UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: BENICAR (OLMESARTAN) PRODUCTS LIABILITY LITIGATION	* * *	MDL 2606
THIS DOCUMENT RELATES TO ALL CASES	* * *	JUDGE ROBERT B. KUGLER MAG. JUDGE JOEL SCHNEIDER

PROPOSED JOINT AGENDA AND REPORT
FOR 30 AUGUST 2016 STATUS CONFERENCE:

1. Report on Docket.

There were 1,718 complaints on file with the clerk's office as of August 22, 2016, and 1,465 complaints have been served on at least one U.S. Defendant. As of August 22, 2016, a total of 218 cases have been dismissed via voluntary stipulations of dismissal with prejudice or Court order pursuant to Case Management Order No. 20 (Doc. No. 272).

2. State Court Litigation.

There are currently 73 cases pending in the New Jersey Multicounty Litigation ("NJ MCL"). There is no MCL case management conference currently scheduled.

3. Core Deficient Plaintiff Fact Sheets

DEFENDANTS' POSITION:

a. Core Deficient Cases - First Time Listed

Defendants have sent a letter to counsel in the following case for core deficiencies, and have not received a response. This is the first time this case is being listed on the agenda.

	Case Caption	Docket Number	Plaintiff Counsel Firm	Reasons PFS determined to be core deficient	PFS Core Deficiency Letter Sent
1.	Antone, Calvin v. Daiichi Sankyo, Inc., et al	1:16-cv-00198	Levin Papantonio Thomas Mitchell Rafferty & Proctor, P.A	Authorizations not provided.	7/15/16

4. Overdue Plaintiff Fact Sheets

a. Overdue PFS - First Time Listed

The following 57 PFS are overdue. This is their first time being listed on the Joint Agenda.

	Case Caption	MDL Case No.	Plaintiff Counsel Firm	Complaint First Service Date	Plaintiff Fact Sheet Due Date	PFS Overdue Letter sent
1	Barr, Bonnie v. Daiichi Sankyo, Inc., et al	1:16-cv-00481	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
2	Best, Debra v. Daiichi Sankyo, Inc., et al	1:16-cv-02417	Wagstaff & Cartmell LLP	5/2/16	8/1/16	8/12/16
3	Bigford, Charleen v. Daiichi Sankyo, Inc., et al	1:16-cv-01475	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
4	Bouknight, Steven K. v. Daiichi Sankyo, Inc., et al	1:16-cv-00256	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
5	Burkhead, Robin v. Daiichi Sankyo, Inc., et al	1:16-cv-01077	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
6	Burks, Vickie R. v Daiichi Sankyo, Inc., et al	1:16-cv-00482	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
7	Calhoun, Myrna M. v. Daiichi Sankyo, Inc., et al	1:15-cv-08599	Wagstaff & Cartmell LLP	5/2/16	8/1/16	8/12/16

8	Campbell, Harold v. Daiichi Sankyo, Inc., et al	1:16-cv-00724	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
9	Corf, Brenda v. Daiichi Sankyo, Inc., et al	1:16-cv-00254	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
10	Davis, Victor v. Daiichi Sankyo, Inc., et al	1:15-cv-04502	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
11	Ellis, Diane v. Daiichi Sankyo, Inc., et al	1:15-cv-08018	Wagstaff & Cartmell LLP	4/28/16	7/27/16	7/29/16
12	Gordon, Georgia v. Daiichi Sankyo, Inc., et al	1:15-cv-08600	Wagstaff & Cartmell LLP	5/2/16	8/1/16	8/12/16
13	Grier, Tasha D. v. Daiichi Sankyo, Inc., et al	1:16-cv-00087	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
14	Henson, Cleopatra v. Daiichi Sankyo, Inc., et al	1:15-cv-07191	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
15	Hornback, Katrina v. Daiichi Sankyo, Inc., et al	1:15-cv-04498	Wagstaff & Cartmell LLP	4/28/16	7/27/16	7/29/16
16	Hower, Sharon v. Daiichi Sankyo, Inc., et al	1:16-cv-01120	Wagstaff & Cartmell LLP	5/2/16	8/1/16	8/12/16
17	Hunt, Beblyn v. Daiichi Sankyo, Inc., et al	1:15-cv-08601	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
18	Hylton, John v. Daiichi Sankyo, Inc., et al	1:16-cv-01078	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
19	Jackson, Nathaniel v. Daiichi Sankyo, Inc., et al	1:15-cv-08602	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/16/16
20	Janowski, Caroline v. Daiichi Sankyo, Inc., et al	1:15-cv-05113	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/16/16
21	Jenkins, Sr., Timothy v. Daiichi Sankyo, Inc., et al	1:15-cv-07462	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/16/16
22	Jernagin, Lavina v. Daiichi Sankyo, Inc., et al	1:16-cv-01079	Wagstaff & Cartmell LLP	5/2/16	8/1/16	8/16/16

23	Jones, Elizabeth S. v. Daiichi Sankyo, Inc., et al	1:16-cv-02281	Snapka Law Firm	5/10/16	8/8/16	8/16/16
24	Kilpatrick, Linda v. Daiichi Sankyo, Inc., et al	1:15-cv-08608	Wagstaff & Cartmell LLP	4/28/16	7/27/16	8/16/16
25	Koecher, Henry v. Daiichi Sankyo, Inc., et al	1:15-cv-08243	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/16/16
26	Legowski, Lawrence v. Daiichi Sankyo, Inc., et al	1:15-cv-07465	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/16/16
27	Lewis, Lisa v. Daiichi Sankyo, Inc., et al	1:15-cv-08603	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/16/16
28	McComber, Gerald v. Daiichi Sankyo, Inc., et al	1:15-cv-05412	Mazie Slater Katz & Freeman LLC	4/14/16	7/13/16	7/26/16
29	McDaniel, Marjorie L, v. Daiichi Sankyo, Inc., et al	1:16-cv-00255	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/16/16
30	McQueen, Earlene v. Daiichi Sankyo, Inc., et al	1:15-cv-07464	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/16/16
31	Migliori, Donna. v. Daiichi Sankyo, Inc., et al	1:15-cv-08604	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/16/16
32	Miller, Nettie v. Daiichi Sankyo, Inc., et al	1:15-cv-08605	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/16/16
33	Miller, Robert v. Daiichi Sankyo, Inc., et al	1:16-cv-00723	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/16/16
34	Milliron, Helen v. Daiichi Sankyo, Inc., et al	1:16-cv-00722	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/16/16
35	Mohead, Bessie v. Daiichi Sankyo, Inc., et al	1:15-cv-08609	Wagstaff & Cartmell LLP	5/2/16	8/1/16	8/16/16
36	Monroe, Addie Givens and John v. Daiichi Sankyo, Inc., et al	1:16-cv-01155	Mazie Slater Katz & Freeman LLC	4/15/16	7/14/16	7/26/16

37	Moore, Edward v. Daiichi Sankyo, Inc., et al	1:15-cv-07193	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/16/16
38	Moore, Elizabeth M. v. Daiichi Sankyo, Inc., et al	1:15-cv-07500	Wagstaff & Cartmell LLP	5/2/16	8/1/16	8/16/16
39	Nowell, Patricia v. Daiichi Sankyo, Inc., et al	1:15-cv-08607	Wagstaff & Cartmell LLP	4/28/16	7/27/16	7/29/16
40	Popwell, Barbara v. Daiichi Sankyo, Inc., et al	1:16-cv-02418	Wagstaff & Cartmell LLP	5/2/16	8/1/16	8/12/16
41	Rentie Jr., Morris v. Daiichi Sankyo, Inc., et al	1:15-cv-04499	Wagstaff & Cartmell LLP	5/2/16	8/1/16	8/12/16
42	Rodriguez, Sherilyn v. Daiichi Sankyo, Inc., et al	1:16-cv-02001	Wagstaff & Cartmell LLP	4/28/16	7/27/16	7/29/16
43	Russell, Cheurlie v. Daiichi Sankyo, Inc., et al.	1:15-cv-08610	Wagstaff & Cartmell LLP	5/2/16	8/1/16	8/12/16
44	Sacca, Vincent v. Daiichi Sankyo, Inc., et al	1:16-cv-02419	Wagstaff & Cartmell LLP	5/2/16	8/1/16	8/12/16
45	Scott, Barbara v. Daiichi Sankyo, Inc., et al	1:16-cv-02420	Wagstaff & Cartmell LLP	5/2/16	8/1/16	8/12/16
46	Shepard, William v. Daiichi Sankyo, Inc., et al	1:15-cv-08611	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
47	Stanley, Tony v. Daiichi Sankyo, Inc., et al	1:15-cv-08613	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
48	Tafoya, Virginia v. Daiichi Sankyo, Inc., et al	1:15-cv-08614	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
49	Wafer, Elizabeth Nicole v. Daiichi Sankyo, Inc., et al	1:15-cv-08990	Excolo Law, PLLC	4/25/16	7/25/16	7/29/16
50	White, Mary v. Daiichi Sankyo, Inc., et al	1:15-cv-08615	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
51	Williams, Letha v. Daiichi Sankyo,	1:16-cv-00721	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16

	Inc., et al					
52	Williamson, Larry T. v. Daiichi Sankyo, Inc., et al	1:15-cv-08021	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
53	Wilson, Jason L. v. Daiichi Sankyo, Inc., et al	1:15-cv-08616	Wagstaff & Cartmell LLP	4/29/16	7/28/16	8/12/16
54	Winkler, Inez v. Daiichi Sankyo, Inc., et al	1:16-cv-02422	Wagstaff & Cartmell LLP	5/2/16	8/1/16	8/12/16
55	Wisecup, Boyd v. Daiichi Sankyo, Inc., et al	1:16-cv-02002	Wagstaff & Cartmell LLP	4/28/16	7/27/16	7/29/16
56	Wright, Danny A. v. Daiichi Sankyo, Inc., et al	1:16-cv-02423	Wagstaff & Cartmell LLP	5/2/16	8/1/16	8/12/16
57	Wright, William v. Daiichi Sankyo, Inc., et al	1:15-cv-08617	Wagstaff & Cartmell LLP	4/28/16	7/27/16	7/29/16

b. Overdue PFS - Second Time Listed

The following PFS is overdue and this is the second time being placed on the Joint Agenda. Pursuant to Case Management Order No. 20 (Doc. No. 272), defendants request that an Order to Show Cause be entered in this case, returnable at the next case management conference, as to why the case should not be dismissed with prejudice.

	Case Caption	**MDL Case No.**	**Plaintiff Counsel Firm**	**Complaint First Service Date**	**Plaintiff Fact Sheet Due Date**	**PFS Overdue Letter Sent**
1.	Joseph, Doris v. Daiichi Sankyo, Inc., et al	1:16:cv-01375	Seeger Weiss LLP	3/15/16	6/13/16	6/21/16

5. Orders to Show Cause:

DEFENDANTS' POSITION:

a. Overdue PFS

Pursuant to Case Management Order Number 20, the Court entered Orders to Show Cause in cases in which a PFS has been overdue for two agendas. The following chart lists the Orders to Show Cause that are returnable on August 30, 2016 and in which a PFS is still overdue. Defendants request that the Court enter an Order dismissing each of these cases with prejudice.

	Case Caption	MDL Case No.	Plaintiff Counsel Firm	Complaint First Service Date	Plaintiff Fact Sheet Due Date	PFS Overdue Letter sent
1.	Bennett, Eileen v. Daiichi Sankyo, Inc., et al	1:15-cv-08965	Kirtland & Packard LLP	1/12/16	4/11/16	6/30/16
2.	Bohdan, Nehanvin v. Daiichi Sankyo, Inc., et al	1:16-cv-01156	Levin Papantonio Thomas Mitchell Rafferty & Proctor, P.A	3/3/16	6/1/16	6/3/16
3.	Hamilton, Darryl and Hollie v. Daiichi Sankyo, Inc., et al	1:16-cv-00181	Taylor Martino, P.C.	1/14/16	4/13/16	6/30/16
4.	Hickey, Kurt E. and Candi v. Daiichi Sankyo, Inc., et al	1:15-cv-08736	Golomb & Honik PC	2/2/16	5/2/16	5/16/16
5.	Pointer, Tiffany M. v. Daiichi Sankyo, Inc.,	1:16-cv-00176	Mazie Slater Katz & Freeman LLC	3/2/16	5/31/16	6/3/16

	Case Caption	MDL Case No.	Plaintiff Counsel Firm	Complaint First Service Date	Plaintiff Fact Sheet Due Date	PFS Overdue Letter sent
	et al					
6.	Stringer, Jeffrey v. Daiichi Sankyo, Inc., et al	1:16-cv-01161	Levin Papantonio Thomas Mitchell Rafferty & Proctor, P.A	3/3/16	6/1/16	6/3/16
7.	Wilson, Sandra v. Daiichi Sankyo, Inc., et al	1:16-cv-00157	Mazie Slater Katz & Freeman LLC	2/29/16	5/30/16	6/3/16

6. Dispositive Motions

DEFENDANTS' POSITION:

At the conference on July 27, 2016, the Court requested that Defendants include in this agenda an update regarding any potential dispositive motions. Defendants respectfully request leave to file a motion for summary judgment in the *Von Eberstein* matter (15-cv-02526) based on Louisiana's one-year statute of limitations for product liability claims. Regardless of whether the case is part of the bellwether pool, the parties have completed the requisite discovery such that a motion for summary judgment is appropriate at this time.

Given the status of discovery, it is premature to comment on potentially dispositive motions in the remaining cases.

PLAINTIFFS' POSITION:

The Court and the parties have been focusing our attention on completing discovery related to general causation and the bellwether Plaintiffs that the Court selected. The *von*

Eberstein case is not a bellwether case. In fact, although *von Eberstein* was in the bellwether pool at one time, Defendants used one of their strikes to remove the case from pool.

The focus of Defendants' discovery and motion practice should remain on those Plaintiffs in the bellwether pool. The purpose of selecting bellwether Plaintiffs is to create efficiency and conserve resources in the MDL. Allowing Defendants to file motions in individual cases that are outside the bellwether pool will lead to a disruption in the process this Court developed.

Plaintiffs hereby notify the Court that Plaintiffs anticipate the filing of a motion for partial summary judgment on the issue of general causation, based primarily upon the numerous admissions in the depositions. Plaintiffs also intend to file a motion for partial summary judgment establishing the inadequacy of the olmesartan products' prescribing information as a matter of law.

7. *Lovelady* Treating Physician Depositions:

DEFENDANTS' POSITION:

At the conference on May 26, 2016, the Court said that the parties could depose more than two physicians in the bellwether pool by agreement or upon a showing of good cause. Defendants request the Court's permission for the deposition of one additional treating physician in the *Lovelady* matter. Plaintiffs initially agreed to but then objected to this request. Good cause exists for this request, as described in detail below.

Plaintiff's Gastrointestinal Physicians

Plaintiff Lovelady was seen by two gastrointestinal physicians. The first, Dr. Marsh, saw her in 2005 in the hospital and then for one follow up visit. He did an endoscopy and colonoscopy. His deposition has been scheduled following the prescriber physician's deposition at the end of September.

The second gastrointestinal physician, Dr. Chow, saw plaintiff in 2011 in the hospital but did not see her in follow up. He likewise performed an endoscopy and colonoscopy. Plaintiff claims Dr. Chow never talked to her following the tests or gave her the results of the testing. Her husband testified similarly but also accused Dr. Chow of hurting his wife during the procedure and running out of the procedure to avoid talking to plaintiff and her husband.

Plaintiffs' counsel Daniel Nigh originally agreed to take both depositions but added a caveat that they both be conducted during the same week as the prescriber. Defense counsel tried very hard, as did plaintiffs' counsel, to see if we could coordinate all three depositions the same week. It proved to be impossible.

Mr. Nigh counsel subsequently advised that he would not agree to the deposition because they could not be scheduled together. He also did not think it was necessary any longer because Dr. Chow only saw plaintiff in the hospital and not in follow up. Defense counsel offered to schedule the deposition by phone or videoconference for Mr. Nigh to participate and avoid the second trip to Yuba City. He declined saying that he could not agree "regardless of how unimportant the doctor's deposition may seem."

Good Cause Exists for Both Depositions

A gastrointestinal physician's deposition could not possibly be "unimportant" in a case involving gastrointestinal issues, especially when the gastrointestinal physician performed procedures bearing directly on the issues in the case. To the contrary, Dr. Chow' findings are critical to the analysis and work up of the case. Taking one gastrointestinal doctor but not the other tells half the story especially given the time interval between the two procedures. Whether Dr. Chow saw plaintiff in follow up is not relevant to the decision about whether he is an important treater in the case whose deposition should be taken.

Moreover, the deposition can be completed in a half of a day. The parties have little control over the availability of the witnesses' schedules, and tried their best to schedule them at the same time. Plaintiffs' preference to take them in one week should not be the deciding factor in whether the deposition should go forward. Plaintiffs' counsel can participate by videoconference if he chooses not to travel. Defendants submit that good cause exists for both depositions and respectfully request that the Court enter an Order allowing same.

PLAINTIFFS' POSITION:

Defendants' request to depose a second treating physician, Dr. Chow, should be denied. Dr. Chow is a gastroenterologist who treated Shirley Lovelady on one occasion when she went to the hospital. Ms. Lovelady never followed up with Dr. Chow and never treated with him at his office at any time.

The Defendants also requested the depositions of gastroenterologist, Dr. Marsh, as the treating physician and Dr. Ammar, as the prescribing physician. The depositions of Dr. Marsh and Dr. Ammar are scheduled for September 27 and 28. Dr. Marsh treated Shirley Lovelady in the hospital on another occasion and also treated her at his office. In addition, Dr. Marsh and Dr. Chow both treat at the same location and medical practice (North Valley Gastroenterology Medical Group). Dr. Ammar, who the defendants picked to depose as the prescribing physician, also treated Shirley Lovelady for her GI complaints on more occasions than both Dr. Marsh and Dr. Chow put together. In addition, Shirley Lovelady followed-up with Dr. Ammar on multiple occasions after the one hospital visit where she treated with Dr. Chow. All of this treatment is documented in the medical records.

Defendants have failed to show good cause for why both Dr. Chow and Dr. Marsh need to be deposed. The only argument that Defendants offer is that Dr. Chow is a

"gastroenterologist" and he "performed procedures". However, most of the bellwether cases involve more than one gastroenterologist who performed procedures.

Defendants mischaracterize plaintiff counsel's offer in an effort to avoid their inability to show good cause. Plaintiff counsel offered to compromise and agree to both GI physicians' depositions ONLY IF they could be deposed in the same week as Dr. Ammar, but there was never an agreement that both depositions were warranted. Defendants admit that it was not possible to schedule both GI physicians in the same week as Dr. Ammar, therefore, there was no agreement to depose both GI physicians. Certainly, there is no good cause to support the extra burden that would be imposed by taking an extra trip to Yuba City, California to depose a physician who treated the plaintiff on one occasion. Defendants' position that plaintiff's counsel should attend the deposition by phone or videoconference does not resolve the lack of good cause, and plaintiff's counsel in this case is unwilling to agree not to be present for any of these depositions.

Defendants have failed to show good cause, thus Dr. Chow should not be deposed.

8. *Phillips* Medical Records:

DEFENDANTS' POSITION:

Defendants have been advised by MCS, the medical records collection vendor, that several of Plaintiff Michelle Phillips' medical providers and employers have refused to produce records, stating they have been instructed by plaintiff not to do so. Specifically, we have been unable to collect records from Dr. Robert Ogesen (plaintiff's psychiatrist), The Women's Place (plaintiff's gynecologist), and Arizona State University (plaintiff's current employer), due to plaintiff's instruction that these facilities not release records notwithstanding receipt of a fully executed authorization for same. Plaintiff has released records from other health care providers

and employers in this case. It is unclear why she has now unilaterally decided to refuse to produce records from these three select providers.

Plaintiff is claiming depression and anxiety as a result of her injuries, leading to short term disability. She testified that she is claiming damages for mental anguish as a result of her alleged injuries, "I related the anxiety and the diarrhea to the health issues. I just lumped it all to health issues." (June 22, 2016 Deposition of Michelle Phillips, T199:6-7). When asked why she left one of her prior jobs, she testified "Again, my health problems, severe stomach pain, chronic diarrhea, having anxiety over it. I actually went on short-term disability on that job." (Id. at T25:23-25). She later testified that she once thought her job was "causing the chronic diarrhea, my stomach pain, nausea. I thought, you know, it was causing too many problems." (Id. at T28:4-6).

Plaintiff's PFS also states that she is claiming "mental anguish & stress leading to a disability claim in 2011." Plaintiff has been on short term disability several times from September 2011 through the present for her "anxiety." (See June 22, 2016 Deposition of Michelle Phillips, T188:10-16). In fact, she was on leave during the time of her deposition. However, to date, defendants have not received records indicating that this disability was a result of her alleged gastrointestinal injuries. Rather, plaintiff's medical records note a long-standing history of anxiety and depression and several instances of short-term disability for various issues unrelated to her alleged gastrointestinal problems, which is further bolstered by the fact that plaintiff alleges her current anxiety and depression is not related to her gastrointestinal problems. It is likely that plaintiff's medical records from Dr. Ogesen will provide a full history of plaintiff's anxiety and depression, which will provide information as to anxiety and depression that plaintiff alleges she experienced while taking Benicar.

If the Court is inclined to adopt Plaintiff's arguments here, the defendants request that all the records at issue be produced immediately by plaintiffs' counsel to the Court for in camera review.

Plaintiff is claiming lost wages in this action and, as noted above, alleges her mental anguish as a result of her alleged injuries led to a disability claim. When asked why she was claiming a wage loss of an annual salary that went from $45,000 to $36,000 she testified "Well, because it was a decrease, because I thought my job was causing me the anxiety, the medical issues . . . I went back and I thought, you know, I think it was because of the Benicar. . . ." (Id. T289:2-12).

Further, defendants are entitled to review a plaintiff's medical records beyond just that of the prescribing physician. Women may provide additional information to gynecologists for various reasons, including information bearing on their mental health. Plaintiff's updated records from The Woman's place may provide information regarding plaintiff's alleged injuries and or information as to the current status of her mental health which directly relate to the claims in this case.

Defendants are entitled to review all of plaintiff's medical records, including those that bear on her mental health, as they directly relate to plaintiff's claims in this litigation. Plaintiff's current employment records are directly relevant to her lost wages claims. A jury should be able to evaluate plaintiff's disability claims throughout the years.

Defendants raised this issue in a letter to Christopher Coffin on July 19, 2016, and followed up with phone calls on July 28, August 4 and August 24. To date, this issue has not been resolved. Defendants request that plaintiff be ordered to remove any instructions not to

produce medical records that she provided to any of her medical providers and/or employers for release of these records prior to the September 30, 2016 discovery deadline.

PLAINTIFFS' POSITION:

To be clear, counsel for the Defendants and counsel for Ms. Phillips have been meeting and conferring about these issues in an attempt to resolve them. In addition, Plaintiff's counsel has been working with their client in an effort to more clearly understand the issues surrounding the records at issue. The issues have not been ignored.

Defendants seek production of records from Plaintiff's current psychiatrist, Dr. Ogesen. However, Plaintiff did not begin seeing Dr. Ogesen until sometime after October 7, 2015, over eleven (11) months after she stopped taking Benicar. As Ms. Phillips testified at her deposition, she began seeing Dr. Ogesen for anxiety and depression related to the death of her beloved brother who died on or about October 7, 2015. The anxiety and depression she experienced as a result of her brother's death, was likewise documented in her primary care physician's records. Although Ms. Phillips was placed on short-term disability during the time period in which she took Benicar, her severe gastrointestinal symptoms and related anxiety and depression stopped when she stopped taking Benicar in November of 2014. Ms. Phillips is not alleging, and did not testify, that her anxiety and depression since October of 2015 was related to her use of Benicar. Rather, her anxiety and depression that led her to see Dr. Ogensen were directly related to her brother's death. Consequently, the records from Dr. Ogensen, which are obviously highly sensitive, are not relevant to the claims or defenses in this case, and Ms. Phillips should not be required to produce them.

Defendants also seek updated records from Plaintiff's gynecologist at The Women's Place. Plaintiff's counsel has not produced records from The Women's Place during the course

of this litigation, as her gynecologist did not prescribed Plaintiff Benicar, and has not treated Plaintiff for her severe gastrointestinal symptoms. Rather, Defendants previously obtained records from The Women's Place via the signed authorization submitted by Plaintiff along with her PFS. At the time of Plaintiff's deposition, Defendants had obtained a certified copy of Plaintiff's records from The Women's Place. The records were certified to by The Women's Place custodian of records to constitute a full copy of Plaintiff's records through the date of March 1, 2016. Presumably, despite any evidence that Plaintiff has continued to experience severe gastrointestinal symptoms since stopping Benicar in November of 2014, Defendants now seek updated records from March 1, 2016 to present. As the records previously collected from The Women's Place clearly reflect, Plaintiff's gynecologist never prescribed Benicar or treated Plaintiff for gastrointestinal symptoms. Consequently, updated records from The Women's Place are not relevant to the claims or defenses in this case, and Ms. Phillips should not be required to produce them.

Lastly, Defendants seek a copy of Plaintiff's personnel file from her current employer, Arizona State University. Upon receiving Defendant's request, Plaintiff was contacted by her employer and was asked if she specifically authorized such a request. Plaintiff responded that she was not aware of any such request, as Defendants had not specifically consulted with her prior to sending the request. At that time, Plaintiff was informed by Arizona State University that they would not release her records to a third party without a subpoena. Plaintiff then attempted to obtain a copy of her employment records on her own. Although, Arizona State University allowed her to review her employment file, she was not permitted to retain a copy. Ms. Phillips was again instructed that in order to obtain a copy of her employment file she would need a subpoena. During the course of a meet and confer, Plaintiff's counsel relayed this

information to Defendants. Although Plaintiff has no objection to her employment records being produced, based on the information readily available to Plaintiff from her employer, it does not appear that a signed authorization alone will be enough to secure the production of her employment file.

9. Bellwether Detail Representative Depositions:

The parties have scheduled detail representative depositions in nine of ten bellwether cases as follows:

- Block, Norman - September 22
- Harris, Amelia - September 8
- Lovelady, Shirley - September 29
- Morgan, Patricia - September 12
- Phillips, Michelle - September 14
- Priest, Allen - September 22
- Stapleton, Kathie - September 20
- Sutton, Susan – August 31
- Williams, Lamar – October 12

In the *Stiles* matter, defendants provided plaintiffs with the detail representative's last known address so that they may serve a subpoena if they so choose.

PLAINTIFFS' POSITION:

The plaintiff in Sutton has asked to change the date from August 31 to later in September, and Defendants have refused. Plaintiffs request that Defendants cooperate with the rescheduling of this deposition.

DEFENDANTS' POSITION:

Defendants have offered five dates for deposition of the detail representative in the Sutton matter – August 29, August 30, August 31, September 3 and September 17. Adam Slater is copied on all emails, although this is not his case. Plaintiffs have not responded to the offers of September dates.

10. Pathology Authorizations:

DEFENDANTS' POSITION:

In seven of the ten bellwether matters, Defendants were informed that Plaintiffs' healthcare providers require a specific authorization for obtaining a recut of pathology slides. The cases at issue are: *Block*, *Lovelady*, *Morgan*, *Priest*, *Stiles*, *Sutton* and *Williams*. On August 25, 2015, Defendants provided Plaintiffs' counsel with copies of the authorizations and requested that they be executed and returned by Monday, August 29, 2016. It is critical that Plaintiffs provide these authorizations immediately so as not to delay discovery.

Plaintiffs now raise for the first time in this agenda a pathology protocol. Defendants will confer with Plaintiffs on this issue as needed, but it should not be used to delay Defendants' access to the pathology materials to which Plaintiffs have had unfettered access for years.

PLAINTIFFS' POSITION:

Defendants have just recently sent the authorizations to Plaintiffs' counsel. The authorizations will be sent to the plaintiffs for signature and returned. Plaintiffs also expect that agreement can be reached on a simple protocol to ensure sharing and exchange of slides, and to ensure that sufficient material exists for the recuts to be produced. This should be addressed in a meet and confer. This is not an effort to delay, in fact Defendants did not seek the pathology specimens or raise the issue prior to August 25, 2016.

11. Production of Forest Custodial Files for Upcoming Depositions.

PLAINTIFFS' POSITION:

On June 30, 2016, Plaintiffs took the deposition of Forest's 30(b)(6) witness, Dr. Joseph Viscosi. In the course of that depositon, Mr. Viscosi provided multiple names of individuals at Forest with relevant information about Forest's handling of, among other things, adverse events and safety issues related to the olmesartan products. Of those individuals, Plaintiffs have narrowed additional Forest depositions to Amy Rubin, Kimberly Li and Paul Reed. Plaintiffs requested that Defendants produce the custodial files for these individuals at least two weeks prior to the scheduled depositions. Defendants have agreed to produce the custodial file of Amy Rubin, but have refused to produce the custodial files of Kimberly Li and Paul Reed, stating that "[o]ver ten months ago, the Court gave plaintiffs the opportunity to choose additional custodians beyond the Forest custodians they already had; you did, and neither Mr. Reed nor Ms. Li was on the list."

Obviously, at the time Plaintiffs created their list of Forest custodians, they did not have the benefit of the 30(b)(6) deposition testimony. The point of the 30(b)(6) deposition was for Plaintiffs to understand who the key people are within Forest that handled issues realted to the olmesartan products. Now, after narrowing the list of deponents significantly, Plaintiffs are requesting the custodial files of two witnesses who were not part of the original custodial file requests. Considering the timing of the requests in relation to the 30(b)(6) deposition and the narrow nature of the requests, Plaintiffs ask that the Court order the production of the custodial files.

DEFENDANTS' POSITION:

With merely a month left to the end of the discovery period, plaintiffs are now seeking to identify two new Forest custodians that had never been previously identified by plaintiffs as custodians. Over ten months ago, the Court gave plaintiffs the opportunity to choose additional custodians beyond the Forest custodians they already had. On September 18, 2015, plaintiff identified 39 additional proposed Forest custodians. After the Court instructed plaintiffs to "sharpen their pencils," plaintiffs narrowed their list to 47 Forest custodians, and neither Mr. Reed nor Ms. Li was on the list. Plaintiffs' belated request for collection and production of custodial files for Mr. Reed and Ms. Li comes over ten months (323 days) after the September 29, 2015 deadline by which plaintiffs were required to finalize their Forest custodian list. As mandated by this Court's Case Management Order No. 13, defendants are not obligated to produce custodial files for non-custodians absent good cause, and plaintiffs have failed to establish good cause in this instance.

Further, plaintiffs had the 30(b)(6) deposition of Dr. Joseph Viscosi, who testified that throughout the co-promotion period from 2002 to 2008, Forest had no responsibility over olmesartan pharmacovigilance, safety assessment, adverse event reporting, or risk management, nor did it perform any medical reviews or causality assessments related to the products. These tasks were handled by Daiichi Sankyo, Inc., and Ms. Rubin, Ms. Li and Mr. Reed will testify to that.

Finally, given the large number of custodians, the only possible yield from new custodial files would be the unlikely event that the witness sent e mails to someone who is not a custodian. That remote possibility does not justify the delay and expense associated with further collections.

12. Plaintiffs' request for continued deposition testimony and related discovery.

PLAINTIFFS' POSITION:

Tina Ho:

Plaintiffs previously requested the continued deposition of Tina Ho, the Executive Director of Pharmacovigilance at Daiichi Sankyo, and this was discussed with the Court during the April 8, 2016 status conference. At that time, the Court indicated that Plaintiffs had made a strong showing of the need to continue the deposition, but the Court deferred the issue in order to entertain all requests to continue depositions at one time.

Tina Ho, one of the four most knowledgeable defense witnesses, as identified by Defendants, and one of the most important causation witnesses in the litigation, could not be deposed in one day, based on the sheer volume of information and documents to be addressed, as well as the ongoing failure to produce complete documents at the time of her deposition. These issues were topped off by the production of thousands of documents shortly before and then **after** the deposition. Instead of working this issue out in reasonable fashion, Defendants sought to extract an agreement by Plaintiffs to drop another deposition if Defendants were to agree to a second day – demonstrating that Defendants' refusal to agree to a second day was purely strategic, without reference to the merits of the issue.

The deposition of Tina Ho took place on March 23, 2016. Tina Ho is the Executive Director of the Clinical Safety and Pharmacovigilance department at Daiichi US ("CSPV"). This is the department responsible for the monitoring and evaluation of the safety of the drugs sold by Daiichi, including whether the drug is the cause of side effects and complications. In other words, this is the department within Daiichi that is looked to as the primary group responsible to determine whether reported side effects and complications are associated with or caused by the

drug in question. This is the core area that is at the heart of this stage of discovery, and this witness has been at the center of this department since 2004. Globally, CSPV is comprised of an integrated organization including Daiichi personnel from the US, Germany, and Japan, thus the questioning of necessity also needs to go into global actions and communications.

Tina Ho was identified by Defendants as the appropriate Daiichi US employee to depose on multiple important subjects. Despite this, in their single-minded zeal to block the continuation of this deposition, they suggest that other people can be deposed on this subject matter instead of the witness they identified as THE proper person to question. The subjects identified include the identification and explanation of all adverse event protocols and Standard Operating Procedures related to the identification and evaluation of adverse events, and required actions in response. A related area is the reporting of adverse events to the FDA. Also, the database management of adverse event information, including on the Argus safety database and its predecessor the ArisG safety database – Tina Ho oversaw the implementation and migration of data to each system and coordination with the global Daiichi organization. In addition, in their discovery responses, Defendants identified Ms. Ho as knowledgeable regarding the approval of the Olmesartan drugs. The massive amount of information that comes within Tina Ho's purview encompasses critical areas that need to be fully explored so that an appropriate foundation can be established for the testimony of other witnesses, and most important for Plaintiffs' experts to rely upon.

The questioning of Tina Ho at the initial deposition was active and covered 57 separate exhibits, although a number of the exhibits were alternative versions of SOPs and Protocols, which were simply identified and authenticated for the record. These documents need to be identified and described so that this groundwork can be relied on in future depositions of people

involved in this area, as well as at trial. Unfortunately, due to the large number of SOPs and Protocols to be addressed, and the failure by Defendants to produce complete sets of final versions, this important part of the questioning could not be completed. For example, Plaintiffs do not have full, complete sets of the Signal Detection Report SOP's and Protocols and the groupings and reports themselves. These reports are detailed and used by CSPV to evaluate potential safety risks with the drugs, throughout the life cycle of the drugs. In addition, Tina Ho has been with Sankyo/Daiichi Sankyo since 2004, resulting in identification of a large number of relevant documents, many of which could not be reached and addressed. Further documents relevant to this deposition have continued to be produced since the initial deposition.

On top of the large volume of information and documents to be reviewed and addressed in this deposition, Defendants produced substantial numbers of documents shortly before the deposition, and had not fully produced general categories of documents relevant to the questioning, such as the largely unredacted versions of the adverse event reports. The productions in the two weeks prior to the March 23, 2016 deposition, and then in the days afterward, demonstrate this issue:

3/10/16 – 377 documents, 12,396 pages - Tina Ho custodial file.

3/10/16 – 2,102 documents, 5395 pages – Tina Ho Email Archive.

3/15/2016 – 4,376 documents, 75,513 pages – Tina Ho Custodial file.

3/15/16 – 308 documents, 559 pages – Tina Ho Email Archive.

3/17/16 – 146 documents, 227 pages – Tina Ho Email Archive.

Deposition on 3/23/16

3/24/16 – 757 documents, 8,290 pages – Tina Ho Custodial File.

3/24/16 – 32 documents, 67 pages – Tina Ho Email Archive.

3/28/16 – 15 documents, 19 pages – Tina Ho Email Archive.

Beginning March 19, 2016, only four days prior to Dr. Ho's deposition, the Defense produced 163 additional versions of SOPs, including as recently as June 7, 2016 and June 14, 2016 (Central Glossary production). These productions encompassed relevant SOPs produced for the first time, as well as prior unproduced versions of SOPs. Examples of these newly produced SOPs include:

1. SOP 504 Documenting Restricted Unblinding of Treatment Assignment in Blinded Clinical Trials for Safety Purposes
2. SOP 516 Restricted Unblinding for Regulatory Submissions of SUSARs from Clinical Trials
3. CSPV-SOI-019 Compliance Tracking and Documentation of FDA Expedited Safety Submissions
4. CSPV-SOI-019 - Compliance Tracking and Documentation of FDA Expedited Safety Submissions
5. CSPV-SOI-023 - Processing SAEs During ARGUS Downtime
6. CSPV-SOI-025 - Legal Case Processing
7. CSPV-SOI-026 - Safety Information Reporting System User Account Management
8. CSPV-SOI-027 - Compliance Review and Tracking of SUSAR and SUR Submissions

In fact, Defendants have still not made a complete production of all versions of Defendant's SOPs/SOIs relevant to adverse events. Plaintiffs request the production be completed in advance of a continued deposition.

Defendants also did not produce, and still have not produced, the performance evaluations found in Tina Ho's personnel file.

Plaintiffs did the best we could in questioning Tina Ho at the initial deposition, attempting to cover as much as possible, while still accomplishing our objectives. For example, it was Plaintiffs' idea to ask defense counsel to have Tina Ho review prior versions of an SOP during lunch, so that the authentication process could be completed more quickly with those documents. There was simply too much information to cover in a single session.

Defense counsel's assertion the last time the issue was raised that the deposition could have been finished in one day if time had not been spent re-asking questions is belied by the record. The protocol does not dictate that a question should not be asked again in the face of evasive or off point responses designed to frustrate the point of the question. The few examples offered by Defendants show that Tina Ho, who is very intelligent and is recognized as an extremely capable employee within Daiichi, would not directly answer certain direct questions that go to the heart of the causation issue we are focused on. For example, at one point the deponent was simply asked to confirm that the document in question, which she received and adhered to in her day to day work, referenced "Olmesartan **induced** sprue-like enteropathy," and that this means sprue-like enteropathy **caused by** Olmesartan. This is the causation question at the heart of the litigation. Instead of just agreeing to this foundational fact, the witness instead testified that the document was poorly written, "I can't comment on that. I think it's a bad choice of words." She then deflected again, stating, "I didn't write this memo." (Ho Tr., 453:19-454:5; 454:8-12). It took inordinate time to get her to ultimately admit, still evasive, that: "Those are the words that are used." (Ho Tr., 502:21-503:1). Later in the deposition, Tina Ho was asked a simple question, whether Daiichi is supposed to notice when reports of severe GI adverse events are reported with the Olmesartan drugs. Instead of answering with a yes or no, she first answered by saying they do so, which was not the question. Then she argued that she would not answer because the question was "positioning" Daiichi as if they did not do so, and ultimately she **refused to answer the question**, and defense counsel sat quietly by. This questioning which extends for five pages (492:8-497:4) was necessitated by the witness's refusal to directly answer straightforward questions, nothing more.

Plaintiffs attempted to resolve this issue but with no success. First, during the deposition we discussed our inability to finish the deposition in one day with the attorney defending the deposition. This attorney advised that he could not agree to anything, and that if Plaintiffs spent 7 hours on direct questioning, he would object to any questioning on re-direct. As a result, we had to stop questioning at 6.5 hours in order to reserve time to question the witness after defense counsel did so. This was placed on the record at the time. Thereafter, we wrote to defense counsel seeking to reach agreement. The most we heard in response was the incongruous offer to give more time IF Plaintiffs drop another deponent from the list. Now, Defendants indicate they will agree to a second day of deposition if limited to three hours, and "new topics previously covered." These limitations are not reasonable or necessary.

Because good cause has been established, Plaintiffs request entry of an order compelling the continuation of the deposition of Tina Ho on a mutually convenient date.

DEFENDANTS' POSITION:

Defendants have made multiple requests to the plaintiffs for a list of witnesses for whom they sought a second deposition, including a letter dated August 1, 2016, to which no response was received. That said, given that the only witness for whom plaintiffs are expressly seeking additional time is former DSI employee, Dr. Tina Ho, Defendants will agree to ask her if she will appear voluntarily for a second day of deposition provided that it is limited to three hours and only new topics not previously covered.

PLAINTIFFS' POSITION:

Mahmoud Ghazzi:

Plaintiffs deposed Mahmoud Ghazzi, who was the Chief Medical Advisor, with global responsibility, in 2012 and 2013, and is the current President of Drug Development, on August

26, 2016. At the deposition it was established that important documents were needed, which would need to be produced from Dr. Ghazzi's custodial file. For example, Dr. Ghazzi received emails referencing reports analyzing the safety and adverse events related to sprue-like enteropathy but could only specifically recall one of the documents. He confirmed that the best way to know what information was available to him regarding this safety issue would be to search within his documents and emails. Plaintiffs searched the documents available through discovery to date and were not able to identify this information.

Dr. Ghazzi is the person who vetoed the team responsible to submit proposed warning language to the FDA as the label was being modified in May, 2013 – causing them to remove a sentence because it more strongly indicated the causal relationship between Olmesartan and sprue-like enteropathy than the language suggested by the FDA. The information available to Dr. Ghazzi, and his own analysis of the issue, as would be reflected in his custodial file, should be compelled, and at that point Plaintiffs can determine if an additional deposition is needed.

DEFENDANTS' POSITION:

Plaintiff's demand for Dr. Ghazzi's custodial file has already been denied by the Court. On April 20, 2016, plaintiffs asked to substitute Dr. Ghazzi for William Bailey as a deponent and requested production of Dr. Ghazzi's custodial file. This request came over six months after plaintiff's served their "final" list of 114 Daiichi US custodians on September 29, 2016, and over three months after plaintiff's served the "final" list of 20 Daiichi US deponents on December 31, 2016. Moreover, pursuant to the Court's January 13, 2016 discovery order, Daiichi U.S. depositions were to occur between March 1, 2016 and April 29, 2016, and the depositions began on March 7, 2016. Thus, plaintiff's April 20, 2016 request to depose Dr.

Ghazzi and for production of his custodial file came 44 days into the depositions of the Daiichi U.S. deponents and nine days before depositions are supposed to be completed.

The parties briefed this issue, and on May 11, 2016, the Court denied plaintiff's request to add Dr. Ghazzi as a custodian. During the May 11, 2016 status conference, the Court stated it "has no reason to believe that relevant documents regarding Dr. Ghazzi are not already included in the multimillion documents ESI production done to date" and "if he is as important as plaintiff seems to think he is, it seems to me it makes logical sense that his relevant documents are going to turn up in the scores of other documents that have already been produced in this case, and nothing has been presented to the Court at this time that there's some gap in production." (*See* May 11, 2016 MDL Case Management Conference transcript, 5:10-12, 5:15-20).

Plaintiffs have not presented any information which changes these circumstances. Nothing has precluded plaintiffs from searching for Dr. Ghazzi's documents in the 60 million pages of documents already produced in this litigation. Plaintiffs know his title, know who reports to him, and are aware of the issues on which he likely has knowledge. Thus, they can search through the documents previously produced to locate those documents regarding which Dr. Ghazzi would likely have knowledge. However, plaintiffs opted not to confront Dr. Ghazzi with these types of documents during his deposition, and simply generalize that the only way to know what information was available to him is to search his documents. Plaintiffs have presented no specific examples of documents that they are missing from Dr. Ghazzi and had ample opportunity to question him on his own analysis of certain issues during his deposition. There is no reason to force Defendants to engage in yet another custodial collection and production.

PLAINTIFFS' POSITION:

Stephan Freudentaler and Ulf Stellmacher:

Dr. Freudentaler is the head of safety and pharmacovigilance in Europe, and Dr. Stellmacher is the Director of the department. Plaintiffs assume that the Defendants maintain their position that these individuals should not be deposed. If so, Plaintiffs have developed a record establishing the relevance of these witnesses, their regular, even daily work with Daiichi US, and that they apparently have unique knowledge relevant to the issues being explored in discovery.

A good example of the need for these depositions was elicited at Dr. Ghazzi's deposition. Documents were discussed, referencing the preparation of a report addressing all sprue-like enteropathy cases in Europe, as an outgrowth of regulatory actions in France and Germany. This analysis is highly relevant, however Plaintiffs have searched and been unable to find this or similar reports in the productions. Dr. Ghazzi testified that he does not know about these reports, and that the proper people to ask would be the European Daiichi witnesses who were involved – including Dr.'s Freudenthaler and Stellmacher. Another source of highly relevant information that they would be knowledgeable about are European Advisory Boards of European physicians thought to be Key Opinion Leaders ("KOLs"), convened by Daiichi Sankyo to address the sprue-like enteropathy issue, especially label changes. These meetings are referenced in emails, but we do not have the actual minutes, presentations, or follow up on these important meetings, and will need to depose these witnesses about the substance of what was discussed and proposed.

If Defendants will not agree to produce these witnesses, Plaintiffs intend to file a motion to compel the depositions, as well as relevant custodial document productions, and particular documents or categories of documents from the European entity.

DEFENDANTS' POSITION:

The Court has already addressed the issue of European discovery. Seven months ago, at the January 13 and 27, 2016 conferences, the Court instructed Plaintiffs that if they wanted to pursue European discovery, they needed to make a formal motion:

> THE COURT: Okay. If you want those documents, Mr. Slater, then that's a motion, and you have leave to file that motion. That is a very, very important issue, and maybe you're comfortable that you have a complete record 1 and you're ready to make your record to say that, Judge, although you ordered -- you limited your order to these countries, we now have good cause to argue that there's relevant and responsive, not cumulative documents in Germany, and we want you to order this, and this is why we think they were in the possession, custody, or control of the U.S. Fine. Make that argument, and you have leave to file that motion. That is a motion. That is a very significant issue, and file that motion whenever you want. I would certainly wait until I see what I get on the 19th and maybe until we resolve this issue on the 27th, but it's a very important issue, and I understand your concern and it's not something I want to deal on letter briefs. So you have leave to file that motion. [Transcript from the January 13, 2016 Case Management Conference, 15:23-16:15]
>
> *****
>
> THE COURT: And then you could make an application for cause and we'll deal with it. [Transcript from the January 27, 2016 Case Management Conference, 78:5-23].

Plaintiffs have failed to do so, and instead attempt to circumvent the Court's explicit instruction by raising the issue as an agenda item with one month left until the close of discovery. At this late juncture, any request for European discovery should be denied.

PLAINTIFFS' POSITION:

Jeff Warmke (ROADMAP 30(b)(6) representative):

Dr. Warmke was deposed on August 23, 2016. During the deposition, Dr. Warmke did not know the answers to certain questions within the scope of the deposition, for example the amounts paid to the investigators, the positions and titles of certain members of the steering committee, the source of certain statements found in the core study documents, and others. Plaintiffs will be following up with a letter to request the information necessary to fill the gaps,

and will then determine if a continued deposition should be requested based on what is provided. Until that information is provided, that decision cannot be made.

DEFENDANTS' POSITION:

This issue is not ripe to be included as an agenda item. Upon receipt of Plaintiffs' written request, Defendants will respond to Plaintiffs on this issue and meet and confer as needed.

13. Plaintiffs' request to commence sales and marketing discovery.

PLAINTIFFS' POSITION:

Discovery into the general causation issue is well along, and Plaintiffs believe it is now appropriate to schedule the sales and marketing discovery to commence during the Fall 2016. Defendants' position that this phase should await the conclusion of the Daubert/Kemp hearings would delay discovery into key areas needed to be able to go trial until well into next year, effectively ensuring that this litigation will not be ready for trial in 2017.

One sub-issue to this phase of discovery is Plaintiffs' continued request to obtain the DOJ investigation documents. On October 2, 2015, the Court issued an Order (Document 152) addressing the production of DOJ documents and requiring that the defendants produce the DOJ "qui tam" subpoena issued by the DOJ and the defendants' "enclosure letters and/or emails served" with the documents produced in response to that subpoena. The Court further stated that "(T)his Order is entered without prejudice to plaintiffs' right to request more "qui tam" documents after the bellwether cases are identified." The bellwether cases have been identified, and substantial fact discovery is ongoing in those cases. Plaintiffs believe it is now appropriate to re-visit the DOJ document issue. As the Court is aware, the DOJ investigation focused on the defendants' over-promotion of Benicar products and the payment of illegal kickbacks to prescribing doctors. A substantial fine was levied against the defendants together with the

imposition of a corporate integrity agreement. As discussed at the most recent case management conference, the information provided to physicians, including through the speaker programs that were at the center of the DOJ investigation, had an impact on the prescribing practices of treating physicians, as well as their understanding of the risks and benefits of the drugs. In turn, this directly impacted the prescription of the drugs to the plaintiffs, as well as the description of risks when the drug was administered, and the information available to the doctors when trying to assess the cause of the serious gastrointestinal issues exhibited by the plaintiffs.

Plaintiffs believe the most expedient approach is an Order directing production of the documents and information produced to the DOJ, which Plaintiffs understand to be electronically saved, and thus easily produced This will provide extensive information regarding the marketing of the drugs, the scope of the illegal (per the DOJ) conduct, and the means and methods actually used – for example the amounts paid and to whom, and the misleading documentation utilized.

The DOJ production letters which the defendants have produced describe the following documents relevant to the "marketing " issues in this case, which Plaintiffs are able to prioritize at this point based on the available information:

a. Promotional Speaker Program documents – these documents purportedly provide details of the speaker programs and honorarium payments, meeting receipts, attendee sign in forms, speaker training programs and meeting records. See for example, OLM-DSI-0004779256-0004779258, and 0004779284-0004779286.

b. Physician Opinion Discussion ("POD") programs – these documents purportedly detail payments made to health care professionals who promoted the drug, training documents, the top 100 sales reps, the amounts spent on POD per year. . See for example, OLM-DSI-0004779393-0004779398, and 0004779404-0004779406.

If the Court is at all hesitant to direct the full production at this point, plaintiffs request that the defendants be required to produce the categories of documents listed above as well as the index of documents produced to the DOJ. The "enclosure letters" which have been produced fail to describe with specificity what was produced. Rather, the defendants have represented to the court that indices of the document were prepared by the defendants and presumably those indices can be used to identify what documents are relevant to this litigation. This will streamline the process significantly. To the extent that there is a claim that those indices are protected by attorney work- product privilege, Plaintiffs request that the indices be produced to the court for an in camera review. However, Plaintiffs reiterate their position that interpretation of production letters and indexes, and potential in camera reviews are unnecessary. The easiest and most effective step is to simply order full production. Plaintiffs also believe that it would be efficient to set a 30(b)(6) deposition on this subject in order to streamline discovery.

DEFENDANTS' POSITION:

The Court has made clear that this stage of the litigation is focused on causation, with the goal being a joint *Daubert/Kemp* hearing with the New Jersey MCL Court. Staggering marketing and causation discovery deadlines serves no good purpose in reaching this goal. The parties' time and resources should not be side tracked with marketing discovery issues, especially when the Court has already ruled on many of these issues, including those related to the Department of Justice matter.

In any event, Defendants have continued to produce marketing related materials in their weekly productions, and have continued to respond to Plaintiffs' marketing related requests, most recently related to speaker programs and discontinued marketing pieces. To the extent

Plaintiffs have additional marketing related requests, Defendants submit that the time to address those issues is after the joint *Daubert/Kemp* hearing and dispositive motions, if the cases remain.

14. Plaintiffs' continued request to obtain full production of ordered marketing documents, and request to obtain speaker program information.

PLAINTIFFS' POSITION:

In response to the Court's order following the last conference, Defendants have produced some but not all of the marketing documents that were invalidated by the FDA 2006 untitled letter. Defendants must complete this production, especially in light of prior representations to the Court that no productions or cooperation with populating a spreadsheet of marketing materials was warranted since Plaintiffs already had all the materials and could do so ourselves – since proven untrue when Defendants admitted they never produced marketing materials invalidated for misbranding due to unsupported claims of superior efficacy and safety.

Following the last conference, Defendants provided information regarding speaker programs attended or led by prescribing and treating physicians. Upon review of the information, Plaintiffs asked Defendants to advise as to how the programs could be matched with the materials utilized at the programs, and Defendants have indicated that this cannot be done. Clearly, it is highly relevant to identify the substantive Powerpoints, marketing documents, or other materials utilized at these programs. Plaintiffs request production of this information.

DEFENDANTS' POSITION:

Defendants have identified production bates numbers for 74 of the 89 requested pieces. Defendants have identified all of the materials identified in the 2013 letter to the FDA. Regarding the marketing materials in the 2006 letter that date back to 2002, 58 of the 73 requested pieces have been identified. The items in the 2006 letter were in circulation prior to the electronic ARC database and are not all saved in one location. Because of this, manual

searches must be conducted to locate the items. Since the last update to Plaintiffs, Defendants identified five additional items from the 2006 letter, all dated between 2003 and 2005, which will be included in this week's production documents.

Regarding Plaintiffs' new request for additional speaker program information, Defendants have responded and there is no issue for the Court. Plaintiffs asked for a "list of what materials were utilized at each speaker program," for these physicians. On August 26, Defendants advised that they did not maintain the specific material used at each speaker program; nor is the material contained in the SCS database, and Defendants are therefore unable to produce such a document. Defendants also advised they have not identified any reasonable method for identifying this information.

Plaintiffs also requested identification of speaker program events "which are implicated by the Department of Justice [("DOJ")] investigation and complaint." On August 26, Defendants responded to plaintiffs and advised that the DOJ investigation did not focus on or "implicate" any specific Olmesartan speaker program events, and there was no discussions regarding specific events with the DOJ. However, as described in Paragraph D of the Settlement Agreement between Daiichi Sankyo, Inc. and the United States Department of Justice effective January 8, 2015 [OLM-DSI-0002550204 - OLM-DSI-0002550220], the DOJ focused generally on speaker programs conducted by DSI with certain characteristics.

Dated: August 29, 2016

Respectfully Submitted,

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