[Doc. No.925]

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: BENICAR (OLMESARTAN)	:	**Master Docket**
	:	**No. 15-2606 (RBK/JS)**
PRODUCTS LIABILITY LITIGATION	:	
	:	**OPINION**

KUGLER, United States District Judge:

Plaintiffs' submitted a request (Doc. No. 925) for leave to file a motion for partial summary judgement on the issue of general causation and accompanied it with fourteen (14) exhibits, either excerpts from defendants' depositions or documents produced by defendants. Plaintiffs assert the exhibits are defendants' admissions of general causation, which show that defendants' pharmaceuticals caused plaintiffs' complained of sprue-like enteropathy ["SLE"]. This opinion accompanies the order denying plaintiffs' request without prejudice (Doc. No. 938) and sets forth the reasons therefor.

I. Fact and Procedural Background

This Multidistrict Litigation ("MDL") involves approximately 1900 plaintiffs, who ingested defendants' olmesartan-containing prescription drugs[1] to alleviate hypertension.

[1] These drugs are Benicar®, BenicarHCT®, Azor®, and Tribenzor®; they are collectively referred to herein as "olmesartan".

The named defendants are Daiichi Sankyo, Inc., Daiichi Sankyo Co., Ltd., Daiichi Sankyo U.S. Holdings, Inc., Forest Laboratories, LLC, Forest Laboratories, Inc., Forest Pharmaceuticals, Inc., and Forest Research Institute, Inc. The Daiichi defendants designed, manufactured and sold the drugs at issue.[2] For a time the Forest defendants marketed the drugs. Daiichi Sankyo, Inc. and Daiichi Sankyo U.S. Holdings, Inc. are U.S. companies. Daiichi Sankyo, Inc. is a wholly-owned subsidiary of Daiichi Sankyo U.S. Holdings, Inc. which operates as a holding company. Daiichi Sankyo Co., Ltd. is the parent company of Daiichi Sankyo U.S. Holdings, Inc. Daiichi Sankyo, Inc. operates as the commercial home office and U.S. corporate headquarters of Daiichi Sankyo Co., Ltd., which is a Japanese corporation with its principal place of business in Japan. *See generally* Master Answer of Daiichi Defendants ¶¶ 20, 23-27, 30-31 [Doc. No. 82].

In order to put the Plaintiffs' request in context, the court's management plan initially focuses only on general and specific causation issues, that is, whether defendants' drugs caused the complained of SLE symptoms, which include nausea, vomiting, diarrhea and weight loss.

To date, plaintiffs have taken at least twenty (20) depositions of present and former Daiichi U.S. employees and eighteen (18) depositions of present and former Daiichi Japan employees. The first phase of fact discovery regarding causation issues was all but completed by 30 September 2016;[3] the litigation has now entered the next phase with plaintiffs' causation expert reports due 30 November 2016, defendants' expert reports due

[2] The Court will collectively refer to all the Daiichi party defendants as "Daiichi."

[3] The Court granted plaintiffs leave to take some additional depositions after September 30, 2016, but cautioned this would not extend any other scheduling deadline. See September 1, 2016 Order at 3. [Doc. No. 874].

31 January 31, 2017, expert depositions to completed by 28 February 2017, and *Daubert* and summary judgment motions due by March 31, 2017. CMO No. 26. [Doc. No. 626]. The date for the *Daubert* hearing has not yet been set.[4]

Turning to plaintiffs' request filed 13 October 2016 [Doc. 925], it comprises a summary of the 14 accompanying exhibits, which are excerpts of defendants' deposition testimony or defendant-produced documents, and characterizes them as admissions that defendants generally caused plaintiffs' injuries. Plaintiffs' request lacks not only an explanation as to how these summaries and excerpts constitute incontestable facts upon which to base a summary judgement motion but also any jurisprudential support that defendant alleged admissions during discovery in and of themselves properly substitute for expert testimony to demonstrate general causation.

Defendants argue that case law requires plaintiffs to offer admissible expert testimony on general causation because, in this case, linking the cause of each plaintiffs SLE injury to defendants' pharmaceuticals is beyond the ordinary understanding of a lay jury. Ds Response at 2. Defendants also argue that the excerpted testimony and documents are insufficient to unequivocally demonstrate that the pharmaceuticals caused the complained of injury in each of plaintiff's cases. *Id*. at 3.

The issue is whether the deposition excerpts and internal documents proffered by plaintiffs substitute as expert testimony reliable and fit under *Daubert v. Merrill Dow*

[4] In addition to the cases in this MDL, approximately 73 related cases are consolidated in New Jersey State Court as Multicounty Litigation ("MCL"). Discovery in the federal MDL and state MCL has been coordinated. The Court anticipates a joint Daubert-type hearing will be held in the spring or summer of 2017. The state equivalent to Daubert is Kemp ex rel. Wright v. State, 174 N.J. 412 (2002).

Pharmaceuticals, Inc., 509 U.S. 579 (1993) to sufficiently inform a jury that defendants' pharmaceuticals caused plaintiffs' SLE in these cases.

II. Legal Standard

Courts generally recognize that plaintiffs in products liability cases must offer admissible expert testimony regarding both general causation and specific causation. *See, e.g.*, *In re Mirena IUD Products Liability Litigation*, ___ F. Supp.3d ____ (S.D.N.Y. 2016) 2016 WL 4059224 at *5, citing *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268 (2d Cir. 2002; *see Rutigliano v. Valley Bus. Forms*, 929 F.Supp. 779, 783 (D.N.J. 1996), *aff'd sub nom. Valley Bus. Forms v. Graphic Fine Color, Inc.*, 119 F.3d 1577 (3d Cir. 1997) and further stating that "substantive law across all relevant jurisdictions holds (reference omitted) that 'where a causal link is beyond the knowledge or expertise of a lay jury, 'expert testimony is required to establish causation' (citations omitted)". *Id.*

Recently, the *Mirena* court found that, although there may be circumstances when defendants' admissions in a product liability case can substitute for expert testimony, those circumstances are "exceedingly rare". *In re Mirena* at *8. Expert testimony is generally required in product liability cases because it prevents the jury from engaging in speculation in determining the causal link between using or ingesting the product and the injuries complained of following that use. *Id.* at *5. Determining that causal link typically requires complex medical information beyond the knowledge, understanding, and experience of a lay juror. Expert testimony typically provides this link. *See generally* Christopher R.J. Pace, *Admitting and Excluding General Causation Expert Testimony: The Eleventh Circuit*

Construct, 37 AM. J. TRIAL ADVOC. 47, 51-60 (2013) (comparing the probative value of various general causation methodologies used by experts to support their testimony as *Daubert* reliable).

Purported admissions offered as substitutes for expert testimony must be "clear, unambiguous, and concrete" and suffice to prove general causation without speculation. *Id.* at *8. They can substitute for expert testimony only when they serve the same purpose as expert testimony, that is, to provide the jury with a scientific, non-speculative basis to assess general causation." *Id*. at *12.

Also recently, a court in the Third Circuit analyzed an analogous issue-- whether the plaintiffs were able to establish general causation with virtually no expert testimony, which had been excluded as inadmissible under *Daubert* and Federal Rule of Evidence (FRE) 702. *In re Zoloft Products Liability Litigation*, ___ F. Supp.3d ____ (E.D. Pa. 2016) 2016 WL 1320799. There, plaintiffs found themselves precluded from offering new expert testimony on the issue of general causation—whether Zoloft caused the complained of birth defects—and were left with arguing that other evidence established causation. Such other evidence included declarations by treating physicians of differential diagnoses, case reports by treating physicians of the occurrence of birth defects, defendants' internal documents including literature reviews and published studies relying on statistics about whether Zoloft was the cause of the complained of birth defects, foreign language documents that contained a warning against pregnant women's ingestion of Zoloft, and drafts of product documents. *Id*. at *9.

The *Zoloft* court found that, taken together, plaintiffs' potentially admissible evidence supported only an association between the drug at issue and the complained of birth defect and therefore presented only a possibility of general causation. *Id*. at *10. The court found that "plaintiffs have not produced sufficient admissible evidence from which a reasonable factfinder could determine, by a preponderance of the evidence, that [the drug at issue] could have caused Plaintiff's injuries." *Id.*

Mirena and *Zoloft* resolve the issue raised by plaintiffs' request. Unless information characterized by plaintiffs as defendants' admissions provide to the jury evidence that is clear, unambiguous, and concrete and suffices to prove general causation without the jury's speculation as to complex medical issues, then such information does not substitute for *Daubert*-admissible expert testimony of general causation.

III. Discussion of Proffered Information by Plaintiffs

Each of the 14 exhibits will be reviewed for its sufficiency to substitute as expert testimony that demonstrates general causation without relying on a jury's speculation as to what the exhibit means.

Exhibit 1: 5 page excerpt (out of at least 461 pages) from the deposition of Crawford Parker, MD, defendants' Senior Director of Clinical Safety and Pharmacovigilance ("CSPV") in the United States.

Plaintiffs' request provides no specific reason for including Dr. Parker's testimony, nor contextualizes this excerpt within the deposition as a whole. Dr. Parker's testimony

relates to certain documents that Dr. Parker provided to Dr. Peter Green, apparently a medical consultant to defendants, in advance of an unidentified meeting at which SLE adverse events were to be discussed. These documents included: a January 2009 review by defendants of celiac disease AE reports; the defendants knowledge of the 2012 Mayo Clinic publication[5]; the FDA request to Defendants to review SLE adverse events; and a September 2012 review by defendants of SLE adverse events.

Despite plaintiffs' repeated attempts, the excerpt shows that Dr. Parker expressly declined to characterize the information in one of defendants' ROADMAP clinical study as "an analysis". Dr. Parker's testimony does not suffice to inform in a clear, unambiguous, and concrete way and without jury speculation as to the complex medical issues involved in determining the mechanism by which olmesartan may generally cause the complained of injuries. This exhibit does not substitute for *Daubert*-admissible expert testimony of general causation.

Exhibit 2. 1 page excerpt (out of at least 165 pages) from the deposition of defendants' employee in Japan, Akinori Nishiwaki.

Plaintiffs' request states no specific reason for including Nishiwaki san's testimony or contextualizes this excerpt within his deposition as a whole nor was Nishiwaki san's role for defendants identified.

Plaintiffs' attorney read the following sentence from an unidentified document: "Before identifying olmesartan as a cause of villous atrophy, we, too, had considered 30

[5] A. Rubio-Tapio *et al.*, *Severe Spruelike Enteropathy Associated with Olmesartan,* MAYO CLIN. PROC. 87(8), 732:738 (2012).

percent of our seronegative patients to have unclassified sprue". Nishiwaki san was then asked to confirm the presence of the word "cause" in the sentence, which he did.

That this one sentence included the word "cause" and that the deponent affirmed the presence of that word is not a clear, unambiguous, concrete, or sufficient demonstration of general causation.

Exhibit 3. 5 page excerpt (out of at least 415 pages) from the deposition of Allen Feldman, MD, head of defendants' CSPV unit in the United States.

Plaintiffs assert that Dr. Feldman "admitted that the only cause he could identify for the [symptoms] suffered by these patients was Olmesartan [emphasis added]." (Ps Letter Request at 4-5). When asked about the meaning of a statement in a Medwatch report[6] (specifically whether the most likely explanation for patients' symptoms was olmesartan given their history of ingestion and dechallenges and positive rechallenges of the drug), Dr. Feldman replied: "The only cause given here [in the Medwatch report] is olmesartan". Feldman Dep. 285:24.

Dr. Feldman was only asked to confirm what a certain Medwatch report states; he was not asked as a medical professional to admit that olmesartan caused plaintiffs' symptoms. Dr. Feldman's deposition testimony is not clear, unambiguous, concrete or sufficient as to demonstrate general causation.

[6] A MedWatch report is a voluntary report to the U.S. Federal Drug Administration (FDA) of an adverse event or undesirable effect associated with using a medical product, including pharmaceuticals and medical devices. The report can be prepared on a one-page FDA form or done via the telephone by health care professionals, patients, and consumers.

Exhibit 4: Email of 2 pages dated 26 March 2015, sent jointly from Ford Parker, MD, the same employee as in Exhibit 1, Ulf Stellmacher, director of defendants' CSPV unit in Europe, and Hideki Tagawa, associate *manager of defendants' CSPV unit in Japan, to all employees in each of defendants' CSPV units (in the US, Japan and Europe).*

Having the subject of "Coding and Expectedness of Sprue-Like Enteropathy for Olmesartan and Olmesartan Combination Products", the email states that the code "Syndrome SLE" was added as an expected reaction to the US Product Insert ("USPI") on 3 July 2013 and to defendants' Company Core Data Sheets ("CCDSs") in September 2013. The email provides recommendations to defendants' CSPV on how to determine expectedness[7] because it is believed they may not understand SLE symptoms. To that end, the email identifies "Syndrome SLE" as including "nausea, vomiting and diarrhea, signs typical of olmesartan induced sprue-like enteropathy, such as weight loss." Exhibit 4, at ¶1. The apparent purpose here is to inform CSVP employees how Syndrome SLE will be reported (presumably by clinicians) and how to code that information in periodic safety reports to regulatory agencies.

The email states: "'Syndrome sprue-like' is currently the DSPD[8] (the "Daichii Sankyo Pharmaceutical Development" functional unit) recommended term in MedDRA Version

[7] From a regulatory perspective and in relation to the periodic safety reports (titled in the U.S. as Development Safety Update Report ("DSURs")) provided to a national regulatory agency by the manufacturer of a drug either under development or that has been marketed and under further study, the term "expectedness" relates to whether a physiological reaction is a statistically expected side effect of the pharmaceutical. *Guidance for Industry. E2F Development Safety Report*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. FOOD AND DRUG ADMINISTRATION, prepared by INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE (ICH), August 2011 (containing nonbinding recommendations), http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073109.pdf.

When categorized as expected, a physiological reaction to drug ingestion must be clearly listed in the Reference Safety Information (RSI) of the DSUR provided by the drug manufacturer to the regulatory agency. *Id*. at 11, 14 and 23.

[8] Defendants' unit that does pharmaceutical research, development, and marketing primarily in the U.S.

16.1"[9] and advises that a report coded as olmesartan-related intestinal villous atrophy should be handled as a sprue-like enteropathy report, in order to conform with the findings in the Mayo Clinic publication (Rubio-Tapio, *supra*) that first publicly reported that villous atrophy in olmesartan-takers was related to their SLE symptoms. Item 4 of the email recommends that, when a clear diagnosis of SLE is not reported (presumably by a clinician), symptoms of diarrhea, malabsorption, or weight loss should be coded not as SLE, but as separate reactions.

Although stating that there are signs typical of olmesartan induced sprue-like enteropathy, this exhibit expressly informs defendants' employees that these signs, when not accompanied by a clear diagnosis, cannot be reported as SLE. Since the exhibit on its face calls for a clinician's diagnosis before defendants will report olmesartan induced SLE, it cannot provide clear, unambiguous, and concrete proof of general causation. Without more, and in light of the entire email, the mere use by defendants of the term "olmesartan induced sprue-like enteropathy" does not suffice to inform a jury as to general causation.

Exhibit 5: Email from Dr. Ulf Stellmacher to Crawford Parker, MD, and Hideki Tagawa, dated to 16 Jan 2015, attaching a summary of the "3rd fatal SLE case we have just processed". The attachment is a Power Point of 3 slides apparently prepared by Dr. Stellmacher, director of defendant's CSPV unit in Europe.

[9] Developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the Medical Dictionary for Regulatory Activities ("MedDRA") provides a globally standardized terminology to regulatory agencies (including the U.S. Food and Drug Administration, the European Medical Agency, and the Japanese Pharmaceutical and Medical Device Agency), pharmaceutical companies, clinicians, and translators, http://www.medra.org.

Slide 2 states that villous atrophy was found in a 70 year-old man living in France who had been taking Olmetec® or Alteis®[10] for an unknown period and who had died. As defendant-manufactured equivalents to the pharmaceuticals issued here, the medications were for hypertension. The slide states that "Causality cannot be denied based on available information. Though diagnosis was not confirmed, this case represents SLE".

This exhibit does not detail the causal link between the injuries complained of and the drugs at issue and cannot demonstrate general causation.

Exhibit 6: 8 page excerpt (out of at least 84 pages) from the deposition of Hideki Tagawa, associate *manager of defendants' CSPV unit in Japan.*

Tagawa san is apparently being asked to comment on the Power Point in Exhibit 5 above. He confirms that it states the cause of the death of a 70 year-old man in France was an olmesartan drug. Tagawa Dep. 58: 9 to 60: 20.

He is then asked to comment on an unidentified Power Point and on other unidentified documents, which leaves this court no point of reference from which to review independently to what Tagawa san is attesting to. Tagawa san confirms that the unidentified Power Point states: (1) based on reports of SLE in the U.S., a causal relationship between olmesartan-containing drugs and severe diarrhea could not be denied; and (2) Japanese and U.S. package inserts were modified to add diarrhea as a

[10] Olmetec® is a trademark registered in Japan to Daiichi Sankyo. Alteis™ is a brand name used by Daiichi Sankyo. These marks identify an olmesartan formulation equivalent to Benicar® and are used to market that in France. http://mpkb.org/home/mp/olmesartan/buying

serious side effect following the U.S. reports. *Id*. at 69-70. He also confirms that he wrote an email stating that U.S. and Japanese reports indicated that chronic diarrhea improves when olmesartan is stopped in most cases. He states that what he wrote in that email is based on what defendants' medical advisors had told him. *Id. at* 83-84.

Although Tagawa san affirms that he wrote certain content relating to SLE and confirms the statements set forth in the documents before him, he clearly indicates he is not an expert able to independently attest to general causation. This exhibit cannot demonstrate general causation.

Exhibit 7: 3 page excerpt (out of at least 173 pages) from the deposition of Yasushi Hasebe, head of defendants' CSVP unit in Japan.

Plaintiffs' request does not contextualize this excerpt within the deposition as a whole.

Hasebe san was asked: "You're not denying that the olmesartan was one of the factors causing the severe diarrhea, dehydration and hospitalizations described in this adverse report. You're not denying that, right?" Hasebe Dep. 127: 14-19. He answers, "Correct, I think that's one of the factors". *Id.* at 127:21-22.

Inasmuch as Hasebe san's answer would lead to jury speculation as to what other factors caused the complained of injuries, the exhibit is not clear, unambiguous, specific or sufficient to demonstrate general causation.

Exhibit 8: 1 page excerpt (out of at least 152 pages) from the deposition of Mahmoud N. Ghazzi, M.D., Ph.D.

Plaintiffs' request states no specific reason for including Dr. Ghazzi's testimony or contextualizes this excerpt within the deposition as a whole nor was Dr. Ghazzi's role for defendants identified. Research from independent sources identifies Dr. Ghazzi as defendants' Global Head of Drug Development, as well as Head of Daiichi Sankyo Pharmaceutical Department in the U.S.

In response to questions about Deposition Exhibit No. 3068, which was neither provided nor summarized, and which the court, therefore, could not review, Dr. Ghazzi confirmed that, in May 2014, defendants were starting to arrange a meeting with key European opinion leaders (presumably in the medical and scientific fields) to understand the mechanism of olmesartan and its effects on patients. Ghazzi Dep. 152: 11-16. The only rational inference to be drawn from this evidence is that defendants' employees do not fully understand the cause of SLE. This excerpt cannot substitute for *Daubert*-reliable testimony as to general causation.

Exhibit 9: 2 page excerpt (out of at least 290 pages) from the deposition of Oliseyenum MacDonald Nwose, M.D., defendants' head of medical affairs and "responsible for the Olmesartan drugs", according to plaintiffs' letter request.

Plaintiffs' request does not contextualize the excerpt within the deposition as a whole.

In response to the question whether it is more likely than not that olmesartan causes SLE and serious gastrointestinal problems in some patients, Dr. Nwose states there have been cases "where olmesartan has been associated with sprue-like enteropathy"

(Nwose Dep. 289:8-14; 290:1-2) and adds that before forming a conclusion as to causation, he would have to "go back and review each of these cases individually". *Id.* at 290: 7-9.

Here, a possible medical expert eschews assigning the label of causation onto olmesartan for SLE symptoms until he has reviewed each case himself. On its face, Dr. Nwose's testimony is no substitute for expert witness testimony.

Exhibit 10. 1 page excerpt (out of at least 151 pages) from the deposition of Anthony Corrado, Defendants' Director of Commercial Regulatory Affairs from 2011 to 2015.

Plaintiffs' request does not contextualize this excerpt within the deposition as a whole.

Mr. Corrado answers "there is a probability" to the question whether defendants agree that some patients do suffer severe gastrointestinal side effects from taking olmesartan-containing drugs. Corrado Dep. 151: 10-15. Mr. Corrado's answer does not resolve the issue of general causation because there is no elimination of other agents possibly causing SLE symptoms in olmesartan patients. This exhibit is not clear, unambiguous, concrete or sufficient to demonstrate general causation.

Exhibit 11: 4 page excerpt (out of at least 147 pages) from the deposition of Diane Benezra-Kurshan, M.D.

Plaintiffs' request does not contextualize this excerpt within the deposition as a whole and appears to identify Dr. Benezra-Kurshan as that member of defendants' Label Review Committee who drafted proposed warning language to physicians regarding

olmesartan use. The date of the proposed warning language is unidentified but after the publication of the Rubio-Tapio article, *supra.*

Dr. Benezra-Kurshan is asked about the meaning of her proposed drug label and its message to physicians. She answers that the label would read to physicians that olmesartan is probably causing the SLE and advises physicians to stop drug ingestion and the SLE symptoms may go away. Benezra-Kurshan Dep. 133:1-8. She adds that the proposed label would also indicate to physicians that, when the drug is stopped, and patients don't improve, then causes other than olmesartan ingestion should be investigated. *Id.* at 147:9-14.

Although this excerpt speaks to defendants' knowledge and response, after the Rubio-Tapio article, *supra,* to the occurrence of SLE symptoms in relation to olmesartan ingestion, it does not suffice as clear, unambiguous, and concrete demonstration of general causation.

Exhibit 12: 12 page excerpt (out of at least 178 pages) from the deposition of Makoto Mizuno, defendants' employee in Japan, *who collaborated on the development of olmesartan*.

Mizuno san is asked: "Based on everything you've seen and the study that you were doing in your company with a team of people, you do agree that there is some number of people –we don't have to argue about how many—some people who do develop sprue-like enteropathy from taking olmesartan, correct?" Mizuno Dep. 177: 23 to 178: 5. He responds: "I think that some patients –among some patients who were taking olmesartan, there were some patients who developed sprue-like enteropathy". *Id*. at 178:8-12.

It is unclear why plaintiffs have proffered this exhibit as evidence of general causation since Mizuno san simply states there is a co-occurrence in some patients taking

olmesartan with their experience of SLE. The exhibit is not clear, unambiguous, and specific evidence sufficient to demonstrate general causation.

Exhibit 13: 27 page excerpt (out of at least 364 pages) from the deposition of Jeffrey Warmke, Ph.D., defendants' witness under Federal Rule of Civil Procedure 30(b)(6).

Dr. Warmke attests that defendants received reports of the occurrence of villous atrophy, and/or gastroenteritis, or collagenous colitis—symptoms complained of in this litigation--in three patients participating in their clinical ROADMAP studies.[11] Warmke Dep. 327:21 to 331:3; 340:18 to 345:18; 348:6 to 349:1. He also attests that defendants' analysts documented that two of these occurrences had a causal relationship to the olmesartan ingestion. *Id.* at 345:6 to 19; 349:13 to 350:10.

Although this exhibit may support specific causation if the patients Dr. Warmke discussed are also plaintiffs in this matter, it does not resolve the issue of the general causation of injuries complained of by all plaintiffs here. *See generally* RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL & EMOTIONAL HARM § 28 comment c (2010) ("The concepts of general causation and specific causation are widely accepted among courts confronting causation issues with toxic agents.").

Exhibit 14: 7 page excerpt (out of at least 137 pages) from the deposition of Dr. Katsuyoshi Chiba, defendants' employee in Japan.

[11] Defendants conducted their own clinical studies of the olmesartan-containing drugs, which were designed to determine a reduction in the level of albumin in a patient's urine. Inasmuch as such albumin is a biochemical indicator of kidney disease due to hypertension, Defendants' ROADMAP tests were to some extent analyzing the statistical effectiveness of olmesartan ingestion on hypertension.

Plaintiffs' request provides no specific reason for including Dr. Chiba's testimony or contextualizes this excerpt within the deposition as a whole nor identifies Dr. Chiba's role for defendants.

Particularly salient in Dr. Chiba's testimony in this exhibit are:

- "it is not possible to reproduce the results of the clinical studies by Mayo Clinic" (Dr. Chiba Deposition Transcript 59:7-8);

-"I think the best scenario would be that this will not be conducted by the non-clinical side" (referring to a non-clinical comparison test of olmesartan with other anti-hypertension drugs that also rely on the action of a TGF-β inhibitor, designed to determine whether all such hypertension drugs are linked to symptoms that plaintiffs complained of) (*Id.* at 64: 21-24);

-" it wasn't a matter of proving or not [the relationship between olmesartan and SLE] but rather it was not possible for us to carry out any kind of nonclinical studies with -- with--in -- in a reliable manner" (*Id*. at 65: 16-19).

This exhibit appears to relate to whether defendants' choice not to conduct non-clinical tests indicated a belief that such tests would show a causal connection between olmesartan ingestion and SLE symptoms. Dr. Chiba's testimony confirms that, since such a test was not conducted, there can be no information pointing to general causation and therefore cannot demonstrate it.

Conclusion

None of the exhibits proffered by plaintiffs either singly or in combination evidences in a clear, unambiguous, and concrete way the mechanism by which the olmesartan-

containing drugs at issue may generally cause the complained of injuries. No exhibit or combination can resolve the inevitable jury speculation as to the complex biochemical, biological, and epidemiological information that underpins the general causation question here.

Consequently, this court declines to find or characterize whether any of the proffered exhibits is an admission by defendants under Federal Rule of Evidence 801(d) (2).

Accordingly, for all the reasons discussed above, plaintiff's Request to File Summary Judgement Motion on Submitted Exhibits has been DENIED in Doc. No. 938.

Dated: 11/8/2016

s/ Robert B. Kugler

ROBERT B. KUGLER

United State District Judge