

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

PROVIDENCE, SC.

Filed May 15, 2009

SUPERIOR COURT

BARBARA BROKAW, RAYMOND :  
MUTZ, TAMMY OAKLEY, and :  
DELZA YOUNG :  
v. :  
DAVOL INC. and C.R. BARD, INC. :

C.A. No. 07-5058  
C.A. No. 07-4048  
C.A. No. 07-1706  
C.A. No. 07-3666

DECISION

GIBNEY, J. Before this Court is the motion of Plaintiffs—Barbara Brokaw, Raymond Mutz, Tammy Oakley, and Delza Young (Plaintiffs)—to compel Defendants C.R. Bard, Inc. and Davol Inc. (“Defendants”) to produce a consultant’s report and related documents (“Quintiles documents”) over which Defendants assert the work product privilege. After a hearing, this Court ordered that the documents in dispute be provided to the Court for an in camera review.

**I  
Factual Background**

The disputed documents consist of an audit report and supporting documentation prepared by Quintiles Consulting (“Quintiles”), an independent consulting firm retained by Bard following Bard’s decision to voluntarily recall certain models of the Composix Kugel Hernia Patch in December 2005 and March 2006. The voluntary recalls were prompted by reports of patient injuries allegedly caused by the malfunction of a ring component inside some of the hernia patches. The first recall was followed by an inspection by the Food and Drug Administration (“FDA”) of Davol’s facilities in

Cranston, Rhode Island in January and February 2006.<sup>1</sup> Following the inspection, the FDA issued a Form 483 letter<sup>2</sup> and an Establishment Inspection Report (“EIR”),<sup>3</sup> which together made certain critical observations relative to Davol’s compliance with applicable federal regulations.

Bard hired Quintiles shortly after the FDA inspection, and Quintiles consultants first appeared at the Davol site in May 2006. Quintiles subsequently issued several audit reports, one major report in June 2006 and two other reports in September and October 2006. The reports were addressed to Bard’s then-Vice President and General Counsel Judith Reinsdorf, and bear the label “subject to attorney work product doctrine.”

In August 2006, the first products liability claims related to the hernia patches in question were filed against the Defendants. Currently, there are over 1000 such cases pending before this Court against these Defendants. On October 23, 2008, the Court heard oral arguments on Plaintiffs’ motion to compel production of the Quintiles documents. After considering the parties’ arguments, the Court ordered that the Quintiles documents be produced for an in camera review. The Court has completed its review and will now render a decision.

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<sup>1</sup> Davol Inc. is a subsidiary of C.R. Bard, Inc.

<sup>2</sup> According to the FDA’s Investigations Operations Manual, the Form 483 Inspectional Observations “is intended for use in notifying the inspected establishment’s top management in writing of significant objectionable conditions, relating to products and/or processes, or other violations of the FD&C Act and related Acts which were observed during the inspection.” Chapter 5.2.3.

<sup>3</sup> FDA investigators frequently file Establishment Inspection Reports (EIRs) after inspections. The reports contain details of the investigator's findings, a list of the negative findings that are also separately described in the Form 483, and general observations regarding the defendant company. Investigations Operations Manual, ch. 5.10.1.

## **II Standard of Review**

“In granting or denying discovery orders, a justice of the Superior Court has broad discretion.” Corvese v. Medco Containment Services, Inc. 687 A.2d 880, 881-882 (R.I. 1997). Moreover, our Supreme Court will not disturb a decision by a Superior Court justice relating to discovery save for an abuse of discretion. Id.; see also Kelvey v. Coughlin, 625 A.2d 775, 776 (R.I.1993)). “The term ‘discretion’ imports action taken in the light of reason as applied to all the facts and with a view to the rights of all the parties to the action while having regard for what is right and equitable under the circumstances and the law.” Hartman v. Carter, 121 R.I. 1, 4-5, 393 A.2d 1102, 1105 (1978).

## **III Analysis**

### **1 The Work Product Doctrine**

The work-product doctrine protects documents and tangible things that are “prepared in anticipation of litigation or for trial by or for another party or by or for that other party’s representative.” Sup. R. Civ. P. 26(b)(3). The first category of work-product, called “opinion” or “core” work-product, consists of an attorney’s mental impressions, conclusions, opinions, or legal theories, and is absolutely immune from discovery. Id.; Crowe Countryside Realty Associates, Co., LLC v. Novare Engineers, Inc., 891 A.2d 838, 842 (R.I. 2006). The second category, called “factual” or “ordinary” work-product, is a qualified privilege that may be overcome “upon a showing that the party seeking discovery has substantial need of the materials in the preparation of the party’s case and that the party is unable without undue hardship to obtain the substantial

equivalent of the materials by other means.” Sup. R. Civ. P. 26(b)(3); Crowe, 891 A.2d 842.

In determining whether a document was prepared in anticipation of litigation, Rhode Island uses the “because of” test. Cabral v. Arruda, 556 A.2d 47, 49 (R.I. 1989). “[T]he test is whether in light of the nature of the document or intangible material and the facts of the case the document can be said to have been prepared or obtained *because of* the prospect of litigation, by or for an adverse party or its agent.” Id. (emphasis added). The underlying rationale for work product protection is to “prevent an attorney from ‘freeloading’ on his or her adversary’s work.” Carbal, 556 A.2d at 48.

The “because of” test is also used by many federal circuit courts. See, e.g., United States v. Roxworthy, 457 F.3d 590, 593 (6<sup>th</sup> Cir. 2006); In re Grand Jury Subpoena, 357 F.3d 900, 907 (9<sup>th</sup> Cir. 2004); Maine v. U.S. Dep’t of Interior, 298 F.3d 60, 68 (1<sup>st</sup> Cir. 2002); United States v. Adlman, 134 F.3d 1194, 1198 (2d Cir. 1998); Nat’l Union Fire Ins. Co. v. Murray Sheet Metal Co., Inc., 967 F.2d 980, 984 (4<sup>th</sup> Cir. 1992); Simon v. G.D. Searle & Co., 816 F.2d 397, 401 (8<sup>th</sup> Cir. 1987); Senate of Puerto Rico v. United States Dep’t of Justice, 823 F.2d 574, 586 n.42 (D.C. Cir. 1987); Binks Mfg. Co. v. National Presto Indus., Inc., 709 F.2d 1109, 1118 (7<sup>th</sup> Cir. 1983); In re Grand Jury Proceedings, 604 F.2d 798, 803 (3d Cir.1979)).

Since the language of Sup. R. Civ. P. 26(b)(3) is substantially the same as the comparable federal rule, this Court may look to federal court interpretations for guidance in this matter. See Hall v. Insurance Co. of North America, 727 A.2d 667, 669 (R.I. 1999) (“[F]ederal-court interpretations of a procedural rule that is substantially similar to

one of our own state rules of civil procedure should serve as a guide to the construction of our own rule.”).

In protecting only documents prepared in “anticipation of litigation,” the “because of” test does not protect documents “assembled in the ordinary course of business, or pursuant to public requirements unrelated to litigation, or for other nonlitigation purposes.” Fed. R. Civ. P. 26(b)(3), Advisory Committee Note; Nat’l Union Fire, 967 F.2d at 984. “Dual purpose” documents, however, created in part because of the prospect of litigation but also due to business or regulatory purposes are protected by the privilege. Wright, Miller, & Marcus, Federal Practice and Procedure, § 2024, n. 11.1 (2008); see also Adlman, 134 F.3d at 1195; In re Grand Jury Subpoena, 357 at 907. Thus, the presence of a business or regulatory purpose does not defeat work-product protection. Rather, the court should examine whether the material in question would have been prepared at all or in its present form but for the anticipation of litigation. Adlman, 134 F.3d at 1204.

The work product doctrine also applies to documents created by agents for the attorney, provided the documents were created in anticipation of litigation. United States v. Nobles, 422 U.S. 225, 239 (1975). The party asserting a privilege has the burden of establishing entitlement to it. Gaumond v. Trinity Repertory Company, 909 A.2d 512, 517 (R.I. 2006) (quoting Moretti v. Lowe, M.D., 592 A.2d 855, 857 (R.I. 1991)).

## 2

### **Whether the Quintiles Documents Were Prepared in Anticipation of Litigation**

The first question in deciding whether the Quintiles documents were prepared in anticipation of litigation is to identify what litigation Defendants might have anticipated. The Defendants maintain that following the December 2005 and March 2006 voluntary

recalls of certain larger-sized Composix Kugel Hernia Patches, they reasonably anticipated both products liability suits and FDA enforcement actions.

As support for this contention, the Defendants have produced the affidavit of Bard's then-general counsel, Judith Reinsdorf, who avers that the Quintiles audits were undertaken at her direction "to prepare for anticipated litigation" and that she "informed Quintiles before they began work that their audits and investigations were to enable the Bard Legal Department to provide Bard with legal advice, and that information acquired in the audit should only be relayed to Bard counsel or to those whom Bard counsel may direct." (Reinsdorf Aff.) The Defendants note that the affidavit postdates the December 2005 recall of certain models of the Composix Kugel Patch due to reported ring breaks leading to patient injuries. In those circumstances, Defendants argue, it would be difficult to imagine a general counsel of a medical device company not contemplating litigation.

The Plaintiffs respond that Quintiles was not hired in anticipation of litigation, but for the ordinary business purpose of addressing ongoing FDA compliance. The Plaintiffs insist that the Quintiles documents would have been created in essentially the same form irrespective of the current litigation and, therefore, they fail to meet Rhode Island's "because of" test. In addition, Plaintiffs note that subsequent remedial measures are both discoverable and admissible in Rhode Island.

The Plaintiffs point to certain circumstantial evidence that they suggest shows that Quintiles was hired solely to comply with FDA regulations. The Plaintiffs first point out that Quintiles, by its own description on its website, provides assistance with product development, marketing, and FDA compliance, not litigation strategies. Furthermore,

based upon certain documents that have already been produced, Plaintiffs assert that Quintiles was hired by Defendants for the purpose of addressing an FDA inspection which occurred nearly a year before any lawsuits were filed. Among other documents, Plaintiffs cite an executive summary of the work performed by Quintiles, which describes its audit as “a full Quality Systems audit and a verification of the corrective action to the FDA form-483 observations issued in the January 2006 FDA audit.” (Pl’s Ex. I.)

Lastly, Plaintiffs point to numerous examples wherein Defendants have changed the privilege asserted with respect to particular Quintiles documents from self-critical analysis “undertaken to evaluate and ensure future compliance with internal regulatory policies” to “prepared at request and direction of legal counsel in anticipation of litigation.” These recent revisions of Defendants’ privilege log, Plaintiffs suggest, are further evidence that the Quintiles documents were truly prepared for the purpose of FDA compliance.

## A

### **Products Liability Litigation**

To determine whether the Quintiles documents can fairly be said to have been prepared because of the prospect of products liability litigation, the Court will consider the parties’ arguments in light of “the nature of the document[s] and the factual situation” surrounding their creation. Cabral v. Arruda, 556 A.2d at 49 (R.I. 1989).

The Plaintiffs first argue that this Court should not accord significant weight to the affidavit of Bard’s general counsel because it is “conclusory” of the fact that Quintiles was hired in anticipation of litigation. The Court agrees that “mere conclusory assertions that the material [wa]s prepared in anticipation of litigation are insufficient.” Ordner v.

K-H Corp., 1999 U.S. Dist. LEXIS 20887 at 6 (D.R.I. 1999); see also Henderson v. Newport County YMCA, -- A.2d ----, No. 2007-308-M.P. 8 (R.I. 2009) (stating that “a party cannot create work product solely by the nomenclature used to entitle documents.”).

The Court views the affidavit as evidence that Bard’s General Counsel had a subjective belief that personal injury litigation was likely when she directed Quintiles to conduct audits and investigations into matters relating to the voluntary recall. Unless her belief is also “tempered by objective reasonableness,” the affidavit, standing alone, is insufficient proof to establish entitlement to the work product privilege. See Martin v. Bally’s Park Place Hotel & Casino, 983 F.2d 1252, 1260 (3d Cir. 1993) (finding that a person’s “unilateral belief” that litigation will result is the initial focus of the inquiry into whether a report was prepared “in anticipation of litigation,” but that the rule is limited by the requirement that anticipation of litigation be objectively reasonable).

There is little question that the series of events that prompted the preparation of the Quintiles documents are ones that are likely to lead to litigation. The Court finds it significant that the December 2005 and March 2006 recalls were a direct response to reports that one of Bard’s medical devices had allegedly caused serious patient injuries. Therefore, by the time Quintiles was hired, following the FDA inspection, potential products liability claims had already accrued. While it is true that the first lawsuits were not filed until some months later, it is not necessary that the documents be prepared after litigation has been commenced. Fireman’s Fund Insurance Co. v. McAlpine, 120 R.I. 744, 748-49, 391 A.2d 84, 87 (1978) (finding that “the protective ambit of Rule 26(b)(2) was not meant to be restricted to material that had been prepared subsequent to the

initiation of litigation. On the contrary . . . the rule was meant to be applied to materials gathered when litigation is merely a contingency[.]”).

Based upon the seriousness of both the reported injuries and the observations made by the FDA after the January 2006 inspection, the Defendants were on notice that it would almost certainly be facing claims. The Court disagrees with Plaintiffs’ view that the situation gave rise to only “a remote prospect of future litigation.” Binks Mfg. Co. v. National Presto Industries, Inc., 709 F.2d 1109, 1119 (7<sup>th</sup> Cir. 1983). Accordingly, the Court is satisfied that Bard’s General Counsel’s belief that products liability litigation was likely at the time Quintiles was hired was objectively reasonable.

The Plaintiffs next argue that the Quintiles documents would have been created in essentially similar form regardless of whether litigation ensued, and therefore, they fail to meet Rhode Island’s “because of” test. See Cabral v. Arruda, 556 A.2d at 49. The Plaintiffs are correct that one of the key inquiries in determining whether documents were prepared in “anticipation of litigation” under the “because of” test is whether they would have been prepared at all or in their present form regardless of the expected litigation. Adlman, 134 F.3d at 1204. However, it seems to the Court very unlikely that the voluntary recall, the surprise FDA inspection that followed, the issuance of an EIR and 483 letter, and the hiring of Quintiles to help Defendants respond to the FDA’s observations, would ever have happened “but for” these personal injuries that would likely result in litigation. The Court is not persuaded, therefore, that the Quintiles documents would have been prepared in similar form irrespective of anticipated products liability litigation. See id. Without the personal injuries, the documents would not have been prepared at all.

Nor is the Court persuaded that the Quintiles documents were prepared in the “ordinary course of business,” as Plaintiffs contend. To the contrary, the facts suggest that Quintiles was hired due to extraordinary circumstances following events that would reasonably result in litigation. The Plaintiffs, however, argue that there is a distinction in the case law between “reports prepared in response to any unfortunate event that may well lead to litigation and material prepared as an aid to litigation.” Ordner v. K-H Corp., 1999 U.S. Dist. LEXIS 20887 (D.R.I. Mar. 12, 1999) (citing Scott Paper Co. v. Ceilcote Co., Inc., 103 F.R.D. 591, 594 (D. Me. 1984)).

It is clear from the Court’s review of the Quintiles documents that they are not simply “a more or less routine investigation” following unfortunate events. See id.; Binks, 709 F.2d at 1119. Rather, the Court finds that the reports, which appear designed to further Defendants’ understanding of their compliance with FDA regulations, are without question a useful “aid to litigation.”

The issue of whether a company complied or did not comply with FDA requirements is relevant to many aspects of the products liability lawsuit. For instance, the majority of states have held that violation of the Food Drug & Cosmetic Act or its state law counterparts is negligence per se. See James T. O’Reilly, Food and Drug Administration, § 26:1, note 5 (2d ed. 2005). The Plaintiffs allege negligence per se against these Defendants. (Brokaw complaint, ¶ 49.)

Compliance with FDA requirements is also a commonly asserted defense of drug and medical device manufacturers. See James L. Gilbert et al., ALTA’s Litigating Tort Cases, § 60:29 (2004). While only a few courts apply a complete “regulatory compliance defense,” most courts considering the issue have held that “compliance with FDA

regulations may be some evidence of due care.” Id. at § 60:29; see, e.g., MacDonald v. Ortho Pharmaceutical Corp., 394 Mass. 131, 140, 475 N.E.2d 65, 70 - 71 (Mass. 1985) (“[c]ompliance with FDA requirements, though admissible to demonstrate lack of negligence, is not conclusive on this issue, just as violation of FDA requirements is evidence, but not conclusive evidence, of negligence.”); Brochue v. Ortho Pharmaceuticals, Corp., 642 F.2d 652, 658 (1<sup>st</sup> Cir. 1981). The Defendants’ have asserted FDA compliance as one of their affirmative defenses in this litigation. (Defs.’ Answer, defense 14.)

Other than negligence, FDA compliance has a potential impact on other products liability theories as well:

Implied warranty litigation under Uniform Commercial Code theories is partially premised on the plaintiff’s reliance on the FDA-regulated skill and judgment of the seller or manufacturer . . . . Misrepresentation theories are sometimes used where fraud is alleged, on the premise that the defendant manufacturer had knowledge of a material fact and concealed it from the FDA during the agency review process. And strict liability . . . operates without the need to prove negligence, where courts or legislative bodies have found a need for societal decisions to redistribute the costs of certain types of injuries once causation and injury have been established by the plaintiff. Food and Drug Administration, at § 26:1.

Here, in addition to negligence, the Plaintiffs allege breach of implied warranty, fraud, and strict products liability, among other theories that may implicate FDA policies and regulations. (Brokaw Complaint, counts 2, 5, and 7.)

Compliance with FDA requirements, therefore, often exerts a profound, yet subtle, effect on a products liability lawsuit. See Carl Tobias, FDA Regulatory Compliance Reconsidered, 93 Cornell L. Rev. 1003, 1004 (2008). Accordingly, the

Court finds that hiring Quintiles to analyze and further Defendants' understanding of the FDA compliance issue is without question useful to this litigation.

The Plaintiffs next contend that since Defendants and all medical device manufacturers are required to comply with FDA regulations, the Quintiles documents were prepared pursuant to "regulatory requirements" and are therefore not protected. Nat'l Union, 967 F.2d at 984. It is well-established that "[m]aterials assembled . . . pursuant to public requirements unrelated to litigation, or for other nonlitigation purposes" are unprotected. Fed. R. Civ. P. 26(b)(3), Advisory Committee Note. However, there is nothing in the advisory committee's note to Fed. R. Civ. P. 26(b)(3) that suggests that the presence of a nonlitigation purpose defeats a litigation purpose, should one exist. Other courts have concluded the same. See In re Grand Jury Subpoena, 357 F.3d 900, 907 (9th Cir. 2004) (work product protection applies to materials prepared in anticipation of litigation and for other purposes); United States v. Adlman, 134 F.3d 1194, 1202 (2d Cir. 1998) (holding that "a document created because of anticipated litigation . . . does not lose work-product protection merely because it is intended to assist in the making of a business decision influenced by the likely outcome of the anticipated litigation"). This Court finds the reasoning of these cases persuasive on this issue.

Here, there is little question that one of the purposes, indeed the immediate purpose, behind creation of the Quintiles documents was to help Defendants comply with FDA regulations. However, the presence of a regulatory purpose does not defeat work product protection under the "because of" standard. "The 'because of' approach is more inclusive than the approach taken by courts that require a document to be prepared 'primarily or exclusively to assist in litigation.'" Moore, Federal Practice 3d, §

26.70[3][a]. As explained by the Ninth Circuit Court of Appeals in In re Grand Jury Subpoena,

[t]he “because of” standard does not consider whether litigation was a primary or secondary motive behind the creation of a document. Rather, it considers the totality of the circumstances and affords protection when it can fairly be said that the “document was created because of anticipated litigation, and would not have been created in substantially similar form but for the prospect of that litigation[.]” In re Grand Jury Subpoena, 357 F.3d at 908 (quoting Adlman, 134 F.3d at 1195).

Based upon a review of the Quintiles documents and the circumstances surrounding their preparation, this Court concludes that it can fairly be said that one of the purposes behind their creation was anticipation of products liability litigation. Moreover, the documents would not have been prepared “but for” the prospect of litigation reasonably resulting from the reported injuries preceding the December 2005 and March 2006 recalls. The fact that the Quintiles documents also serve a regulatory purpose does not override the litigation purpose.

## **B**

### **FDA Litigation**

The Court will next address Defendants’ claim that the Quintiles documents were also prepared in anticipation of litigation with the FDA. The Defendants contend that in light of the FDA’s vast powers to bring civil and criminal enforcement litigation and the circumstances surrounding the voluntary recalls, it was reasonable to anticipate such litigation. The Plaintiffs respond that FDA compliance occurs in the regular course of business and is not litigation.

The Restatement provides the following definition of “litigation” in the context of the work product doctrine and is used by many courts:

‘Litigation’ includes civil and criminal trial proceedings, as well as adversarial proceedings before an administrative agency, an arbitration panel or a claims commission, and alternative-dispute-resolution proceedings such as mediation or mini-trial. It also includes a proceeding such as a grand jury or a coroner's inquiry or an investigative legislative hearing. In general, a proceeding is adversarial when evidence or legal argument is presented by parties contending against each other with respect to legally significant factual issues. Restatement (Third) of the Law Governing Lawyers § 87 cmt. h (2000).

“‘Adversarialness’ is the touchstone of this approach to the ‘litigation’ question . . . .” In re Grand Jury Subpoena, 220 F.R.D. 130, 147 (D.Mass. 2004).

There is little question that the FDA has vast enforcement authority. Food and Drug Administration, at § 6:1. Indeed, the FDA’s strongest enforcement powers appear to be within the medical device area. Id. at 18:13. A sampling of the FDA’s device enforcement authority includes traditional methods, such as criminal prosecution, seizure, and injunctions, as well as special powers, like banning, notification, repair, refund, and replacement, administrative detention, device restriction, and civil penalties. Id.

Not all dealings with the FDA, of course, are “litigation” for purposes of the work product doctrine. Most courts have concluded that a governmental investigation itself generally does not constitute litigation, but that once a governmental investigation has begun, a corporation may reasonably be said to anticipate litigation. In re Grand Jury Subpoena, 220 F.R.D. 130, 147 (D. Ma. 2004) (and cases cited therein). Prior to hiring Quintiles, the Defendants underwent an FDA inspection, which resulted in an EIR and Form 483 that listed eight critical observations that required responses within a certain

time frame. The Defendants were clearly under FDA investigation during this time period. At this early stage, though, it does not appear that the investigation was sufficiently adversarial to constitute “litigation” for purposes of the work product doctrine. Id. However, without disclosing the contents of the documents reviewed in camera, the Court is satisfied that the Quintiles reports justify Defendants’ position that there were reasonable grounds to expect that the investigation might lead to more adversarial enforcement actions. The Court’s conclusion that the Quintiles documents were prepared in anticipation of products liability litigation, however, obviates the need to analyze whether the FDA enforcement actions Defendants reasonably anticipated constitute litigation under the work product doctrine.

### 3

#### **Substantial Need**

Finding that Defendants reasonably anticipated products liability actions and FDA enforcement actions when it engaged Quintiles does not end the matter. Ordinary work product may still be obtained “upon a showing that the party seeking discovery has substantial need of the materials in the preparation of the party’s case and that the party is unable without undue hardship to obtain the substantial equivalent of the materials by other means.” Sup. R. Civ. P. 26(b)(3) (emphasis added). The Defendants make no claim that the Quintiles documents contain anything but “ordinary” work-product.

Accordingly to Professor Moore, “substantial need for material otherwise protected by the work product doctrine is demonstrated by establishing that the facts contained in the requested documents are essential elements of the requesting party’s prima facie case.” Federal Practice, § 26.70[5][c]. The Plaintiffs argue that they have

“substantial need” for the Quintiles documents because they contain information essential to proving their negligence claim, i.e., how Defendants allegedly failed to comply with FDA regulations. Specifically, Plaintiffs allege that Defendants “breached their duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion distribution, and/or sale of the Composix Kugel Patch.” (Brokaw Complaint, ¶ 49.) In addition, the Plaintiffs point out that Defendants have pleaded affirmative defenses that make their compliance with FDA regulations relevant. (Def.’s answer, defenses 9, 14, 23.)

As discussed supra, the issue of whether Defendants complied with FDA regulations is highly relevant in this litigation. The information is an important aspect of Plaintiffs’ negligence case and important to disproving Defendants’ regulatory compliance defense, should the Court recognize it. The Court, therefore, accepts Plaintiffs’ argument that they have substantial need for information about whether Defendants complied with FDA regulations.

However, the Court does not agree with Plaintiffs that the only way they can discover this information is through obtaining an audit report created by Defendants’ consultant. A great deal of useful information on this issue is available directly from the FDA under the Freedom of Information Act. See Food and Drug Administration, § 26:2. Furthermore, to the extent that Plaintiffs hope to introduce the actions Defendants took following the recall, including hiring Quintiles, as evidence of subsequent remedial measures, those facts may be obtained through other means of discovery, such as depositions. The work product doctrine “does not protect facts concerning the creation of

work product, or facts contained within work product.” Moore, Federal Practice 3d, § 26.70[2][a]. The Plaintiffs have not yet taken the depositions of Defendants’ employees who were involved with the recall process. What they did in response to the recall, the remedial measures that were taken, are discoverable, even though the Quintiles reports are not. The work product doctrine protects the analysis contained in the Quintiles reports, not what Defendants’ employees did in response to Quintiles recommendations. Therefore, the Court concludes that Plaintiffs have thus far failed to make a sufficient showing that they are unable without undue hardship to obtain what they need through other discovery options. As discovery proceeds, however, the Court may revisit this issue if necessary.

### **Conclusion**

For the reasons stated herein, Plaintiffs’ motion to compel is denied. Counsel shall submit an appropriate order for entry.