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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

<p>IN RE: ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION</p>	<p>MDL No. 2921 Civil Action No.: 2:19-md-2921 (BRM)(ESK)</p> <p>SPECIAL MASTER CASE MANAGEMENT ORDER NO. 30</p>
<p>This Order Relates to All Actions:</p> <p><i>In re Allergan Biocell Textured Breast Implant Product Liability Litigation, MCL No. 634</i></p>	

This matter comes before us by way of the parties ongoing dispute related to the scope of CMO 15.

I. PROCEDURAL HISTORY

The parties are familiar with the facts surrounding the underlying action and claims. Accordingly, we will recite only the relevant procedural and factual background necessary to address the disputes at hand, namely the scope of Allergan’s obligations with respect to the Defense Fact Sheet (“DFS”).

At the outset, the parties agreed that the proceeding would follow the typical bellwether paradigm for multidistrict litigation matters. (ECF No. 386 at 2). As part of the process, approximately 426 Plaintiffs will provide a Plaintiff Fact Sheet (“PFS”) containing medical and personal information. (ECF No. 397 at 2). Allergan is then required to respond within 90 days with a DFS relating to each Plaintiff. *Id.* The parties will then use the information derived from the fact sheets to select bellwether cases for further discovery. *Id.*

On May 17, 2022, the parties submitted a joint agenda letter in advance of the May 19, 2022 discovery status conference that described six issues for resolution at the conference. The third issue, “DFS Disputed Issues” related to the proposed Defense Fact Sheet (“DFS”).

At the May 19, 2022 conference, we heard argument related to the DFSs. On May 20, 2022, I entered Special Case Management Order No. 15 and ordered the parties to adopt “Exhibit A” as the operative DFS. (ECF No. 388). The approved DFS requires Allergan to provide, among other things, information relating to contacts between its sales representatives and a plaintiff’s treating physician, including the marketing materials the sales representative showed the physician, information the sales representatives shared with the physician regarding the safety and efficacy of the BIOCELL implants, and Allergan’s training of the sales representatives in promoting the BIOCELL implants.

On June 10, 2022, Allergan filed its appeal of Special Master CMO 15. (ECF No. 389). On June 28, 2022, Plaintiffs filed their opposition to the appeal. (ECF No. 391). On July 12, 2022, Allergan filed its reply. (ECF No. 393).

On August 9, 2022, the Honorable Brian Martinotti, U.S.D.J., affirmed CMO 15.

In subsequent case management conferences on May 23, 2023 and July 26, 2023 issues again arose with respect to the DFSs, this time related to the scope of Allergan’s obligations

pursuant to the operative DFS in light of Judge Martinotti's order affirming CMO 15.

II. The May 23, 2023 conference

At the May 23, 2023 conference, Plaintiffs took the position that Allergan's production of DFSs and responsive materials is incomplete and inconsistent with Judge Martinotti's Order and CMO 15, mainly with respect to Allergan's searches for sales representative marketing materials.¹ Plaintiffs' position, in large part, arose when Allergan stated that the search for materials responsive to § (III)(B)(7) (i.e. training materials provided to sales representatives) is "not something that is coming out of the custodial file [of the sales representative]." (May 23, 2023 Tr. 107:17-19). Instead, Allergan is searching separately to identify marketing materials that would have been provided to the sales representatives for training purposes or to be disseminated to the doctors. (*Id.* at 114:3-8). Allergan submits that it is compliant with Judge Martinotti's Order and CMO 15 because it has searched the custodial files of the sales representatives by using the agreed upon search terms, the surgeon's names, and the specific plaintiff's names. (May 23, 2023, Tr. 98:3-100:19). Further, Allergan articulated its understanding of its obligations pursuant to CMO 15 and Judge Martinotti's order, with respect to the sales representatives, as to "identify the contacts and references to and from the sales rep..." (*Id.* at Tr. 115:23-116:2).

Allergan maintains that Judge Martinotti's order and CMO 15, with respect to the sales representative custodial file issue, is focused on identifying contacts between the sales representative and the surgeon related to the device at issue. (May 23, 2023 Tr. 108:4-9).

¹ Although it is clear that Plaintiffs have not waived the right to receive all of the categories set forth in the DFS, the disputes highlights the controversy over the marketing discovery.

III. The July 26, 2023 Conference

During the July 26, 2023 conference, Plaintiffs again raised the issue of the scope of Allergan’s searches related to the DFS. Plaintiffs sought clarification that Allergan “is actually searching all locations for the communications....not just e-mails, but all types of communications” and that the phrase “communications” also includes “sales training” and “marketing materials.” (July 26, 2023, Tr. 10:9-14; 11:8-15). In response, Allergan stated that they have searched “the files for communications between the [sales] rep and the doctor. And then also any references to the physician. So either direct communications between the [sales] rep and the doctor or references by the [sales] rep to the particular physician.” (*Id.* at 12:4-15). Allergan described its search as a “limitation” that is clear from Judge Martinotti’s Order. (*Id.* at Tr. 12: 16-20). Plaintiffs disputed Allergan’s position regarding its obligations pursuant to the DFS.

IV. DISCUSSION

The purpose of this order is to clarify Allergan’s obligations pursuant to CMO 15 and Judge Martinotti’s opinion affirming CMO 15.

In his review of CMO 15, Judge Martinotti did not change the scope or otherwise limit Allergan’s discovery obligations with respect to the DFSs nor did Judge Martinotti modify CMO 15. The issue is not relevance of the information sought. There is no dispute among the parties that the sales representative records are relevant. (ECF No. 397 at 7)(“The parties agree communications between the sales representatives and Plaintiffs’ treating physicians, along with other sales representative records, are relevant and should be produced at some stage of the proceeding.”); (May 23, 2023, Tr. 128:10-14)(“...Judge Martinotti’s decision is all about the

importance of Plaintiffs knowing the communications between the reps and the doctors, and we all agree.”). Of importance, Allergan always agreed to produce the following: (1) provider information, (2) communications with or about plaintiff, (3) manufacturing/device information, (4) explant information. (ECF No 389-18 at 1). Allergan also agreed to produce the training of sales representative materials. And indeed, they have produced some of those materials, just not from the custodial files. Thus, the issue is the manner in which Allergan is searching for the information.

At the May 23, 2023 conference, Allergan stated that the search for materials responsive to § (III)(B)(7) (i.e. training materials provided to sales representatives) is “not something that is coming out of the custodial file [of the sales representative].” (May 23, 2023 Tr. 107:17-19). Instead, Allergan is conducting separate searches for training materials in other sources. Then at the July 26, 2023 conference, Allergan stated that it has searched for only communications between the sales representative and the doctor and described its “limitation” as clear from Judge Martinotti’s Order. (July 26, 2023 Tr. 12:4-20). Allergan’s limitation derives from the court’s acknowledgment that, “[c]ommunication concerning the safety and efficacy of BIOCELL implants between Allergan’s sales representatives and Plaintiffs’ treating physicians is essential to both the claims and defenses in the litigation.” (ECF No. 397 at 8); (May 23, 2023 Tr. 138:1-14). However, the court’s statement is merely that, an acknowledgment. It does not limit Allergan’s obligations under CMO 15 nor does it alter, amend, or otherwise change CMO 15. If the Court had intended otherwise, it would have clearly amended CMO 15.

The relevant sales representative section of the operative DFS, attached as Exhibit A to CMO 15, requires Allergan to:

As to each SALES REPRESENTATIVE who had any contact with a TREATING HEALTHCARE PROVIDER identified in Plaintiff's PFS, beginning ten (10) years prior to the implantation surgery date, set forth the following:

1. Identity of TREATING HEALTHCARE PROVIDER.
2. Identity and last known address and telephone number of the SALES REPRESENTATIVE[S].
3. The work history and current relationship, if any, between ALLERGAN and the SALES REPRESENTATIVE.
4. Identity of the SALES REPRESENTATIVE's supervisor(s) during his/her employment for the response period.
5. The BIOCELL device(s) that the SALES REPRESENTATIVE marketed, sampled, provided to, or otherwise presented to or discussed with the TREATING HEALTHCARE PROVIDER.
6. Identify all sales and marketing literature or other information utilized or referenced by the SALES REPRESENTATIVE in communications with the TREATING HEALTHCARE PROVIDER with regard to the BIOCELL device(s).
7. Set forth the details of all training and instruction provided to the SALES REPRESENTATIVE with regard to the sale and marketing of the BIOCELL device(s).
8. Set forth all information provided by the SALES REPRESENTATIVE to the TREATING HEALTHCARE PROVIDER with regard to the safety, use, or efficacy of the BIOCELL device(s).
9. Set forth all information provided by the TREATING HEALTHCARE PROVIDER to the SALES REPRESENTATIVE with regard to the safety, use, or efficacy of the BIOCELL device(s).
10. Set forth all information provided by the TREATING HEALTHCARE PROVIDER to the SALES REPRESENTATIVE with regard to Plaintiff.
11. Set forth the date and location of each operation or procedure performed on Plaintiff that was attended by the SALES REPRESENTATIVE; or whether the SALES REPRESENTATIVE was present at the identified facility on the date of implantation or explanation.

(ECF No. 388 at pp. 7-8 of 12).

I understand that in response to paragraph 7 above, Allergan has been providing a narrative information about the training and instruction Allergan gave to the sales representatives and then specifically identifying bates numbers of documents that are responsive to paragraph 7. (May 23, 2023, Tr. 136:14-19). That may or may not be compliant with CMO 15. The problem is, only Allergan knows what is in the custodial file. If documents relevant or necessary to complete each DFS are only in the custodial file, then it must be searched. Unless of course all of these communications are found elsewhere and are being produced by Allergan as described hereinabove.

As it currently stands, Allergan's searches for only communications between the sales representative and the treating physician from the sales representative files would not yield communications between the sales representatives/managers, between Allergan and the sales representatives, and any guidance or instruction emails that the sales representatives may have received from Allergan all of which would be relevant and necessary to guide the parties' selection of the first pool of bellwether cases. It was noteworthy that in negotiation of the DFS, Allergan agreed to Section 5 under the Sales Representative section, which required this information. Thus, pursuant to CMO 15, the search for the marketing materials must include a search of the sales representative custodial files because the custodial files may include information related to, at a minimum, paragraphs 6-8 above.

To be clear, Allergan *is not* obligated to produce the entire sales representative custodial file at this juncture. However, Allergan *is* obligated to produce the information called for in the DFS. To that end, Allergan is obligated to search the sales representative custodial files for documents responsive to paragraphs 1-11 above. If the same information is available from other, more efficient sources, Allergan can certainly produce the information from those sources, but

not at the expense of missing relevant information contained only in the sales representative custodial files. Allergan cannot simply leave or fail to include documents that may only appear in the custodial files and that are necessary to the bellwether selection process.

One final point warrants mention. The parties previously discussed the issue of implementing Technology-Assisted Review (“TAR”) in this case to assist in the review of documents. The parties were unable to agree on a TAR protocol so Allergan proceeded with its manual review. It has become apparent, yet again, that this case would benefit from implementing a TAR protocol. This is to alert the parties that I am preparing a TAR Order, which I expect to complete in approximately three (3) weeks. The parties may wish to meet and confer regarding a TAR protocol.

CONCLUSION & ORDER

For the foregoing reasons, it is on this 4th day of August, 2023:

ORDERED that as part of its DFS production, Allergan must search the custodial files of the sales representatives for responsive materials. The search should not be limited to only communications between the sales representative and the treating doctor.

SO ORDERED.

/s/ Joseph A. Dickson

Hon. Joseph A. Dickson, U.S.M.J. (Ret.)
Special Master

/s/ Gregg A. Padovano

Hon. Gregg A. Padovano, J.S.C.

Date: August 22, 2023