FILED

DEC 09 2014

RON C. JOHNSON, J.S.C.

Court Prepared

SHELLY RAHMAN and ABU RAHMAN, Wife and Husband,

Plaintiffs,

v.

DAIICHI SANKYO, INC., et al.,

Defendant

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION, ATLANTIC COUNTY

DOCKET NO. ATL-L-504-14

ORDER

THIS MATTER having been brought before the Court upon the application of Robins Kaplan Miller & Ciresi, LLP, Attorneys for Plaintiffs, for an Order Compelling Defendants' production of specific documents, and the Court having reviewed and considered the pleadings, briefings and submissions of the parties, both in support of and in opposition to the Motion, and having heard the arguments of counsel, if any, and for good cause shown,

IT IS ON THIS 9th day of December, 2014, hereby

ORDERED that Plaintiffs' Motion to Compel is **GRANTED;**

ORDERED that Defendants will produce to Plaintiffs' the following categories of documents on or before January 9, 2015:

1. All adverse event reports, and all formal and informal complaints or reports of complications or injuries to your clients; All reports of adverse events to the FDA; and All reports of adverse events to foreign regulatory entities. The production of these documents shall be limited to those reports related to Benicar, Benicar HCT and the generic version of those products. Since Plaintiffs alleged injuries are limited to intestinal or colonic disease manifestations known as sprue-like enteropathy and/or lymphocytic colitis, microscopic colitis, or collagenous colitis, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration, the discovery of adverse event reports shall be limited to those symptoms;

2. The promotional and marketing documents and materials provided or communicated to physicians and patients. The production of these documents shall be limited to those reports related to Benicar, Benicar HCT and the generic version of those products;
3. All clinical and pre-clinical studies, published or unpublished, and any bibliography of studies, in Defendants' possession, with regard to the safety and efficiency of the *olmesartan* products;
4. The complete New Drugs and/or Investigation Drug Applications. The production of these documents shall be limited to those reports related to Benicar, Benicar HCT and the generic version of those products;
5. All communications to and from the FDA with regard to proposed or implemented label changes, or warnings to physicians and patients, with regard to Benicar, Benicar HCT and the generic version of those products;
6. Documentation of each insurance policy that may apply to the claims (whether primary, excess, or through reinsurance) including declaration pages and policies, together with all endorsements; and
7. Answers to Plaintiffs' properly served initial set of interrogatories.

IT IS FURTHER ORDERED that a copy of this Order shall be served upon all parties within seven (7) days of its receipt.

HON. NELSON C. JOHNSON, J.S.C.

SUPERIOR COURT OF NEW JERSEY

NELSON C. JOHNSON, J.S.C.

1201 Bacharach Boulevard
Atlantic City, NJ 08401-4527
(609) 594-3384

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

TO: Rayna E. Kessler, Esq.
Robins, Kaplan, Miller & Ciresi, LLP
601 Lexington Avenue, Suite 3400
New York, New York 10022-4611
212-980-7400
Attorney for Plaintiffs, Shelly and Abu Rahman

Susan M. Sharko, Esq.
Drinker, Biddle & Reath, LLP
600 Campus Drive
Florham Park, NJ 07932
973-549-7000
Attorney for Defendants, Daiichi Sankyo, Inc. and Daiichi Dankyo U.S. Holdings, Inc.

RE: Rahman v. Daiichi Sankyo, Inc., et al. **DOCKET NO.** ATL-L-504-14

NATURE OF MOTION(S): Plaintiffs' Motion to Compel Discovery

HAVING CAREFULLY REVIEWED THE MOVING PAPERS AND ANY RESPONSE FILED, I HAVE RULED ON THE ABOVE CAPTIONED MOTION(S) AS FOLLOWS:

Nature of Motion and Procedural History

Plaintiffs, Shelly and Abu Rahman ("Plaintiffs"), bring this motion to compel Defendants, Daiichi Sankyo, Inc. and Daiichi Dankyo U.S. Holdings, Inc. ("Defendants"), to produce specific documents responsive to two items of discovery: (1) Plaintiffs' initial set of interrogatories; and (2) Plaintiffs' second set of requests for the production of documents. Defendants oppose Plaintiffs' motion to compel. Defendants previously filed a cross motion for a protective order which has been withdrawn following this Court's December 8, 2014 Amended Protective Order.

Plaintiffs filed their Complaint on February 6, 2014. Defendants filed their answer on April 15, 2014. The Complaint alleges that Plaintiff Shelly Rahman developed personal

injuries— including intestinal or colonic disease manifestations known as sprue-like enteropathy and/or lymphocytic colitis, microscopic colitis, or collagenous colitis, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration—as a result of her treatment with the prescription medications Benicar (*olmesartan medoxomil)*, and/or Benicar HCT (*olmesartan medoxomil hydrochlorothiazide)*, which is manufactured, marketed and sold by the Defendants for the treatment of hypertension.

Plaintiffs served Defendants with an Initial Set of Interrogatories in May 2014 pursuant to R. 4:17, and Defendants' responses were due on or before sixty (60) days of the request. Plaintiffs served Defendants with their First Request for the Production of Documents on June 11, 2014 pursuant to R. 4:18, and Defendants' responses were due on or before thirty-five (35) days of the request. The Court received the oral arguments of counsel on October 31, 2014. Thereafter, there were exchanges on proposed language for a global protective order which culminated in the Court's December 8, 2014 Amended Protective Order. The issues remaining from the parties' motion practice are addressed herein.

Parties' Contentions Prior to the Issuance of a Protective Order

Plaintiffs:

In support of their motion to compel, Plaintiffs state that Defendants are wholly deficient in responding to both requests to date. On July 7, 2014, Defendants requested by letter to Plaintiffs a ninety (90) day extension to respond the discovery requests. Plaintiffs responded that a flat ninety (90) day extension was unreasonable because the majority of the requests were directed towards readily available documents in defense counsel's possession.

On July 17, 2014, the parties held an in-person meet and confer regarding a schedule for Defendants' production of documents. The parties could not agree to a schedule because Defendants requested an extension on all discovery obligations until October 27, 2014 and Plaintiffs sought the production of prioritized documents by August 1st with less important discovery being produced thereafter on a rolling basis. The discrete categories of discovery Plaintiffs sought on or before August 1st were:

1. All adverse event reports; All formal and informal complaints or reports of complications or injuries to your clients;

2. All reports of adverse events to the FDA;
3. All reports of adverse events to foreign regulatory entities;
4. The promotional and marketing documents and materials provided or communicated to physicians and patients;
5. All clinical and pre-clinical studies, published or unpublished, and any bibliography of studies, in your clients' possession, with regard to the safety and efficiency of the *olmesartan* products;
6. The complete New Drugs and/or Investigation Drug Applications;
7. All communications to and from the FDA with regard to proposed or implemented label changes, or warnings to physicians and patients, with regard to the products at issue; and
8. Documentation of each insurance policy that may apply to the claims (whether primary, excess, or through reinsurance) including declaration pages and policies, together with all endorsements.

Thereafter, the parties could not agree to a schedule for discovery. Plaintiffs are only requesting that this Court compel the production of these categories of documents.

Defendants:

In opposition to Plaintiffs' motion to compel, Defendants assert that the discovery has been delayed due to the parties' failure to agree on a protective order. At the July 17, 2014 meet and confer, Defendants agreed to prioritize the production of certain documents provided that a protective order was entered. On July 24, 2014, Defendants sent Plaintiffs a proposed protective order, which was based on other orders entered in product liability litigation involving Plaintiffs' counsel. According to defense counsel, Plaintiffs never responded to the Defendants proposed order, despite defense follow up.

On September 9, 2014, Plaintiffs requested that the parties use a different protective order drafted by the Plaintiffs. Plaintiffs made no effort to edit or comment on the order that the Defendants proposed. In an effort to reach an agreement on the protective order, Defendants undertook the effort to red-line the Plaintiffs' proposed order and, on September 15, sent a red-lined version back to Plaintiffs' counsel for review.

On September 24, the parties again met and agreed on the essential terms of a case management order setting a discovery schedule, and Defendants began production of unprotected documents. However, the parties could not agree on the form of a protective order. Thereafter, the Court became involved in the process, culminating in the December 8, 2014 Amended Protective Order.

Plaintiffs:

In reply to Defendants' opposition to their motion to compel discovery, Plaintiffs argue that the Court should compel the production of the discrete categories of documents because Defendants have no legitimate basis to withhold production. First, Plaintiff have made a good faith effort to obtain the discovery at issue. Plaintiffs served complete responses to the Defendants' Request for Form A and Supplemental Interrogatories, provided signed medical and employment authorizations, and produced more than one thousand pages of medical records in support of Plaintiffs' claims. Plaintiffs have also addressed deficiency letters sent by Defendants that request new or additional information. Plaintiffs have not received any deficiency letters since August 21, 2014.

Furthermore, Plaintiffs assert that the production of specific documents is not unduly burdensome or impossible. Defendants' arguments are refuted by the FDA being able to produce many of the same documents within thirteen days of Plaintiffs' FOIA request. If it is not burdensome for the FDA, Plaintiffs argue that it should not be burdensome for the resourceful Defendants whom are the originators of these documents.

Parties' Contentions Following the Issuance of a Protective Order

On December 3, 2014, Defendants withdrew their cross-motion for a protective order in anticipation of this Court's Amended Protective Order. However, the parties have been unable to agree to a discovery schedule regarding the specific categories of documents that were the original subject of Plaintiffs' motion to compel.

Plaintiffs propose that the Court enter an Order compelling the production of these documents on or before December 15, 2014. In support of their proposed deadline, Plaintiffs argue that there is no dispute that they are entitled to these documents and that production

remains long overdue. Plaintiffs emphasize that defense counsel represented on multiple occasions that these documents were ready for production following the entry of an umbrella protective order.

Additionally, Plaintiffs state that the parties jointly agreed at the November 13, 2014 CMC that the production of these documents would begin within a week of the protective order's entry. However, Defendants have submitted a proposed form of Order that orders Defendants to produce the specific categories of discovery on a rolling basis beginning on December 15, 2014 subject to the Amended Protective Order.

Discussion

R. 4:10-2(a) provides,

> Parties may obtain discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the pending action, whether it relates to the claim or defense of the party seeking discovery or to the claim or defense of any other party, including the existence, description, nature, custody, condition and location of any books, documents, electronically stored information, or other tangible things and the identity and location of persons having knowledge of any discoverable matter. It is not ground for objection that the information sought will be inadmissible at the trial if the information sought appears reasonably calculated to lead to the discovery of admissible evidence; nor is it ground for objection that the examining party has knowledge of the matters as to which discovery is sought.

Additionally, R. 4:23-5(c) provides,

> Prior to moving to dismiss pursuant to subparagraph (a)(1) of this rule, a party may move for an order compelling discovery demanded pursuant to R. 4:18-1 or R. 4:19. An order granting a motion to compel shall specify the date by which compliance is required. If the delinquent party fails to comply by said date, the aggrieved party may apply for dismissal or suppression pursuant to subparagraph (a)(1) of this rule by promptly filing a motion to which the order to compel shall be annexed, supported by a certification asserting the delinquent party's failure to comply therewith.

In addition, the rules of discovery are to "be construed liberally in favor of broad pretrial discovery," Payton v. New Jersey Turnpike, 148 N.J. 524, 550 (1997). This policy is based upon the principle that "[o]ur court system has long been committed to the view that essential justice is

better achieved when there has been full disclosure so that the parties are conversant with all the available facts." Jenkins v. Rainner, 69 N.J. 50, 56-57 (1976).

As an initial matter, the Court is satisfied that both parties have acted in good faith. The parties have communicated multiple times through letters, emails, and in-person meet and confers to resolve discovery disputes. Despite their efforts, the parties simply have not been able to come to an agreement on a discovery schedule or a form of a protective order. This disagreement, absent other evidence, does not establish bad faith. Following the issuance of the Amended Protective Order, Defendants can no longer justify withholding the discovery sought by Plaintiffs. Nevertheless, this Court will address the several categories of discovery in dispute.

Adverse Event Reports: The first three categories can be addressed by the Court simultaneously. These categories pertain to—(1) All adverse event reports, and all formal and informal complaints or reports of complications or injuries to your clients; (2) All reports of adverse events to the FDA; and (3) All reports of adverse events to foreign regulatory entities.

Plaintiffs have already obtained some of these documents through the FDA, but need authenticated versions for use at trial. As an initial matter, these reports are relevant to the underlying litigation. Plaintiffs claim that they experienced intestinal or colonic disease manifestations known as sprue-like enteropathy and/or lymphocytic colitis, microscopic colitis, or collagenous colitis, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration as a result of ingesting Defendants' product Benicar and/or Benicar HCT. The existence of other similar injuries, at the very least, may lead to additional discoverable evidence. However, Plaintiffs are not entitled to unfettered discovery unrelated to Plaintiffs' claims against Defendants.

Considering the competing interests discussed above in light of the liberal discovery rules of New Jersey and the relevance of these materials in the instant litigation, this Court GRANTS Plaintiffs' motion to compel the production of these documents subject to the Amended Protective Order. However, the production of these documents shall be limited to those reports related to Benicar, Benicar HCT and the generic version of those products, because those drugs are relevant to the Plaintiffs' claims and Defendants' knowledge of side effects. Since Plaintiffs alleged injuries are limited to intestinal or colonic disease manifestations known as sprue-like enteropathy and/or lymphocytic colitis, microscopic colitis, or collagenous colitis, chronic

diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration, the discovery of adverse event reports is expressly limited to those symptoms.

Marketing Materials: These are the promotional and marketing documents and materials provided or communicated to physicians and patients. As an initial matter, these documents are relevant to the underlying litigation because the documents pertain to product information, including side effects that were communicated to physicians and patients. Defendants state, and the Court appreciates, that these documents reflect detailed information regarding health care providers and consumer marketing profiles, sales histories and projections, costs allocations and expenditures, and specific demographic and market forecasts that are not necessarily available for public dissemination.

After considering the competing interests discussed above, the Court issued the Amended Protective Order that limits the Plaintiffs' ability to disseminate the discovery they receive under this category. Otherwise, in light of the liberal discovery rules of New Jersey and the relevance of these materials in the instant litigation, this Court GRANTS Plaintiffs' motion to compel the production of these documents. However, the production of these documents shall be limited to those reports related to Benicar, Benicar HCT and the generic version of those products, because those drugs are relevant to the Plaintiffs' claims and Defendants' knowledge of side effects.

Clinical Studies: This category refers to all clinical and pre-clinical studies, published or unpublished, and any bibliography of studies, in Defendants' possession, with regard to the safety and efficiency of the *olmesartan* products. These are publically available documents that originate in entities other than Defendants. Defendants cannot claim that these documents are theirs to protect. These studies are also relevant to the underlying litigation because they address the safety and efficiency of the Defendants' products, or otherwise will directly lead to information regarding medical causation and Defendants' knowledge of the same. Therefore, in light of the liberal discovery rules of New Jersey and the relevance of these materials in the instant litigation, this Court GRANTS Plaintiffs' motion to compel the production of these documents.

NDAs: The complete New Drugs and/or Investigation Drug Applications. Plaintiffs' counsel obtained approximately one thousand pages of the Benicar Drug Application pursuant to their FOIA request to the FDA. The data contained in NDAs are not subject to public disclosure

and the FDA's limited response to Plaintiffs' FOIA request is telling of the value derived from these documents. The information contained in NDAs form the foundation of Defendants' pharmaceutical business. Nevertheless, NDAs contain relevant information, at least as limited to the drugs allegedly ingested by the Plaintiffs, or otherwise may lead to discoverable evidence suggesting the negligence of Defendants.

Considering the competing interests discussed above, this Court GRANTS Plaintiffs' motion to compel the production of these documents as limited by the Amended Protective Order. The Court concludes that the protective order is necessary to prevent Plaintiffs' counsel from disseminating or disclosing the information contained in the narrow class of NDAs. However, the production of these documents shall be limited to those reports related to Benicar, Benicar HCT and the generic version of those products, because those drugs are relevant to the Plaintiffs' claims.

Communications with the FDA: These communications pertain to proposed or implemented label changes, or warnings to physicians and patients, with regard to the products at issue. This category is already limited to the relevant products allegedly ingested by Plaintiffs. This category of discovery is also relevant to the substantial claims made by Plaintiffs regarding the adequacy of warnings to patients and physicians. Many of these communications have already been disclosed to Plaintiffs through their FOIA request to the FDA. Defendants' briefs do not directly and meaningfully address this discrete category of discovery. Nonetheless, the Court finds that the proposed discovery category correctly limits the communications with the FDA to the products at issue: Benicar, Benicar HCT, and the generic versions of those products. Otherwise, this Court GRANTS Plaintiffs' motion to compel the production of these documents.

Insurance: Documentation of each insurance policy that may apply to the claims (whether primary, excess, or through reinsurance) including declaration pages and policies, together with all endorsements. The Court agrees that these documents are routinely obtained in discovery. Defendants also do not address this category of discovery in their briefs. Thus, this Court GRANTS Plaintiffs' motion to compel the production of these documents.

Interrogatories: Defendants do not meaningfully justify ignoring the Plaintiffs' properly served initial set of interrogatories. Should the answers intrude on Defendants' confidential information, trade secrets, or otherwise should be subject to a protective order, then

it is Defendants burden to specifically identify interrogatories that should be subject to the Amended Protective Order. Here, the Defendants have not met their burden. Thus, Plaintiffs motion to compel answers to their initial set of interrogatories is GRANTED.

Considering that discovery in this case has been a long-standing issue before this Court, Defendants shall produce the above mentioned categories of documents by January 9, 2015. An appropriate order has been entered. Conformed copies accompany this Memorandum of Decision.

Nelson C. Johnson

NELSON C. JOHNSON, J.S.C.

Date of Decision: 12-9-14