

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION**

**TERRA JOHNSON, Individually and as next
friend and mother of TAMARIO MILLER,
a minor,**

Plaintiffs,

v.

Civil Action No. 2:08-cv-2376

**ADVANCED BIONICS, LLC d/b/a
ADVANCED BIONICS CORPORATION,
ADVANCE BIONICS HOLDING
CORPORATION d/b/a ADVANCED
BIONICS CORPORATION, and ASTRO
SEAL, INC.,**

Defendants.

**CHRISTINE PURCHASE, Individually and
as next friend and mother of CLYCE
("CHASE") PURCHASE WEATHERLY, a
minor,**

Plaintiffs,

v.

Civil Action No. 2:08-2442
[This case has been consolidated
with No. 2:08-cv-2376 by Order
dated September 18, 2008]

**ADVANCED BIONICS, LLC d/b/a
ADVANCED BIONICS CORPORATION,
ADVANCE BIONICS HOLDING
CORPORATION d/b/a ADVANCED
BIONICS CORPORATION, and ASTRO
SEAL, INC.,**

Defendants.

**ORDER GRANTING PLAINTIFFS' THIRD MOTION TO COMPEL PRODUCTION OF
DOCUMENTS BY DEFENDANT ADVANCED BIONICS, LLC**

Before this Court is Plaintiffs' Third Motion to Compel Production of Documents by Defendant Advanced Bionics, LLC ("Advanced Bionics"). (D.E. #81). The instant motion was referred to United States Magistrate Judge Charmiane G. Claxton for determination. (D.E. #82). For the reasons set forth herein, Plaintiffs' motion is hereby GRANTED.

I. Introduction

The instant case arises from allegations that a medical device manufactured by Advanced Bionics contained a defective component manufactured by Astro Seal, Inc.¹ ("Astro Seal"). The device at issue is the HiRes 90k cochlear implant, a Class III medical device that provides a sense of sound by direct stimulation of the auditory nerves. The device was implanted in the minor Plaintiffs and subsequently failed, which allowed their devices to contain unsafe levels of moisture.

During the discovery phase, Plaintiffs served their First Request for Production of Documents. Specifically, Plaintiffs' Request for Production No. 26 sought as follows: "All documents related to quality audit procedures, quality audits, and quality re-audits related to the Device, including any conducted pursuant to 21 C.F.R. § 820.22."² Pls' Third Mot. to Compel, Ex. A, at 21. In response, Advanced Bionics stated that it would provide copies of quality audit procedures that relate to hermeticity or moisture content of the HighRes 90k device, but Advanced

¹ All claims against Astro Seal have been dismissed with prejudice following a settlement between the parties, which the Court approved on July 14, 2009. (D.E. #127, 128).

² 21 C.F.R. § 820.22 states as follows:

Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a reaudit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and reaudit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and reaudits shall be documented.

Bionics objected to the requests for production of the quality audits and the quality re-audits related to the implant. Id.

In Advanced Bionics' Responses to Plaintiffs; Request for Production No. 26, it stated several objections to the requests, including "a privilege for critical self-evaluation." Pl's. Third Mot. to Compel, Ex. A. at 21. Additionally, in Advanced Bionics' privilege log, it further contends that certain documents are protected by the "Critical Self-Evaluation Privilege." Pls.' Third Mot. to Compel, Ex.B, *passim*.

On March 17, 2009, Plaintiffs filed the instant motion to compel asserting that the critical self-evaluation privilege does not exist under Tennessee law. Accordingly, Plaintiffs requested that this Court compel Advanced Bionics to produce any documents that it is withholding due to its reliance on this privilege. Advanced Bionics responded by admitting that neither the Tennessee legislature, the Tennessee Supreme Court, nor the Tennessee appellate courts have recognized the critical self-evaluation privilege. However, Advanced Bionics requests that this Court establish the critical self-evaluation privilege under Tennessee law based upon "common law principles," the policies behind FDA's audit requirements for medical device manufacturers, the policy behind the Food and Drug Administration's ("FDA") decision to exempt those audits from disclosure to the FDA, and the stated policy in the Tennessee Peer Review Law of 1967, see Tenn. Code Ann. § 63-6-219(b)(1), which includes fostering and encouraging candid evaluations in order to promote public health.

II. Analysis

The sole issue presented in the instant motion to compel is whether Tennessee law should recognize the critical self-evaluation privilege. Under Rule 26 of the Federal Rules of Civil

Procedure, “[p]arties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party.” Fed. R. Civ. P. 26(b)(1). Relevant evidence must appear “reasonably calculated to lead to the discovery of admissible evidence.” Id. The scope of discovery is both broad and liberal, Hickman v. Taylor, 329 U.S. 495, 507 (1947), and is “within the broad discretion of the trial court,” Lewis v. ABC Business Servs., Inc., 135 F.3d 389, 402 (6th Cir. 1998).

The United States Supreme Court has advised that privileges “are not lightly created nor expansively construed for they are in derogation of the search for truth.” United States v. Nixon, 418 U.S. 683, 710 (1974). Additionally, the United States Supreme Court has held that privileges hinder the fundamental principle that “the public . . . has a right to every man’s evidence.” Trammel v. United States, 445 U.S. 40, 50 (1980) (quoting United States v. Bryan, 339 U.S. 323, 331 (1950)). Privileges must be strictly construed and tolerated “only to the very limited extent that permitting a refusal to testify or excluding relevant evidence has a public good transcending the normally predominant principle of utilizing all rational means for ascertaining truth.” Trammel, 445 U.S. at 50. Based upon these principles, the United States Supreme Court has cautioned district courts in creating new privileges. Id.

When a federal court exercises jurisdiction based upon the diversity of citizenship, the court must look to state law to determine the existence of any privilege. Surles ex. rel Johnson v. Greyhound Lines, Inc., 474 F.3d 288, 296 n.1 (6th Cir. 2007). Accordingly, a federal court should “apply state law in accordance with the then controlling decision of the state’s highest court.” Angelota v. Am. Broadcasting Co., 820 F.2d 806, 807 (6th Cir. 1987). If the state’s highest court has not considered the issue, a federal court “must ascertain the state law from ‘all relevant data.’” Id. “A state’s intermediate appellate court decision announcing a rule of law is a ‘datum for

ascertaining state law which is not to be disregarded by a federal court unless it is convinced by other persuasive data that the highest court of the state would decide otherwise.” Id.

In the instant case, it is undisputed that neither the Tennessee General Assembly nor the Tennessee appellate courts have recognized the critical self-evaluation privilege. Thus, this Court does not have clear guidance on the issue presented in the instant motion. Accordingly, the Court will begin with considering the origins of privileges in Tennessee.

Under Tennessee law, privileges arise from five sources: (1) constitution; (2) statutes; (3) common law; (4) the Tennessee Rules of Evidence; or, (5) any other rules promulgated by the Tennessee Supreme Court. Tenn. R. Evid. 501. In the instant case, Advanced Bionics initially argues that this Court should recognize the critical self-evaluation privilege because Tennessee law recognizes common law privileges. It is critical to the analysis, however, to clarify that Advanced Bionics does not assert that the critical self-evaluation privilege existed under the common law of Tennessee. Rather, Advanced Bionics requests that the Court look to general “common law principles” that would support the creation of such a privilege. Advanced Bionics posits that such a reliance is appropriate because the Tennessee Supreme Court has previously resorted to common law principles in its analysis of the attorney-client privilege. See, e.g. Johnson v. Patterson, 81 Tenn. 626, 649, 1884 WL 3292, *10 (Tenn. 1884); see also Royal Surplus Lines Ins. Co. v. Sofamor Danek Group, 190 F.R.D. 463, 484 (W.D. Tenn. 1999) (reasoning that, “in accordance with the Tennessee Rule of Evidence 501, the courts of Tennessee are often guided by state and federal common law when fashioning the contours of the attorney-client privilege).

In Johnson v. Patterson, the Tennessee Supreme Court noted that the statute “embodied but the common law principle” of the attorney-client privilege. 81 Tenn. at 649. The court noted,

however, that “there is much if not all of the matter that is not within the settled rules of the law on this subject.” Id. Specifically, the statute discussed communications made to the attorney in the confidence of the relationship. Id. However, the Court noted that “there are many transactions between attorney and client, that have no element of confidence in them,” such as proving a client’s handwriting and proving payment of monies. Id. The court thus cited two legal treatises to support its conclusion that such communications are not within the scope of the attorney-client privilege. Id.

The circumstances presented in Johnson v. Patterson are highly distinguishable from the present case. In Johnson v. Patterson, the Tennessee Supreme Court was considering the scope of a privilege established under the common law and codified by the Tennessee legislature. The court elected to rely upon treatises to determine the *scope* of the privilege, but looked directly to the statute and to common law together to determine the *existence* of the privilege under Tennessee law. In the instant case, the critical self-evaluation privilege was not recognized by common law and has not been codified by the Tennessee legislature. Accordingly, the rationale utilized in Johnson v. Patterson does not provide support for this Court to create an entirely new privilege under Tennessee law.

Likewise, in Royal Surplus Lines, the Court considered the scope of the attorney-client privilege. 190 F.R.D. at 484. The Court began its analysis by noting that the attorney-client privilege is “established ‘by statute and case law.’” Id. (citing State v. Bobo, 724 S.W.2d 760 (Tenn. Crim. App. 1981)). The Court further concluded that, “when fashioning the contours of the attorney-client privilege,” it was “guided by state and federal common law” and would consider “authority from other jurisdictions” and “treatises.” Id. Thus, as in Johnson v. Patterson, the Royal

Surplus Lines court was merely attempting to determine the proper scope of the attorney-client privilege rather than the existence of the privilege itself. As the Royal Surplus Lines court clearly references, the attorney-client privilege existed at common law and has been codified by the legislative body. However, the privilege advocated by Advanced Bionics in the instant case has no such common law or statutory basis. Thus, the Court finds that the Royal Surplus Lines analysis regarding the use of persuasive authority to determine the scope of a well-established privilege is not instructive to this Court when considering whether to create an entirely new privilege under Tennessee law. Quite simply, as the privilege did not exist at common law, the Court cannot use the common law as a basis under Rule 501 of the Tennessee Rules of Evidence for recognizing this privilege. Finally, even if this Court were inclined to look to general common law principles, Advanced Bionics has not cited any such principle that would support the establishment of the critical self-evaluation privilege. Accordingly, the Court declines to recognize the critical self-evaluation privilege on the basis of common law.

In addition to Advanced Bionic's argument that the Court should recognize the critical self-evaluation privilege based upon the common law, Advanced Bionics posits that the privilege should be recognized for two other policy-based reasons: (1) because the policy behind the self-evaluation privilege is to promote candid, conscientious and objective evaluations, which the Tennessee General Assembly has recognized as a worthy goal in adopting the Tennessee Peer Review Law of 1967, see Tenn. Code Ann. § 63-6-219; and, (2) because quality audits and re-audits required by the Food and Drug Administration ("FDA") must not be disclosed to the FDA, see 21 C.F.R. § 820.22.

Advanced Bionics' assertions regarding the policy aims of the critical self-evaluation privilege in Tennessee are not sufficient to convince this Court to create a new privilege under

Tennessee Law. Rule 501 of the Tennessee Rules of Evidence does not allow courts to recognize privileges based upon arguments that the privilege would further a sound policy objective. Instead, as the Tennessee Supreme Court has noted, “the General Assembly, not this Court, establishes the public policy of Tennessee.” Schneider v. City of Jackson, 226 S.W.3d 332, 344 (quoting State v. Cawood, 134 S.W.3d 159, 167 (Tenn. 2004)). Even though the Schneider court admitted that it was “sympathetic to . . . concerns about the potential consequences of disclosing” the requested information, the Tennessee Supreme Court declined to recognize a new privilege because it was not proper for the court to perform this function. Id.

This Court further notes that the Tennessee General Assembly has already established the public policy of Tennessee when it codified the common law privileges and when it enacted the Tennessee Peer Review Law of 1967, Tenn. Code Ann. § 63-6-219. Although Advanced Bionics relies heavily upon the stated purpose of the Tennessee Peer Review Law, which requires candid, conscientious and objective evaluations of peer physicians, the General Assembly solely made this privilege applicable to “committees made up of Tennessee’s licensed physicians.” Tenn. Code Ann. § 63-6-219(b)(1). The General Assembly elected not to create a similar privilege for audits and re-audits by medical device manufacturers. Further, the General Assembly elected not to create a critical self-evaluation privilege even though the FDA has exempted such audits and re-audits from being disclosed to the FDA through its protocol. See 21 C.F.R. § 820.22. Thus, the Tennessee General Assembly has explicitly chosen not to create a privilege that would apply to the circumstances of this case. Accordingly, as the Schneider court explicitly determined, Advanced Bionics’ assertions regarding the arguably sound policy aims of a critical self-evaluation privilege in Tennessee are appropriate to be presented to the legislature, not to this Court.

Finally, Advanced Bionics asserts that the court could further look to “the decisional law of the Tennessee Supreme Court in analogous cases and relevant dicta in related cases, positions expressed in the restatement of law, law review commentaries and decisions from other jurisdictions or the majority rule for guidance.” See Royal Surplus Lines Ins. Co., 190 F.R.D. at 485. Although Advanced Bionics has cited persuasive authority to support the establishment of the critical self-evaluation privilege in Tennessee, the Court does not find that any persuasive authority is necessary when neither the Tennessee Supreme Court, the Tennessee Court of Appeals, the Tennessee General Assembly, nor the sources listed in Rule 501 of the Tennessee Rules of Evidence have recognized the existence of the critical self-evaluation privilege in Tennessee.

III. Conclusion

For the reasons set forth herein, the Court declines to establish a critical self-evaluation privilege under Tennessee law. Accordingly, Plaintiffs’ Third Motion to Compel Production of Documents by Advanced Bionics is GRANTED. Advanced Bionics, LLC is ORDERED to produce all documents that it has withheld on the basis of its assertion of the critical self-evaluation privilege.

IT IS SO ORDERED this 28th day of July, 2009.

s/ Charmiane G. Claxton
CHARMIANE G. CLAXTON
UNITED STATES MAGISTRATE JUDGE