation simpler or cheaper for litigants; depositions will be taken anyway in each case and the purpose of Stempler would be thwarted. Therefore, this Court will continue to follow its previous decision to deny defendant's request to engage in *ex parte* communication with plaintiff's physicians.

Defenses' main objection in these motions is to obtain an order that prohibits plaintiffs' counsel from engaging in *ex parte* communications with their clients' treating doctors. Defense argues it is unfair to allow unequal access to the treaters because plaintiffs are using this access to advocate for their clients. Counsel for Roche pointed to three instances to demonstrate this alleged unfairness, which were described above. For the following reasons, this Court will not bar plaintiffs' counsel from communicating with their clients' physicians.

Based on the record there is no showing of wrongdoing on the part of plaintiff's counsel. The record does not demonstrate that plaintiff's counsel abused her right to communicate with her client's treating physicians. In addition, besides the opinion in Guas v. Novartis Pharmaceuticals, which is not binding, this Court is not aware of any other decision which restrains counsel from talking to their clients' own doctors. In fact, an early candid conversation with a treater can allow plaintiffs' counsel to assess their ability to prove the case and could result in an early dismissal.

Physicians have an ethical duty to communicate with his patient and the patient's representative, and to aid his client in litigation. Section 9.07 of the Code of Medical Ethics provides:

> As a citizen and as a professional with special training and experience, the physician has an ethical obligation to assist in the administration of justice. If a patient who has a legal claim requests his physician's assistance, the physician should furnish medical evidence, with the patient's consent, in order to secure the patient's legal rights.

This Court has previously noted the physician's duty to aid patients in litigation. "Members of the medical profession 'owe their patients more than just medical care for which payment is exacted; there is a duty of total care; that includes and comprehends a duty to aid the patient in litigation, to render reports when necessary and to attend court when needed. That further includes a duty to refuse affirmative assistance to the patient's antagonist in litigation.'" Stempler v. Speidell, 100 N.J. 368, 381 (1985) (citation omitted).

Additionally, there is a fiduciary relationship between a patient and his physician and a patient may want his counsel to communicate with the physician in order to aid in the litigation. A patient cannot pursue a claim without medical verification, which should be done by the patient's attorney before the case gets to trial. The patient has relied on his doctor for his treatment and medical advice and once a case is going to trial he is relying on the doctor to testify truthfully as to his diagnosis, treatment and his opinion on causation. To protect this relationship, a patient should be able to ask his attorney to talk to his physician. Physicians have a duty to aid clients in litigation and plaintiffs' counsel should be able to communicate with their client's physicians.

Finally, there is no lack of fundamental fairness because defendants cannot present their side of the case to the treating doctors. The defendant manufacturers have a duty to communicate risks and benefits to the doctor before the drug was prescribed. Defendants, through their sales representatives and marketing departments, have repeatedly had "*ex parte*" conversations with the doctors about the drug, which distinguishes pharmaceutical litigation from other tort cases. Defendant's sales representatives can and do discuss the drug with doctors

and provide literature about the drug. The defendants have a duty to warn and therefore they have been communicating with the doctors since the drug was on the market. To now claim it is fundamentally unfair to allow plaintiffs' counsel to communicate *ex parte* with the physicians ignores the fact that defendant has been communicating with the doctor since the drug was placed on the market. In this case, defendants had over twenty-five years to communicate and discuss the risks and benefits of Accutane with the physicians as well as discuss general causation issues with them. There is no fundamental unfairness in now allowing plaintiffs' counsel to communicate with the physicians, who have a duty to aid their patients in litigation, while not allowing defendants to have *ex parte* communications with the physicians which could effect the doctor-patient relationship.

CONCLUSION

Defendants' motions to amend the March 6, 2009 order regarding *ex parte* communications with treaters is denied. The informal reconsideration of this ruling is also denied.

CAROL E. HIGBEE, P.J.Cv.