

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

**IN RE: WRIGHT MEDICAL
TECHNOLOGY, INC.,
CONSERVE HIP IMPLANT
PRODUCTS LIABILITY
LITIGATION**

MDL DOCKET NO. 2329

ALL CASES

1:12-MD-2329-WSD

ORDER

This matter is before the Court on the parties' request for the Court to clarify CMO-1 and CMO-3, relating to the scope of production of certain materials in discovery in this matter.

I. BACKGROUND

Before the Court is the parties' request for clarification regarding the scope of the Court's requirement that Defendant produce information and documents concerning payments to physicians and consultants who provided services to Defendant concerning the CONSERVE line of hip replacement products ("Physician and Consultant Materials"). This issue was discussed during the February 11, 2013, monthly telephone conference in this matter. The Court did not then resolve whether Defendant was required to produce Physician and

Consultant Materials from among those materials created in connection with or following Defendant's entry into a deferred prosecution agreement with the United States Department of Justice (the "DPA"), which included a compliance program monitoring by an independent law firm in Tennessee. Defendant acknowledges that it has withheld DPA materials relating to physicians and consultants that provided services to Defendant and that the information withheld could concern physicians and consultants providing services to Defendant regarding the CONSERVE line of hip replacement products. Defendant argues that the Court has declined to require Defendant to produce information "regarding the entire DPA, regardless of whether such discovery relates to the CONSERVE® line of products" when such information is requested "under the guise of the Court's Order granting discovery regarding payments to consulting physicians with respect to CONSERVE® products." (Agenda and Pos. Stat. dated Feb. 7, 2013, at 5). Defendant argues further that the "opening paragraph of the DPA, [provides] 'that neither this DPA nor the Criminal Complaint alleges the Company's conduct adversely affected patient health or patient care.'" (Id.). Because this litigation concerns alleged physical injury, the DPA preamble, Defendant argues, renders irrelevant any information about or relating to the DPA. Finally, Defendant argues that any DPA-related information regarding Physician and Consultant Services

provided to Wright is not required to be provided unless it specifically identifies or segregates out Physician and Consultant Services provided for the CONSERVE line of products. For these reasons, Defendant argues that DPA-related information about Physician and Consultant Services is not required to be produced.

Plaintiffs contend the information is discoverable. They argue they learned during discovery that “Defendants paid surgeons and consultants on a guaranteed lump sum quarterly basis and as a percent of sales on a royalty basis, purportedly in return for research, publications, presentation of Wright-sponsored studies and other promotional activities.” (*Id.* at 3). Plaintiffs appear to argue that information about payments made to physicians and consultants, including to support Wright-sponsored studies and “other promotional activities,” could have been to encourage acceptance of the CONSERVE line of products or suppress a critical evaluation of the products. They believe documents may exist in the DPA-related materials referring to or discussing this objective effect.

The standard in Federal Rule of Civil Procedure 26(b)(1) is that

Parties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party. . . Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence.

Fed. R. Civ. P. 26(b)(1). Because the Court did not have sufficient information about the withheld Physician and Consultant Discovery to evaluate the application of the Rule 26(b)(1) standard to it, the Court required Defendant to submit DPA-related Physician and Consultant Material to the Court for *in camera* review. (Tr. of Feb. 11, 2013, Tel. Conf. at 13-16). The Court required Defendant to submit for *in camera* review the Quarterly Reports of the Federally-Appointed Monitor for Wright Medical Technology (the “Quarterly Compliance Reports”) and the DPA-related documents for the months of June 2011 and June 2012. These materials were received by the Court on March 6, 2013 (the “In Camera Documents”).

The Court has completed its review of the In Camera Documents and these are its findings on the review.

II. FINDINGS

A. Quarterly Compliance Reports

These reports generally concern the Monitor’s review of Defendant’s development and implementation of the compliance program required by the DPA. The Compliance Program is multifaceted, putting into place programs and procedures to ensure prudent review of Defendant’s business and ethical conduct among Defendant’s management and workforce. There are a few portions of the Quarterly Compliance Reports that pertain to services provided by physicians and

consultants for compensation. While these portions do not report on Defendant's pre-DPA conduct, they do result from the impact of it and these portions may provide insight into the sort of conduct that gave rise to the DPA and its resulting compliance program, including Defendant's conduct in compensating physicians and consultants for services performed.¹ The First Quarterly Report, for example, discusses the justification for the "royalty rate," discusses consulting agreements including how to memorialize "arrangements to engage and pay Consultants in exchange for Services to" Defendant, requires the deletion of language in agreements requiring Consultants to use their "best efforts, within the applicable professional standards of ethics, [to] promote the use of the Products," and the form of a Services Agreement. (WMTICR0000018, WMTICR0000019, WMTICR0000028, WMTICR0000069, WMTICR00000103). The Second Quarterly Report discusses how and where to conduct training for healthcare professionals, consultant qualifications, and documentation of the "substantial contribution" by a provider. (WMTICR0000326, WMTICR0000346, WMTICR0000395). The Third Quarterly report discusses one clinical research agreement relating to 1,000 CONSERVE Plus hip implants and the compensation relating to the conduct of certain follow-up work and interviews at CONSERVE

¹ The Quarterly Reports also contain Defendant's response to the report and put the report comments into context.

Plus Hip and Knee study sites. (WMTICR0000670). In the Fourth Quarterly Report, there are references to the CONSERVE resurfacing system and its promotion, CONSERVE Plus PMA application, and consultant qualification information for future hip and knee events. (WMTICR0001012, WMTICR0001013, WMTICR0001028). The Fifth and Sixth Quarterly Reports contain scant references to the CONSERVE Thin Shell LTF² and marketing of it in light of the requirements of Section 510(k) of the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq. The Court notes that as the Compliance Program matured, the later Quarterly Reports become redundant as the Company developed and modified specific compliance safeguards and training. That is, the already slight relevancy of the documents becomes marginal as the compliance program develops and the quarterly reports are populated by forms and procedures the company began to use and apparently is using. The reports also become significantly shorter with few, if any, references to CONSERVE and those do not appear to relate to the issues in the MDL litigation.

Having reviewed the Quarterly Reports, the Court concludes that those portions of the Quarterly Reports that discuss or pertain to Physician and Consultant Services and compensation are reasonably calculated to lead to the

² It is unclear to the Court whether this product is at issue in this litigation.

discovery of relevant evidence about the CONSERVE line of products and, thus, the Quarterly Reports are required to be produced in accordance with the specific production requirement at the end of this Order.

B. June 2011 and 2012 Documents

The other documents reviewed relating to the DPA are varied³ and include, by way of example, email communications with the monitor, documents discussing the processes for compliance review and approval after execution of the DPA, including forms and procedures developed, documentation of specific approvals and payments to consultants after the DPA was enacted, approval of consultants recently retained for medical research-type work, including their curriculum vitae (few of which were for hip research or matters), and Manufacturing Site Visit agenda for tours of sites where devices apparently were manufactured, at least, in May and June 2011. (WMTICR0011480, WMTICR0015359). While minimally relevant to the Physician and Consultant Information, there are a small number of documents, such as the Needs Assessment Process Rationale and Substantiation Guidance manual for use in assessing the need for consultant services and documents referencing relationships with consultants after the DPA, that arguably are reasonably calculated to the discovery of admissible evidence. (See, e.g.,

³ There is considerable redundancy in these documents with more than one copy of a document among the scope of materials the Court required to be produced.

WMTICR0002494, WMTICR0002989, WMTICR0007894). The document references themselves are not relevant and the Court observes that Plaintiffs are unlikely to find anything productive in these materials, among the few of them that may be required to be produced. Plaintiffs' counsel, who is more familiar with the Physician and Consultant Materials issue, is entitled to make this determination even if the universe of documents produced is small.

III. CONCLUSION

Overall, the Court's *in camera* review (which took approximately 6 hours) disclosed few documents that are themselves relevant to physicians and consultants who provided services to Defendant concerning the CONSERVE line of hip replacement products during the time period relevant to this litigation. There are documents that, reasonably extrapolated, could be reasonably calculated to lead to the discovery of admissible evidence and thus technically meet the Rule 26(b) production standard, although the Court's own extrapolation suggests that the documents that Defendant will be required by this Order to produce will be small.⁴ Considering the issues raised in this case and understanding that the time-intensive review the Court requires Defendant to conduct, the Court defines what is required to be produced as follows:

⁴ The Court does not consider or reach any conclusions regarding the admissibility of any evidence that might be produced.

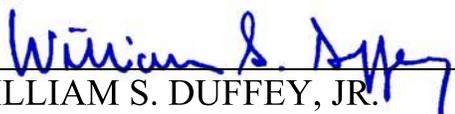
1. Documents and other information that constitute or relate to the DPA, or the compliance program developed and conducted pursuant to the DPA, which references, discusses, reflects, or resulted from conduct involving payments to physicians and consultants who provided services to Defendant concerning the CONSERVE line of hip replacement products, whether or not the CONSERVE line of products are specifically and separately addressed in such documents or materials.

2. Documents and other information that refer, by name, to any physician or consultant who provided services to Defendant.

3. Documents and other information that mention the word “CONSERVE” or which otherwise refers to the CONSERVE line of products regardless of whether the document or information relates to payments to physicians and consultants who provided services to Defendant concerning the CONSERVE line of hip replacement products.⁵

⁵ Defendant is allowed to redact material from documents other than that which is required by this Order to be produced.

SO ORDERED this 18th day of March, 2013.



WILLIAM S. DUFFEY, JR.
UNITED STATES DISTRICT JUDGE