IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION

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| IN RE MENTOR CORP. OBTAPE | * | MDL DOCKET NO. 2004 |
| TRANSOBTURATOR SLING PRODUCTS | * | ALL CASES |
| LIABILITY LITIGATION | * | 4:08-MD-2004 |

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O R D E R

These actions arise from complications Plaintiffs suffered after they were surgically implanted with ObTape, a product sold by Defendant Mentor Corporation and designed to treat stress urinary incontinence. Presently pending before the Court is Plaintiffs' Motion to Compel Production of Documents Identified in Defendant's Privilege Log for French Documents (Doc. 48). For the following reasons, Plaintiffs' motion is granted in part and denied in part.

FACTUAL BACKGROUND

Plaintiffs' presently pending motion to compel stems from documents received from France pursuant to the Hague Convention on the Taking of Evidence Abroad in Civil or Commercial Matters, July 27, 1970, 23 U.S.T. 2555. The French documents at issue were obtained from Nathalie Gremaud and Dr. Catherine Ortuno, former employees of Mentor-Porges, a wholly-owned subsidiary of Mentor Corporation in France. Once the documents were received in this Court, copies of the documents were produced to Defendant's counsel. Defendant was instructed to review the documents for privilege, file

a privilege log with the Court, and provide Plaintiffs' counsel with copies of any documents Defendant agreed were not privileged.

Defendant complied with these instructions and identified a number of documents it contends are privileged. The privileged documents identified by Defendant fall into two broad categories. First, Defendant contends that federal regulations require it to redact the names of any physicians who reported adverse events involving ObTape; second, Defendant contends that it does not have to produce the remaining documents because they are subject to the attorney-client privilege.[1]

DISCUSSION

**I. Documents Relating to the Identity of Physicians**

Plaintiffs first contend that they are entitled to discover the names of physicians who reported adverse events involving Defendant's products. Defendant asserts that Food and Drug Administration ("FDA") regulations require the redaction of the reporting physicians' names. Plaintiffs respond that (1) the FDA regulations do not apply to the redactions at issue in this case because Defendant has made no showing that the requested records were

[1]Defendant originally contended that two of the documents at issue were subject to the "work product" privilege. It is clear, however, that because these documents were not prepared in anticipation of litigation, the work product privilege is inapplicable. *See, e.g., Spivey v. Zant*, 683 F.2d 881, 885 (5th Cir. Unit B 1982) ("[T]he work product doctrine does not apply to the situation in which a client seeks access to documents or other tangible things created or amassed by his attorney during the course of the representation."). Defendant has therefore abandoned its assertion of the work product privilege and now contends these documents are subject to the attorney-client privilege.

"adverse event reports" voluntarily submitted to the FDA; (2) they are entitled to receive a copy of all reports that involve a Plaintiff in this case; and (3) at least some of the redacted names are those of foreign physicians who would not be entitled to protection under the FDA's regulations. To the extent Plaintiffs seek disclosure of the physicians' identities, the Court grants Plaintiffs' motion in part and denies it in part.

A. Background on the FDA Adverse Event Reporting System

The FDA considers its task of "monitor[ing] the safety of human drugs, biologics, and devices in the marketplace" to be "[a] critical public health activity." Protecting the Identities of Reporters of Adverse Events & Patients; Preemption of Disclosure Rules, 59 Fed. Reg. 3944, 3944 (proposed Jan. 27, 1994). In order to accomplish this task, the "FDA relies heavily on its adverse event reporting systems" for postmarketing surveillance of FDA-approved drugs and medical devices. *Id.* The agency "uses adverse event reports from health professionals and industry to identify possible problems in marketed products. Based on the reports, the [FDA] evaluates the seriousness of the health hazard, takes corrective action if necessary, and communicates that action to the health professional community." Protecting the Identity of Reporters of Adverse Events & Patients; Preemption of Disclosure Rules, 60 Fed. Reg. 16962, 16962 (Apr. 3, 1995).

Complaints about an adverse event are submitted to the FDA in a number of different forms. First, a medical device manufacturer, such as Defendant, is required to report to the FDA when it receives information reasonably suggesting that one of its products caused or contributed to a serious injury or has malfunctioned to the extent that the device would be likely to cause or contribute to a death or serious injury. 21 U.S.C. § 360i(a); *see also, e.g.,* 21 C.F.R. § 803.52. These reports are typically called "medical device reports." *See Contratto v. Ethicon, Inc.*, 225 F.R.D. 593, 594 (N.D. Cal. 2004). A "device user facility," such as a hospital or nursing home, is also required to report adverse events to the FDA or the manufacturer under similar circumstances or when it receives information that a device "may have caused or contributed to the serious illness of, or serious injury to, a patient of the facility[.]" 21 U.S.C. § 360i(b); *see also, e.g.,* 21 C.F.R. § 803.30. These reports are known as "user facility reports." *See Contratto*, 225 F.R.D. at 594-95. Finally, FDA regulations require device manufacturers to maintain "complaint files." *See* 21 C.F.R. § 820.198. A "complaint" is defined as "any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution." 21 C.F.R. § 820.3(b). Once a manufacturer receives a "complaint," it must be reviewed, evaluated, and documented. *See, e.g.,* 21 C.F.R. § 820.198(b). In some cases,

complaints are formally investigated, *see, e.g.,* 21 C.F.R. § 820.198(c), or trigger the manufacturer's mandatory reporting obligation under 21 C.F.R. § 803.30.

The FDA also relies heavily on *voluntary* reports by patients, consumers, physicians, and other healthcare professionals describing their adverse experiences with medical devices. *See* 59 Fed. Reg. at 3944; *Contratto*, 225 F.R.D. at 595. The FDA strongly believes "that preserving the confidentiality of the identities of the patient and of third parties involved with an adverse event report, such as the physician or others identified in the report, is essential to the success of the adverse event reporting system." 59 Fed. Reg. at 3944. Accordingly, various laws and regulations seek to protect the identities of the reporters and patients involved in these voluntary adverse event reports. *See, e.g.,* 21 U.S.C. § 360i(b)(3) (making voluntary "device user reports" by physicians inadmissible in most civil actions involving private parties). The FDA regulations that "protect[] the confidentiality of the patient, reporter, and institution involved in the adverse event," 59 Fed. Reg. at 3944, are at issue in this case.

B. Redaction of Voluntary Reporter Names

Regulations currently in place protect the release of confidential information—including the names of voluntary reporters of adverse events—by both the FDA and device manufacturers. *See, e.g.,* 21 C.F.R. § 20.63(f); 21 C.F.R. § 20.111; 21 C.F.R. §

803.9(b)(3). Defendant contends that it must redact the names of the reporting physicians in this case pursuant to one of these regulations which provides, in part,

> The names and any information that would identify the voluntary reporter or any other person associated with an adverse event involving a . . . medical device product shall not be disclosed by the Food and Drug Administration or by a manufacturer in possession of such reports in response to a request, demand, or order.

21 C.F.R. § 20.63(f).[2] The regulation specifically preempts any state or local "law, rule, regulation, or other requirement that permits or requires disclosure of the identities of the voluntary reporter or other person identified in an adverse event report except as provided

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[2]In their privilege log, Defendant also contends that 21 C.F.R. § 20.111 and 21 U.S.C. § 360i prohibit it from releasing voluntary reporters' names. 21 C.F.R. § 20.111(a) applies to "data and information submitted voluntarily to the Food and Drug Administration" that would not otherwise be required to be submitted to the FDA. In contrast with section 20.63(f), section 20.111 does not place a duty of confidentiality directly on the device manufacturer. *See* 59 Fed. Reg. at 3944 (noting that regulations including 21 C.F.R. § 20.111(a) "do[] not protect the release of [patient, reporter, and institution information] contained in reports held by drug, biologic, and device manufacturers").

Likewise, 21 U.S.C. § 360i does not speak directly to the manufacturer's duty of confidentiality. Instead, it provides that voluntary device reports made by physicians are not admissible into evidence and may not be "otherwise used in any civil action involving private parties unless the facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report." 21 U.S.C. § 360i(b)(3)(C). At least one circuit court has found that this provision precludes the *discovery* of voluntary user facility and physician reports in a products liability action. *See In re Medtronic, Inc.*, 184 F.3d 807, 811 (8th Cir. 1999); *see also Adcox v. Medtronic, Inc.*, 131 F. Supp. 2d 1070, 1076 (E.D. Ark. 1999) (holding, based on *In re Medtronic*, that "[n]on-mandatory reports or complaints submitted by physicians or device user facilities who were not obligated to make the reports . . . are *not* discoverable"). Defendant does not appear to take this position, since it has produced the substance of the underlying reports after masking the identities of the reporting physicians. *See, e.g., Contratto*, 225 F.R.D. at 597 (finding that § 360i(b)(3) was not intended to prohibit discovery of voluntary physician reports).

in this section." 21 C.F.R. § 20.63(f)(2); *see also* 59 Fed. Reg. at 3944.

Plaintiffs assert that 21 C.F.R. § 20.63(f) applies only to "adverse event reports" that have been disclosed by the manufacturer to the FDA. Furthermore, Plaintiffs argue that 21 C.F.R. § 20.60 limits section 20.63 by providing that "[t]he exemption[] . . . shall apply to all *Food and Drug Administration records*[.]" 21 C.F.R. § 20.60(a) (emphasis added). Plaintiffs argue that Defendant has failed to demonstrate that the allegedly privileged documents constituted "adverse event reports" and that such reports were ever transmitted to the FDA and thus became "Food and Drug Administration records." Accordingly, Plaintiffs argue section 20.63(f) does not apply by its own terms, and the documents must be produced in their unredacted form. Plaintiffs also argue that FDA regulations cannot apply to those documents that originated in France and describe ObTape-related injuries or complications reported by foreign doctors.

Defendant takes the position that "adverse event report" is not a term of art limiting the scope of 21 C.F.R. § 20.63(f). Defendant also contends that the policy underlying the regulation is so vitally important to the FDA's voluntary reporting system that the regulation's prohibition on disclosure extends to formal and informal voluntary reports of device complaints, regardless of whether such reports were ultimately transmitted to the FDA. The Court agrees

with Defendant that redaction of some, but not all, of its records is appropriate in this case.

First, the Court concludes that the documents identified by Defendant that contain only the names of foreign physicians shall be produced to Plaintiffs in their entirety. Defendant has cited no authority for the proposition that any reports by these physicians are subject to FDA regulations. *See Contratto*, 225 F.R.D. at 594 (defendant drug companies "conceded that they ha[d] no grounds to protect complaints by patients or foreign users, and withdrew such documents from the scope of their protective order"). The party invoking a privilege bears the burden of proving its existence. *See, e.g., In re Grand Jury Investigation*, 842 F.2d 1223, 1225 (11th Cir. 1987). Defendant has failed to meet this burden with respect to the foreign documents which contain the names of foreign physicians "who reported complications observed with their European patients to Mentor's former foreign affiliate, Porges." (Def.'s Resp. to Pls.' Mot. to Compel 11 & nn. 4-5 [hereinafter Def.'s Resp.].) Accordingly, documents 00113-14, 000121-24, 00321-23, 00332-33, 00342-45, 00379-80, 00381-84, 00571-74, 03486-87,[3] 03488, 03490,

[3]The Court was not provided a copy of document number 03487, but document 03486 appears to be the first page of a two-page email that was also produced as document 00113-14, and the Court assumes that 03487 is the second page of that email.

03492-93, 03495, 03517-22, and 03531 are not privileged and shall be produced to Plaintiffs in their unredacted form.[4]

With respect to the redaction of the names of American physicians who are voluntary reporters, however, the Court agrees with Defendant that the physicians' names should be redacted. The FDA has expressly stated that "adverse event report" is not a term of art that limits the scope of 21 C.F.R. § 20.63(f).[5] (*See* Ex. 1 to Def.'s Resp., Br. for the United States as Amicus Curiae 30, Apr. 1999 [hereinafter Amicus Br.].) The FDA has also taken the position that section 20.63(f) applies to documents that may or may not be transmitted to the FDA. (*See id.*) An agency is entitled to considerable deference "when it adopts a reasonable interpretation of

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[4]Defendant alleges only a single possible basis under foreign law for redacting the names of these foreign physicians in the documents at issue in this case. Defendant contends that

> pursuant to Articles 6 and 13 of the French Law No. 78-753 of July 17, 1978, as amended in 2009 . . ., the French agency responsible for the safety of medical devices[] may order that medical secret information, trade secrets or any information relating to privacy be redacted before a document is produced to a third-party.

(Def.'s Resp. 11.) Defendant fails to argue how or why the Court should apply this provision to this case.

[5]"Adverse event report" does not appear to be defined in the relevant regulations, and the Court notes that the fact that the FDA's "interpretation comes to [the Court] in the form of a legal brief . . . does not, in the circumstances of this case, make it unworthy of deference." *Auer v. Robbins*, 519 U.S. 452, 462 (1997). Plaintiffs have pointed the Court to no "reason to suspect that the interpretation does not reflect the agency's fair and considered judgment on the matter in question." *Id.* Likewise, Plaintiffs have failed to direct the Court to any authority suggesting that the FDA has changed its position since the filing of its Amicus Brief in 1999.

regulations it has put in force." *See, e.g., Fed. Express Corp. v. Holowecki*, 128 S. Ct. 1147, 1155 (2008). The Court must "accept the agency's position unless it is 'plainly erroneous or inconsistent with the regulation.'" *Id.* (quoting *Auer*, 519 U.S. at 461).

The Court finds that the FDA's interpretation of 21 C.F.R. § 20.63(f) is reasonable and entitled to deference. 21 C.F.R. § 20.63(f) was intended to place an affirmative duty of confidentiality on manufacturers in precisely the circumstances presented by this case. *See, e.g.,* 59 Fed. Reg. at 3944 (finding that the promulgation of 21 C.F.R. § 20.63(f) was necessary because "[r]ecently, plaintiffs in several product liability and medical malpractice cases have attempted to discover the identities of reporters and patients named in adverse event reports in the possession of the product manufacturers"); *id*. at 3947 (observing that "[t]he increase in product liability and medical malpractice litigation has heightened the reluctance of health professionals to report events observed by them if they are not given meaningful promises of confidentiality"). The FDA reasons that because a person who voluntarily lodges a complaint with the manufacturer may not know how or whether his complaint will be forwarded to the FDA, "FDA's interest in protecting voluntary reporter and patient confidentiality, and in protecting voluntary reporting from the pressures of litigation," applies with equal force to all "complaints," regardless of whether the complaint triggers the manufacturer's mandatory reporting obligations. (Amicus

Br. at 31.) The Court cannot say that the agency's reasoning is clearly erroneous.

Plaintiffs also argue, however, that the FDA's interpretation of 21 C.F.R. § 20.63 is inherently inconsistent with 21 C.F.R. § 20.60. Plaintiffs submit that 21 C.F.R. § 20.60(a) limits the application of section 20.63 to only those records submitted to the FDA, since section 20.60(a) provides that the requirement of nondisclosure applies "to all Food and Drug Administration records." This position is untenable. Section 20.60(a) does not state that it applies *only* to FDA records. Indeed, 21 C.F.R. § 20.63(b), which is also subject to the purported limitation found in 21 C.F.R. § 20.60(a), requires the deletion of information identifying patients and research subjects *before* any records containing such information are submitted to the FDA. The Court finds that FDA's interpretation of 21 C.F.R. § 20.63(f) is consistent with 21 C.F.R. § 20.60(a).

Furthermore, courts addressing analogous issues have found that the need for confidentiality counsels in favor of the redaction of physicians' names from FDA records within the manufacturer's possession. *Cf., e.g., York v. Am. Med. Sys., Inc.*, No. 97-4306, 1998 WL 863790, at *2, *4 (6th Cir. Nov. 23, 1998) (unpublished opinion) (affirming magistrate's protective order permitting the defendant-manufacturer to redact names of all patients, physicians, and hospitals from medical device reports submitted to the FDA after finding that 21 C.F.R. § 20.63(f) "grant[s] a blanket prohibition

against disclosure of confidential information by manufacturers"); *Contratto*, 225 F.R.D. at 597 (finding that 21 U.S.C. § 360i(b)(3) would not bar discovery of voluntary reports of adverse events, complaint files, and related documents containing information derived from such reports, but noting that "*masking the identity of the reporter before producing them* should be adequate" to encourage the continued filing of reports (emphasis added)); *In re Rezulin Prods. Liab. Litig.*, No. CIV.00 CIV.2843 LAK, 2002 WL 24475, at *1 (S.D.N.Y. Jan. 10, 2002) (permitting non-parties to the litigation to redact any information that 21 C.F.R. § 20.63(f) would prohibit the FDA from disclosing, even though 21 C.F.R. § 20.63(f) imposes a duty of confidentiality on manufacturers, not private parties); *Harris v. Upjohn Co.*, 115 F.R.D. 191, 192-93 (S.D. Ill. 1987) (permitting manufacturer to redact the names of patients and physicians mentioned in its adverse reaction and drug experience report files because "release of the names of physicians who communicated to [the manufacturer] would be against public policy").

Plaintiffs' argument that "allow[ing] manufacturers to keep secret the identity of doctors who make product-related complaints would not serve any legitimate public purpose or policy, and instead would only provide an incentive and means for the manufacturer to withhold this information from the public and from the FDA" is misplaced. (Pls.' Mot. to Compel 6.) It is clear that the public has an interest in ensuring the ability of the FDA to effectively

monitor the safety of medical devices; protecting the confidentiality of voluntary reporters enhances the FDA's ability to achieve this goal. *See, e.g.,* 60 Fed. Reg. at 16962 (noting that "voluntary reporting has revealed significant adverse effects . . . associated with products that could not be identified during preapproval testing"); *see also* 59 Fed. Reg. at 3947 (noting the existence of empirical studies suggesting that fear of disclosure, the possibility of ensuing litigation, and the potential for breaches of physician-patient privilege play a significant role in physicians' decisions to decline to voluntarily report an adverse event). Plaintiffs in this case have "ready access to the substance of the reports and remain[] free to use other means apart from FDA's adverse event reporting system . . ., such as advertising, to attempt to identify patients or medical personnel who have relevant information and . . . wish to come forward[.]" (Amicus Br. at 28.)

Finally, Plaintiffs argue that Defendant has not met its burden of demonstrating that each of the redacted names is associated with a voluntary adverse event report. Although the Court agrees with Plaintiffs, this failure is irrelevant in this case. If a *physician* is identified as the initial reporter then the report must be voluntary. Physicians are never obliged to make mandatory adverse event reports to the FDA; they are simply encouraged to make voluntary reports. *See generally* 21 C.F.R. part 803 (covering medical device reporting requirements for device user facilities,

importers, and manufacturers). Thus, when a physician is also identified as the voluntary reporter, redaction of "[t]he names and any information that would identify the voluntary reporter or any other person associated with an adverse event involving" ObTape is appropriate. 21 C.F.R. § 20.63(f).

With respect to the remaining redactions, Defendant has failed to demonstrate that the information was derived from voluntary adverse event reports as opposed to mandatory reports required, for example, under 21 C.F.R. part 803. Absent any evidence that this information was derived from a voluntary report, it would therefore be inappropriate for the Court to require the redaction of the name of any initial *reporters* who were not physicians. *See* 21 C.F.R. § 20.63(f) ("This provision does not affect disclosure of the identities of reporters required by a Federal statute or regulation to make adverse event reports."). The Court finds, however, that it is still appropriate to redact the physicians' names from the remaining documents, since 21 C.F.R. § 20.63(f) requires redaction of the "names and any information that would identify . . . any other person associated with an adverse event," seemingly without regard to whether the report was mandatory or voluntary. *See York*, 1998 WL 863790, at *4 (permitting manufacturer to redact physicians' names from mandatory medical device reports). Because Defendant has redacted only physicians' names from its records, its failure to distinguish between mandatory and voluntary reports is immaterial.

In sum, the Court defers to the FDA that "the public health interest in securing information from health professionals about potential hazards associated with marketed products far outweighs the interest an individual plaintiff may assert to obtain reporters' identities in private tort actions." 59 Fed. Reg. at 3948. Accordingly, Defendant shall not disclose "[t]he names and any information that would identify the voluntary reporter or any other person associated with an adverse event involving a . . . medical device product." 21 C.F.R. § 20.63(f).[6] Defendant may accordingly redact the names of the U.S. physicians in any entries in the following spreadsheets which document adverse event reports: Bates Nos. 00088-100; 00350-351; 00388-401; 03473; 03476-77; 03481-82; 03486-87; and 03498-502.

C. Other Exceptions to 21 C.F.R. § 20.63

Plaintiffs also contend they are entitled to receive an unredacted copy of any report involving one of the Plaintiffs in this case. The Court agrees in part. 21 C.F.R. § 20.63(f)(1)(iii) permits disclosure of any "report, excluding the identities of any

[6]In light of the FDA's reasonable position that 21 C.F.R. § 20.63(f) is not limited to formal reports that have been previously submitted to the FDA, the Court also finds it immaterial that the identifying information is contained in the spreadsheets found in Defendant's files. The goal underlying 21 C.F.R. § 20.63(f) would be significantly undermined if Defendant were required to disclose the otherwise protected name of a voluntary reporter or other person simply because the name was mentioned in documents prepared for Defendant's convenience. *See, e.g., York*, 1998 WL 863790, at *5 ("The entire reporting scheme of the FDA is based on confidential reporting by manufacturers, physicians, and patients. To encourage voluntary reporting, it is necessary to ensure reporters that their information will be kept in confidence and not cavalierly disclosed in various litigation.").

other individuals . . . to the person who is the subject of the report upon request." The Court notes, however, that Defendant may be required to redact some information even from these reports. *See* 21 C.F.R. § 20.63(f)(1)(iii); *see also* 60 Fed. Reg. at 16965 (clarifying that reports provided under 21 C.F.R. § 20.63(f)(1)(iii) "will be disclosed to the subject of the report without inclusion of any other names, including that of the voluntary reporter").

**II. Documents Protected by Attorney-Client Privilege**

Plaintiffs next contend that they are entitled to discover various documents over which Defendant asserts the attorney-client privilege. "Both for corporations and individuals, the attorney-client privilege serves the function of promoting full and frank communications between attorneys and their clients." *Commodity Futures Trading Comm'n v. Weintraub*, 471 U.S. 343, 348 (1985). A party attempting to invoke the attorney-client privilege must establish the following elements:

> (1) the asserted holder of the privilege is or sought to become a client; (2) the person to whom the communication is made (a) is (the) member of a bar of a court, or his subordinate and (b) in connection with this communication is acting as a lawyer; (3) the communication relates to a fact of which the attorney was informed (a) by his client (b) without the presence of strangers (c) for the purpose of securing primarily either (i) an opinion on law or (ii) legal services or (iii) assistance in some legal proceeding, and not (d) for the purpose of committing a crime or tort; and (4) the privilege has been (a) claimed and (b) not waived by the client.

*United States v. Kelly*, 569 F.2d 928, 938 (5th Cir. 1978).[7] "The burden is on the party claiming the privilege to establish those facts that constitute the essential elements of the privileged relationship." *Abdallah v. Coca-Cola Co.*, No. CIV A1:98CV3679RWS, 2000 WL 33249254, at *3 (N.D. Ga. Jan. 25, 2000). This burden must be met "by an evidentiary showing based on competent evidence," and it is not "discharged by mere conclusory or *ipse dixit* assertions." *Id.* (internal quotation marks omitted). Defendant contends that four sets of documents are subject to the attorney-client privilege, and the Court will address each in turn.

A. Cook-Scherff Emails[8]

The first document Defendant asserts is privileged is an email from Delia Cook, the Women's Health Market Manager for Mentor, to Clarke Scherff, Mentor's Vice President for Regulatory Compliance/Quality Assurance. (Pls.' Mot. to Compel 12.) The email is copied to Chris Fawzy, Mentor's in-house counsel; Kathleen Beauchamp, Vice-President for Global Sales; Lisa Reich, Marketing Manager for Surgical Urology; Amy Kennedy, Marketing Coordinator for Surgical Urology; Dave Amerson, Vice President for Global Sales - Surgical Urology and Healthcare; Catherine Ortuno, Clinical Research

[7]In *Bonner v. City of Prichard*. 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc), the Eleventh Circuit adopted as binding precedent all decisions of the former Fifth Circuit handed down prior to the close of business on September 30, 1981.

[8]The same email was produced several times. (*See* Bates Nos. 00087, 00219, 00402, 00588, & 03536.)

Specialist for Mentor-Porges; and Randi Plachetka, Program Specialist in the Product Evaluation Department. (*See id.* at n.6.) The email was also forwarded to one other Mentor-Porges employee, Nathalie Gremaud.[9] Defendant describes the content of the email as addressing its "stance . . . in regards to [Defendant's] ***legal*** policy" on certain topics. (Def.'s Resp. 13.)

After reviewing this document *in camera*, the Court concludes that this communication was from an employee of Defendant to counsel for Defendant acting as such, in order to secure legal advice from counsel. This is the type of communication typically covered by the attorney-client privilege. *See Upjohn Co. v. United States*, 449 U.S. 383, 394-95 (1981) (finding that communications made by corporate employees to counsel in order to secure legal advice are protected against compelled disclosure).

Defendant, however, still bears the burden of establishing that the privileged documents have remained confidential, since "at the point where attorney-client communications are no longer confidential, i.e., where there has been a disclosure of a privileged communication, there is no justification for retaining the

[9]Though the briefing does not identify Ms. Gremaud's title or relationship to Defendant, the Court's *in camera* review of Defendant's documents reveals that Ms. Gremaud was, at the time of the email, a Mentor-Porges employee who worked with others, including Dr. Ortuno, on projects related to Defendant's stress urinary incontinence products. Also, Plaintiffs previously represented that Ms. Gremaud was a Mentor-Porges marketing and sales employee whose work related to Mentor's stress urinary incontinence products.

privilege." *See, e.g., United States v. Suarez*, 820 F.2d 1158, 1160 (11th Cir. 1987). To establish the confidentiality of an allegedly privileged document, the party asserting the privilege must show that the document was "(1) intended to remain confidential *and* (2) under the circumstances was *reasonably* expected and understood to be confidential." *Bogle v. McClure*, 332 F.3d 1347, 1358 (11th Cir. 2003) (internal quotation marks omitted). Applying this principle in the context of a corporation, the "applicable standard is . . . whether the documents were distributed on a need to know basis or to employees that were authorized to speak or act for the company." *FTC v. GlaxoSmithKline*, 294 F.3d 141, 147 (D.C. Cir. 2002) (internal quotation marks omitted); *Santrade, Ltd. v. Gen. Elec. Co.*, 150 F.R.D. 539, 545 (E.D.N.C. 1993) (noting that confidentiality is not destroyed in the corporate context so long as privileged documents are transmitted between non-attorneys "to relay information requested by attorneys" or "so that the corporation may be properly informed of legal advice and act appropriately"); *see also Upjohn*, 449 U.S. at 390-91.

Plaintiffs contend that even if the email did contain legal advice, "Defendant has made no showing that each of the individuals to whom this email was sent, or to whom it was eventually forwarded, had authority to act on Defendant's behalf with respect to the subject matter of this email." (Pls.' Reply to Def.'s Resp. 11.) Defendant has made no assertion that the email was intended to remain

confidential and was reasonably expected and understood to be confidential: the email is not designated "private," "confidential," or "privileged." Absent any assertion whatsoever that the email was intended and understood to remain confidential, the Court cannot say that Defendant has met its burden to demonstrate the Cook-Scherff emails are subject to the attorney-client privilege. Accordingly, Bates Nos. 00087, 00219, 00402, 00588, and 03536 are discoverable and shall be produced to Plaintiffs in their unredacted form.

B. Mounts Email Chain

The second document Defendant asserts is privileged is described by Defendant as "a series of emails between and among Porges employees and Porges' outside counsel." (Def.'s Resp. 14.) The email series involves Adri Hoogwerf, President of Mentor-Porges in France; outside counsel Phoebe Mounts; Dr. Ortuno; Franck Lespinasse, Director of Quality Assurance and Device Vigilance for Mentor-Porges; and Vincent Monsaingeon, Director of Marketing and Medicine for Mentor-Porges. (Pls.' Mot. to Compel 13.) Defendant contends that the series begins with a Porges employee asking Mounts "what she considers to be the appropriate position for Mentor to take regarding certain governmental requests for information," and "[t]he second email contains Ms. Mounts' legal advice provided in response." (Def.'s Resp. 14.)

After reviewing this document *in camera*, the Court concludes that the email chain constitutes an attempt by Defendant's employee

to secure legal advice from counsel. This document is therefore protected by the attorney-client privilege unless otherwise waived. *See Upjohn*, 449 U.S. at 394-95. Unlike the Cook-Scherff email chain, this particular email chain contains disclaimers identifying its contents as privileged and confidential. Typically,

> when a corporation provides a confidential document to certain specified employees . . . with the admonition not to disseminate further its contents and the contents of the documents are related generally to the employees' corporate duties, absent evidence to the contrary [the Court] may reasonably infer that the information was deemed necessary for the employees' . . . work.

*FTC*, 294 F.3d at 148. There is no indication that this email chain was ever distributed further than among each identified recipient in the chain, and the contents of the email appear reasonably related to the recipients' job titles. The Court therefore concludes that the Mounts email chain (Bates No. 00168-69) is privileged and not discoverable.

C. Memorandum

Defendant next asserts attorney-client privilege over a paragraph from a memorandum which "discusses an employee's meeting with Attorney Mounts on regulatory issues and reflects Ms. Mounts' advice." (Def.'s Resp. 15.) Plaintiffs argue that because Defendant "offers no explanation of who purportedly authored this memorandum, or to whom it was ultimately disseminated," it could not have met its burden of demonstrating that the document was confidential and

disseminated only among those employees who required access to it. (Pls.' Reply to Def.'s Resp. 12.)

While the Court's *in camera* review of the memorandum reveals that it does appear to contain legal advice provided by Mounts, the Court cannot determine from the documents themselves, Defendant's privilege log, or subsequent briefing that the memorandum itself was intended to be confidential. Although the email to which the memorandum is attached is marked "private," the memorandum itself contains no similar designation. Defendant has made no effort to explain who authored the memorandum and to whom the memorandum was distributed. It is Defendant's burden to provide this information. *See, e.g., Bogle*, 332 F.3d at 1358 (finding that the fact "[a]ppellants did not present evidence regarding who, if anyone, received the memoranda other than [two identified recipients], what [the identified recipients] did with the memoranda once received, or whether [the attorney-author or the recipients] understood the memoranda to be confidential" suggested that the memoranda would not be privileged). Again, the Court simply cannot say that Defendant has met its burden of showing that the memorandum is privileged. The memorandum (Bates No. 00171) is therefore discoverable and shall be produced to Plaintiffs in its unredacted form.

D. Draft Letters of Intent

Finally, Defendant asserts attorney-client privilege over "draft letters of intent between Mentor and Abiss, the manufacturer of

ObTape." (Def.'s Resp. 15.) Defendant contends that the letters are "legally operative document[s]" which "necessarily reflect[] the judgments of Mentor's counsel about various provisions" in the letters. (*Id.*) Defendant further notes that these particular drafts "postdate the final version of the letter of intent with Abiss that Mentor has already produced to plaintiffs, and there is no indication that these drafts were ever shared with Abiss or any other third-party." (*Id.*)

"[P]reliminary drafts of contracts are generally protected by attorney-client privilege, since [p]reliminary drafts may reflect not only client confidences, but also the legal advice and opinions of attorneys, all of which is protected by the attorney-client privilege." *Muller v. Walt Disney Prods.*, 871 F. Supp. 678, 682 (S.D.N.Y. 1994) (second alteration in original) (internal quotation marks omitted); *see also Schenet v. Anderson*, 678 F. Supp. 1280, 1283 (E.D. Mich. 1988) (finding that the attorney client privilege extends "to all information conveyed by clients to their attorneys for the purpose of drafting documents to be disclosed to third persons and all documents reflecting such information, to the extent that such information is not contained in the document published and is not otherwise disclosed to third persons"). Defendant has asserted that the documents in question were prepared by an attorney and reflect legal advice, that the information contained in these draft contracts was not disseminated to any third party, and that the draft letters

postdated the final letter of intent already produced to Plaintiffs, further suggesting that the contents of the drafts were never published. *Cf. Santrade,* 150 F.R.D. at 544 (noting that preliminary drafts of documents, including attorney's notes necessary to the preparation of the document, are not privileged when the documents are ultimately published). The Court concludes that discovery of the draft letters of intent (Bates No. 04225-30 & 04231-36) are therefore privileged and not discoverable.

CONCLUSION

In sum, the Court makes the following rulings:

1. Defendant shall identify which documents, if any, in its possession constitute a report of an adverse event suffered by a Plaintiff in this case. Any such reports shall be produced to Plaintiffs in accordance with 21 C.F.R. § 20.63(f)(1)(iii).
2. Defendant shall produce, in their entirety, the foreign documents containing the names of foreign physicians who reported complications with their European patients: Bates Nos. 00113-14; 000121-24; 00321-23; 00332-33; 00342-45; 00379-80; 00381-84; 00571-74; 03486-87; 03488; 03490; 03492-93; 03495; 03517-22; and 03531. Defendant has failed to demonstrate any basis for redacting these physicians' names.
3. Defendant may redact the names of the U.S. physicians in any entries in the following spreadsheets which document adverse

event reports: Bates Nos. 00088-100; 00350-351; 00388-401; 03473; 03476-77; 03481-82; 03486-87; and 03498-502.

4. The Mounts email chain, Bates Nos. 00168-69, and the draft letters of intent, Bates Nos. 04225-30 and 04231-36, are subject to the attorney-client privilege and are therefore not discoverable and shall not be produced to Plaintiffs.

5. Defendant has failed to meet its burden of demonstrating that the Cook-Scherff emails, Bates Nos. 00087, 00219, 00402, 00588, and 03536, and the memorandum, Bates No. 00171, are privileged. These documents are therefore discoverable and shall be produced to Plaintiffs.

Plaintiffs' Motion to Compel (Doc. 48) is therefore granted in part and denied in part.[10]

[10]Today, the Court received Defendant's supplemental privilege log relating to the translated documents obtained from Ms. Gremaud and Dr. Ortuno. Defendant asserts that this privilege log supplements its earlier privilege log and that the issues raised in the log have been fully briefed by the parties. Today's Order is intended to cover only those documents identified in Defendant's initial privilege log. The Court notes, however, that today's decision will likely have an effect on some of the documents Defendant identified as privileged in its supplemental privilege log, and Defendant should make a good faith effort to produce documents consistent with the Court's rulings in today's Order. If Defendant remains uncertain as to its obligations regarding the disclosure of documents in the privilege log filed today, Defendant shall file an amended motion for protective order within fourteen days of today's Order that is restricted to the documents it maintains are not discoverable in light of today's Order.

IT IS SO ORDERED, this 9th day of July, 2009.

S/Clay D. Land
CLAY D. LAND
UNITED STATES DISTRICT JUDGE