UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

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

Plaintiff,

v. Case No. 2:08-cv-02376-JPM

ADVANCED BIONICS, LLC d/b/a
ADVANCED BIONICS CORPORATION
and ADVANCED BIONICS HOLDING
CORPORATION d/b/a
ADVANCED BIONICS CORPORATION and
ASTRO SEAL, Inc.

Defendants.

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

Plaintiff,

v. Case No. 2:08-cv-02442-JPM

ADVANCED BIONICS, LLC d/b/a
ADVANCED BIONICS CORPORATION
and ADVANCED BIONICS HOLDING
CORPORATION d/b/a
ADVANCED BIONICS CORPORATION and
ASTRO SEAL, Inc.

Defendants.

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' THIRD MOTION TO COMPEL PRODUCTION OF DOCUMENTS BY DEFENDANT ADVANCED BIONICS

COME NOW the Plaintiffs, Terra Johnson, Individually and as next of friend and mother of Tamario Miller, a minor, and Christine Purchase, Individually and as next of friend and mother of Clyce ("Chase") Purchase Weatherly, a minor, by and through their counsel of record,

Glassman, Edwards, Wade & Wyatt, P.C., and file this Third Motion to Compel as to Defendant Advanced Bionics, LLC. In further support of this Motion, Plaintiffs would respectfully show unto the Court as follows:

BACKGROUND

I. Factual Background.

These claims arise from a defective medical device, an Advanced Bionics HiResolution 90k cochlear implant (also known and referred to as the HiRes90k cochlear implant and the CII-x cochlear implant). Both of the minor Plaintiffs were implanted with the HiRes 90k, a class III medical device that provides a sense of sound by direct stimulation of the auditory nerves by means of electrodes. The cochlear implants, manufactured by Advanced Bionics, were defective and were not waterproof. Advanced Bionics' specification for moisture content in the HiRes 90k is 0.5%, but as the proof will show in these cases, the devices were adulterated by FDA standards and failed while implanted in the minor Plaintiffs because of a lack of hermeticity. Specifically, the proof will show that Chase Purchase's device had an incredibly high moisture content of 61.3379% water/vapor. Tamario Miller's device contained 26.983% water/vapor. Both of these levels were astronomically higher than the limits imposed by Advanced Bionics.

The "defective" component of the HiRes 90k was a feed-through (also "feed-thru" or "feedthru"), manufactured by Defendant Astro Seal, Inc. Astro Seal's feed-through component was never submitted to the FDA for approval, as was required by the Code of Federal Regulations and applicable federal law. Advanced Bionics will not produce a supplemental pre-market approval application for the Astro Seal component because one was never prepared and submitted. Advanced Bionics contends that Astro Seal is an "at fault" party.

On or about September 24, 2004, Advanced Bionics (which was then a subsidiary of Boston Scientific Corporation), issued its first recall of the HiRes90k, Supplier B ("Astro Seal")

because of a “potential presence of moisture” in the internal circuitry of its Vendor B model cochlear implants. This recall included, supposedly, all cochlear implant devices that had not yet been surgically implanted.

On or about February 1, 2005, FDA inspections at the Advanced Bionics facility showed numerous defects with the HiRes90k, including moisture issues and lack of testing and management oversight issues. Training and inspection were also highlighted in an eleven (11) page warning letter from the FDA to Advanced Bionics. It is undisputed Advanced Bionics continued to sell vendor B / Astro Seal, Inc. cochlear implants following receipt of this eleven (11) page warning letter.

Thereafter, on or about March 10, 2006, Advanced Bionics issued a second recall of the HiRes 90k because of “moisture-related device failure rate,” or specifically because the HiRes90k vendor B implants may be linked to an elevated risk of moisture-related device failure. Defective Advanced Bionics devices that had already been implanted in patients were to be left inside and implanted in the patient until a problem developed.

The FDA eventually filed a civil complaint and two supplemental amended civil complaints against Advanced Bionics seeking $2.2 Million Dollars in fines for wrongful conduct by the medical device maker. The FDA Complaint was amended to allege numerous causes of action for inappropriate conduct in violation of FDA rules and regulations, and pointed out that the FDA had dealt with “issues” surrounding leakage issues with Advanced Bionics cochlear implants since 2001. The FDA alleged that Advanced Bionics’ devices were not sold with the required federal approval, and, therefore, were adulterated and sold in violation of federal law.

II. Procedural Background.

Plaintiffs have supplied detailed and specific requests for production of documents to Advanced Bionics, and in return, Advanced Bionics has forwarded over seventy (70) CD/DVD discs to Plaintiffs to-date, all of which except two (2) contain non-searchable, unorganized files.

These discs are not organized in response to the specific requests for production submitted by Plaintiffs to Advanced Bionics. In fact, a review of each disc does not distinguish which documents are responsive to each request for production.

The issue in this motion deals with the critical self-evaluation privilege, a privilege currently not recognized by the State of Tennessee. Plaintiffs' Request for Production No. 26, and Advanced Bionics' response, is as follows:

> REQUEST FOR PRODUCTION NO. 26:
> 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.
>
> RESPONSE TO REQUEST FOR PRODUCTION NO. 26:
> Subject to the objections stated below and to the Preliminary Statement, Advanced Bionics will produce copies of quality audit procedures that deal in a reasonably direct manner with hermeticity or moisture content of the HiRes 90K and that Advanced Bionics can locate through the reasonable searches described in the Preliminary Statement. Without limiting this response in any way and solely to the extent that the request demands a different or additional response, Advanced Bionics objects on the grounds stated in Objection Nos. 1 (Privilege or Work Product), <u>**including a privilege for critical self-evaluation**</u>, 2 (Trade Secret), 3 (Confidential Patient or Reporter Infonnation), 4 (All Documents or All Communications), 5 (Failure to Limit Time), and 6 (Hermeticity or Moisture Content). Advanced Bionics also objects on the grounds that the request is overly broad, seeks documents neither relevant to any claim or defense in these actions nor reasonably calculated to lead to the discovery of admissible evidence, and is unduly burdensome and oppressive.

<u>See</u> Advanced Bionics Request for Production Responses (Ex. A) (emphasis added).

Advanced Bionics has also produced three privilege logs, one of which is forty-one (41) pages in length. <u>See</u> Privilege Log (Ex. B). In its privilege log, Advanced Bionics contends that numerous documents are protected by the "Critical Self-Evaluation Privilege." While there is no means to be certain Advanced Bionics is withholding only documents responsive to Request for Production No. 26 (as the privilege log does not state which documents are being withheld pursuant to which request for production), a search through the Defendant's discovery responses reveals only one discovery response (No. 26) where the critical self-evaluation privilege is asserted.

LAW AND ARGUMENT

I. Discovery is broad, and the burden lies with the party asserting a privilege.

"Parties 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). Relevancy means that the evidence "appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1); see also Coleman v. Am. Red Cross, 23 F.3d 1091, 1097 (6th Cir. 1994). The Court should broadly interpret whether evidence is relevant. See Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340, 351 n.12 (1978) (quoting 4 J. Moore, Federal Practice § 26.96[1], at 26-131 n.34 (2d ed. 1976)). In this Circuit, the scope of discovery is extremely broad under the Federal Rules of Civil Procedure and "is . . . within the broad discretion of the trial court." Lewis v. ACB Business Servs. Inc., 135 F.3d 389, 402 (6th Cir. 1998). The United States Supreme Court has also noted that discovery should be both broad and liberal. See Schlagenhauf v. Holder, 379 U.S. 104. 114-15 (1964) (citing Hickman v. Taylor, 329 U.S. 495, 507 (1947)).

A party asserting a privilege exemption from discovery bears the burden on demonstrating its applicability. See In re Santa Fe Internl Corp., 272 F.3d 705, 710 (5th Cir. 2001); United States v. Landof, 591 F.2d 36 (9th Cir. 1978) (holding that the party objecting to discovery on the basis of privilege has the burden of establishing the existence of a privilege).

As noted by the United States Supreme Court (albeit analyzing the applicability of a federal privilege), 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); see also American Civil Liberties Union of Mississippi, Inc. v. Finch, 638 F.2d 1336, 1344 (5th Cir. 1981) (holding that privileges are strongly disfavored in federal practice). Under Rule 26 of the Federal Rules of Civil procedure, there is a broad policy which favors full disclosure of facts during discovery. Wei v. Bodner, 127 F.R.D. 91, 95-96 (D.N.J. 1989). Obviously, the existence of a privilege prevents the full disclosure of facts, including relevant facts; therefore, consistent

with the liberal discovery policy of the federal judiciary, privileges are not favored. Herbert v. Lando, 441 U.S. 153, 175 (1979); In re Grand Jury, 103 F.3d 1140, 1149 (3d Cir. 1997).

Further, as noted by the United States Supreme Court, 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)); see Jaffee v. Redmond, 518 U.S. 1 (1996). 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 (quoting Elkins v. United States, 364 U.S. 206, 234 (1960) (Frankfurter, J, dissenting)).

The United States Supreme Court has cautioned district courts in creating new privileges under federal law, which should be similarly applied in the context of a state-recognized privilege. See Trammel, 445 U.S. at 50.

II. There is no self-evaluation privilege in Tennessee.

A. Privileges in Tennessee

It is undisputed that because this case is based on diversity of citizenship, the Court should look to state law to determine the existence of a privilege. Surles ex. rel Johnson v. Greyhound Lines, Inc., 474 F.3d 288, 296 n. 1 (6th Cir. 2007). In fact, this Court should "apply state law in accordance with the then controlling decision of the state's highest court." Angelotta v. Am. Broadcasting Co., 820 F.2d 806, 807 (6th Cir. 1987).

Pursuant to the Tennessee Rules of Evidence, "[e]xcept as otherwise provided by constitution, statute, common law, or by these or other rules promulgated by the Tennessee Supreme Court, no person has a privilege to: (1) Refuse to be a witness; (2) Refuse to disclose any matter; (3) Refuse to produce any object or writing; or (4) Prevent another from being a witness or disclosing any matter or producing any object or writing." Tenn. R. Evid. 501.

B. There is no recognized Critical Self-Evaluation Privilege in Tennessee

As noted in the Angelotta case, this Court should look to whether the critical self-evaluation privilege is recognized by the Tennessee Supreme Court. Despite thorough research, Plaintiffs have been unable to find any authority showing whether the critical self-evaluation privilege is recognized in the state of Tennessee. This fact and conclusion is admitted by counsel for Advanced Bionics. See Letter from Craig May to Ed Wallis (dated February 28, 2008) (Ex. C).

As a result, Advanced Bionics is, in a sense, asking this District Court to create a new privilege in the state of Tennessee. This is such even though all three divisions of the Tennessee Court of Appeals have never recognized the privilege, and even though the Supreme Court in the State of Tennessee has never recognized the privilege, either.

In Purcel v. Advanced Bionics, No. 3:07-cv-1777-M (N.D. Tex.), Advanced Bionics relied upon Shipes v. BIC Corp., 154 F.R.D. 301, 306-07 (M.D. Ga. 1994), to establish that a federal district court can recognize a privilege despite there being no such privilege codified by state law or otherwise recognized by state common law. See Response Brief of Advanced Bionics in Purcel to Motion to Compel (Ex. D). This exact argument was **subsequently rejected and criticized** in Lara v. Tri-State Drilling, Inc., based on the Shipes court's "leap of state law interpretation absent a recognition of the self-critical analysis privilege by the Georgia state courts or the state legislature." 504 F. Supp. 2d 1323, 1326-29 (N.D. Ga. 2007). Respectfully, this Court's decision to recognize a privilege that has never been recognized before in the State of Tennessee would be a similar "leap of state law interpretation."

C. The Tennessee Medical Malpractice Peer Review Act is Irrelevant

Arguments that the existence of the Tennessee Medical Malpractice Act's peer review privilege is somehow binding or persuasive on this Court is misplaced. In another district court

case in Texas involving a failed HiRes90k cochlear implant, Advanced Bionics argued that a district court in Texas should recognize the self-critical evaluation privilege because it is analogous to Texas' statutory privilege for medical peer review. See Response of Advanced Bionics to Motion to Compel, Purcel v. Advanced Bionics (attached as Ex. D). A similar argument is likely in this case; however, there is a sharp distinction between these two purported privileges in the state of Tennessee: the Tennessee Medical Peer Review is codified and recognized by Tennessee courts, and the critical self-evaluation privilege is not.

While some states have recognized the privilege in terms of medical review committee minutes, Tennessee has not. Further, medical peer review is different than analysis into why children's cochlear implants have failed for moisture damage. Medical peer review compared to internal investigations into failed medical devices is not an apple to apple comparison; it is synonymous to comparing apples and oranges.

D. There is no uniform recognition of the self-critical evaluation privilege

Worth mentioning, not only is the self-critical evaluation privilege not recognized in Tennessee, it (1) is not uniformly recognized among the states, (2) is only recognized in a minority of Federal Circuits, and (3) does not garner uniform support among scholars. See Spencer Sav. Bank v. Excell Mortgage Corp., 960 F. Supp. 835, 839 (D.N.J. 1997) (rejecting the self-critical evaluation privilege under federal common law the court and detailing the lack of consensus among courts and scholars with regard to its viability and application). In Spencer Savings Bank v. Excell Mortgage Corp., a savings and loan association sued a mortgage company asserting both federal and state causes of action. The mortgage company sought an order compelling disclosure of reports from financial service provider and association's loan review committee, but the District Court held that self-critical analysis privilege did not exist under federal common law. The Excell case makes several key points concerning this purported privilege:

1. States do not routinely recognize the privilege

Few states have agreed as to whether the privilege should exist. This is apparent when reviewing citations of the numerous courts to have denied such recognition. See, e.g., Jolly v. Superior Court, 112 Ariz. 186, 540 P.2d 658, 662-63 (1975) (refusing to extend privilege to internal safety investigation report of company); Combined Communications Corp. v. Public Service Co., 865 P.2d 893, 898 (Colo. Ct. App. 1993) (noting that Colorado courts do not recognize self-critical analysis privilege); Southern Bell Telephone & Telegraph Co. v. Beard, 597 So. 2d 873, 876 n. 4 (Fla. Dist. Ct. App. 1992) (noting that privilege is not expressly accepted in state of Florida); Scroggins v. Uniden Corp. of America, 506 N.E.2d 83, 86 (Ind. Ct. App. 1987) (stating that no self-critical analysis privilege exists in Indiana) University of Kentucky v. Courier-Journal & Louisville Times Co., 830 S.W.2d 373, 378 (Ky. Sup. Ct. 1992) (refusing to adopt privilege for responses to inquiries of collegiate athletic association); Nazareth Literary & Benevolent Inst. v. Stephenson, 503 S.W.2d 177, 178-79 (Ky. Sup. Ct. 1973) (refusing to extend privilege to internal hospital reports concerning methods of treatment and correction of mistakes); State ex rel. Celebrezze v. CECOS Int'l. Inc., 66 Ohio App. 3d 262, 583 N.E.2d 1118, 1121 (1990) (noting that Ohio courts have not adopted self-critical analysis privilege); Davison v. St. Paul Fire & Marine Ins. Co., 75 Wis. 2d 190, 248 N.W.2d 433, 440-42 (1977) (refusing to recognize privilege to protect reports and minutes of hospital peer review committee); Rhodes v. AIG Domestic Claims, Inc., 20 Mass. L. Rptr. 491 (Mass. Supr. 2006) (Massachusetts does not recognize the self-critical analysis privilege); Roman Catholic Diocese of Jackson v. Morrison, 905 So. 2d 1213, 1245 (Miss. 2005) (holding that because there is no such privilege recognized, “self-critical documents may not be included in the privilege log”); Wells Diary, Inc. v. Am. Indus. Refrigeration, Inc., 690 N.W. 2d 38, 49 (Iowa 1004) (refusing to extend self-critical privilege beyond statutory-enacted provisions).

2. Federal courts have not routinely recognized the privilege

"The Supreme Court and circuit courts have neither definitively denied the existence of such a privilege, nor accepted it and defined its scope." Dowling v. American Hawaii Cruises, Inc., 971 F.2d 423, 425 n. 1 (9th Cir.1992). This only goes to show why the creation of such a privilege by this court would be improper.

A majority of Circuits have refused to recognize or apply the critical self-evaluation privilege. See In re Qwest Communications Intern, Inc., 450 F.3d 1179, 1198 n. 8 (10th Cir. 2006) (only a minority of states have recognized the self-critical analysis privilege); Burden-Meeks v. Welch, 319 F.3d 897, 899 (7th Cir. 2003) (declining to recognize the self-critical evaluation privilege); Union Pacific R. Co. v. Mower, 219 F.3d 1069, 1076 n. 7 (9th Cir. 2000) (declining to recognize the self-critical evaluation privilege); Reynolds Metals co. v. Rumsfeld, 564 F.2d 663, 667 (4th Cir. 1977) (refusing to apply the privilege to protect disclosures to the E.E.O.C.). Several district courts have similarly looked at the existence of this privilege, and have concurred that the privilege is not to be recognized. See, e.g., Capellupo v. FMC Corp., 46 F.E.P. Cases 1193 (D. Minn. 1988); Hardy v. New York Times, Inc., 114 F.R.D. 633 (S.D.N.Y. 1987); Witten v. A.H. Smith & Co., 100 F.R.D. 446 (D. Md. 1984); Siskonen v. Stanadyne, Inc., 124 F.R.D. 610 (W.D. Mich. 1989).

The Third Circuit Court of Appeals recently showed its displeasure for a district court's decision to rely on the self-critical analysis privilege. The court held that "we are unpersuaded by the [District] Court's reliance on the so-called 'self-critical analysis privilege' as a basis for sealing [the case record]. The self-critical analysis privilege has never been recognized by this court and we see no reason to recognize it now." Alaska Elec. Pension Fund v. Pharmacia Corp., 554 F.3d 342, 351 n. 12 (3d Cir. 2009) (citations omitted).

3. There is no uniform support among legal scholars.

As noted in Excell, Dean Wigmore has never addressed a common law self-critical analysis privilege. One critic has even argued that the privilege is not supported by Wigmore's analysis. See McNab, Criticizing The Self-Criticism Privilege, 1987 U. Ill. L. Rev.. 675, 683-84 (1987).

Further, as noted in Excell, critics who have discussed the privilege disagree on whether it should be recognized. See, e.g., D. Hittmer et al., Federal Civil Procedure Before Trial P. 11:20-P 11:83.7 (The Rutter Group of Texas, Ltd., 5th Circuit ed.1996); 23 C. Wright & K. Graham, Jr., Federal Practice and Procedure § 5431 (1996 Supp.); Leonard, Codifying A Privilege For Self-Critical Analysis, 25 Harv. J. on Legis. 113 (Winter 1988); McNab, Criticizing The Self-Criticism Privilege, 1987 U. ILL. L. REV. 675 (1987); Flanagan, Rejecting A General Privilege For Self-Critical Analyses, 57 Geo. Wash. L. Rev. 551 (1983).

The Excell court notes that "[o]pponents of the self-critical analysis privilege argue that it 'does not provide the desired benefit of encouraging self-evaluative communications within institutions Instead, the self-criticism privilege impedes discovery without providing any measurable off-setting benefit.'" Excell, 960 F. Supp. at 841 (citing McNab, at 675). Such an argument should be deemed persuasive in this case.

Further, the lack of consistent support among legal scholars show why recognition of such a privilege is inappropriate.

4. There is no privilege included in the Rules of Evidence

As stated above, there is no self-evaluation privilege in the Tennessee Rules of Evidence. See generally Tenn. R. Evid. Further, there is no self-evaluation privilege in the Federal Rules of Evidence. See generally Fed. R. Evid. "[T]he self-critical analysis privilege was omitted from the list of privileges identified by the Advisory Committee on Rules of Evidence in 1972." Excell, 960 F. Supp. at 841-42 (citations omitted). While these Rules of

Evidence were not adopted by Congress, "the proposed rules provide a useful reference point and offer guidance in defining the existence and scope of evidentiary privileges in the federal courts." In re Grand Jury Investigation (Appeal of United States), 918 F.2d 374, 380 (3d Cir. 1990).

"The omission of the self-critical analysis privilege from the proposed privileges strongly indicates that the Advisory Committee, similar to the majority of state legislatures, did not find the privilege 'indelibly ensconced' in the federal common law." Excell, 960 F. Supp. at 842. "A federal court should give due consideration, and accord proper weight, to the judgment of the Advisory Committee and of state legislatures on this issue when it evaluates whether it is appropriate to create a new privilege pursuant to Rule 501." In re Grand Jury, 103 F.3d at 1151. Because there is no specific recognition of the privilege, the Court should not find the privilege allowable in this case.

5. There is no privilege included in the Code of Federal Regulations.

The Code of Federal Regulations, specifically 21 C.F.R. § 803.1 *et seq*, were promulgated by the Food and Drug Administration for governance and regulation for medical device reporting of adverse events attributable to the malfunctioning of medical devices. The FDA has also promulgated regulations on how situations such as the one at issue in these cases are to be investigated and corrected and what records must be maintained related thereto. See specifically 21 C.F.R. § 820.100 Corrective and Preventive Action which requires that medical device manufacturers establish and maintain procedures for correcting the harm done by defective medical devices such as the HiRes 90K cochlear implant. In pertinent part this regulation states **(b) All activities required under this section, and their results, shall be documented**. Id. (emphasis added). In other words, the activities to which the communications contained in the documents sought to be withheld by the Defendant are to be preserved. There is absolutely no provision in the C.F.R. providing that such "activities required

under this section" are privileged, nor does the Defendant cite to any such authority. The Court should not impose a privilege where none exists under the regulations governing and regulating the Defendant.

6. The privilege does not foster important public interests.

A significant number of courts (as outlined above) have refused to acknowledge the existence of this privilege. This is important because the privilege prevents injured persons from proving the defendant was the cause-in-fact of their injuries. As noted in Excell in terms of an employment law scenario, the privilege, if recognized, could prevent a party from obtaining the evidence needed to prove discriminatory intent. The same is true for this case in terms of whether the Defendant knew or should have known it failed to comply with federal laws and otherwise caused injuries to Plaintiffs. "In resolving the tensions between the opposed needs of disclosure [and] confidentiality we are reminded that the discovery rules are to be accorded broad and liberal treatment, particularly where proof of intent is required." Excell, 960 F. Supp. at 843.

Second, refusing to recognize the privilege will not have some long-lasting effect on medical device companies as the Defendant will attempt to have the Court believe. The audits that are not being produced are required by Federal regulations, and Advanced Bionics and similar companies must prepare these regardless of whether they may be caused by the reckless conduct of the company. Worth remembering, these lawsuits were filed after the FDA sued Advanced Bionics alleging the failure of the company to comply with FDA Regulations.

Third, Advanced Bionics seeks not only to withhold documents relevant to Plaintiffs' claims, but to expand the scope of privileges recognized in the state of Tennessee. Advanced Bionics not only has the burden of proving that this privilege should be recognized and adopted by this Court contrary to any precedent, it also bears the burden of proving why it should be adopted in this particular case. Moreover, the documents in question appear to bear directly on

Plaintiffs' claims regarding quality audits, quality assurance, and failure to timely report device failures to the FDA. These documents would specifically go to show wrongdoing and potential punitive conduct by the Defendant. This Court should reject Advanced Bionics' invitation to substitute its judgment in favor of Tennessee lawmakers and create a new, unrecognized and controversial privilege in this case.

IV. The documents sought are relevant and discoverable.

As noted above, the scope of discovery is extremely broad in this Court. It is expected Defendant will object to the production of selected materials labeled "self-evaluation" on the grounds of relevance, as well. Presumably, Advanced Bionics will object to producing documents relating to quality audits from 2006 and 2007 claiming that they lack relevancy since the devices of the two minor Plaintiffs were manufactured and/or removed in years preceding he dates of these documents. It is also expected Advanced Bionics will assert and argue that the burden and expense related to the production of these documents outweighs any likely benefit. These arguments ring hollow for several reasons.

To date, Advanced Bionics has produced voluminous documents dated 2006 and 2007 in these two cases. In another case in Texas (Purcel v. Advanced Bionics), where the Defendant has produced more documents than in these cases, Advanced Bionics has produced without objection 4,991 documents that are specifically dated 2007. Advanced Bionics has also produced 4,216 documents in the Texas Purcel case that are identified as encompassing documents generated in 2007 (i.e., correspondence 2002-2007). See Reply Brief to Motion to Compel, Purcel, (Ex. E). Based on the thousands of documents produced in both these and other cases across the country dated 2006, 2007 and 2008, it is disingenuous for Advanced Bionics to now argue that the time frame is not relevant and that the production of documents listed and labeled as protected by the "self-evaluation privilege" would be unduly burdensome.

The withheld documents relating to quality audits from that time frame encompass four categories: (1) moisture investigations pertaining to the HiRes 90K; (2) ongoing or anticipated investigations by the FDA; (3) quality assurance policies or procedures; (4) and maintenance of HiRes90K patient complaint files. All of these issues pertain directly to the Plaintiffs' claims and were ongoing and unresolved during this time frame. See Complaints (in both cases). Investigation into failure analysis necessarily requires a retrospective analysis. Further, considering that the scope of discovery is extremely broad, it would not be unexpected for moisture failure, Astro Seal feedthru issues and the like to be discussed in 2006, 2007, 2008 and even 2009 documents. Astro Seal feedthrus continue to fail, meaning the hermeticity issues are still ongoing and of concern to Advanced Bionics.

Other important dates render relevant the audit related documents from 2006-2007. The FDA filed a complaint against AB and its CEO in November 2007 based on the same allegations that have been made in this case. See FDA Complaint (Ex. F); FDA Amended Complaint (Ex. G). The devices for Plaintiffs Miller and Purchase were tested by Advanced Bionics in November 13, 2007 and November 18, 2005, respectively. See Miller Failure Analysis Report (Ex. H); Purchase Failure Analysis Report (Ex. I). The results of those tests, and those of other patient devices manufactured during the time Advanced Bionics was utilizing Astro Seal feed-thrus (but were not explanted until several years later), make the documents relating to quality audits during 2006-2007 very relevant because the investigation and analysis into the moisture and quality assurance problems were ongoing.

If Plaintiff Miller's device was not even explanted until 2007, it seems somewhat perplexing why 2007 documents would be irrelevant to these claims. For example, if the documents show that all devices implanted should have been explanted, this type of evidence is clearly relevant to these claims. Further, if 2006 and 2007 testing shows testing results from prior years, the documents are relevant. The scope of discovery is extremely broad, and the

documents should be produced. It must be remembered that admissibility is not the criteria in which to test for whether a document is discoverable or not.

For these reasons, the documents sought are relevant and should be produced.

E. The Purcel Court has ruled these documents discoverable.

A district court in Texas has ruled the documents purportedly protected by the self-evaluation privilege are discoverable. See Texas litigation docket entry (Ex. J); Order Granting Motion to Compel (to be filed as late-filed exhibit). This only goes to show that a similar order is appropriate in this case. Like Texas, Tennessee has never recognized the self-critical evaluation privilege before, and the Northern District of Texas was not convinced by Advanced Bionics' arguments. The Texas court's order should be deemed persuasive to this Court when making a similar determination.

Worth noting, following the ruling as to the Motion to Compel in the Purcel litigation, Plaintiffs again attempted to consult with Advanced Bionics concerning the relief sought in this motion, but Advanced Bionics refused to produce these documents.

V. The Federal Rules of Evidence specifically provide for the admissibility of these documents.

Presumably, the documents which Defendant seeks to withhold are a part and parcel of the internal investigation which led to not one but two recalls of the defective product at issue in these cases, the HiRes 90K cochlear implant. The nature of the privilege sought to be imposed by the Defendant informs that the documents sought to be withheld are detrimental to the Defendant's position in these cases. Federal Rule of Evidence 801(d)(2)(D) specifically addresses the hearsay exception for admission by a party-opponent. The Privilege Log demonstrates that the documents sought to be withheld were made by employees within the scope and course of their employment with the Defendant in furtherance of responsibilities to investigate repeated failures of the product at issue. Consequently, those communications are

admissible. Moore vs. Kuka Welding Sys. & Robot Corp. 171 F. 3d 1073 (6th Cir.1999). For this Court to apply a privilege in this situation would be to diminish the significance of this Rule.

VI. Alternatively, redacted documents should be produced.

Even assuming this Court orders the creation of a new privilege in the state of Tennessee, the documents should still be produced in redacted format. "Even where a self-critical analysis privilege has been held to exist, . . . that privilege is clearly limited to expressions of opinion or recommendations, and not to facts underlying such opinions or recommendations." Price v. County of San Diego, 165 F.R.D. 614, 619 (S.D. Cal. 1996) (citing Granger v. Nat'l R.R. Passenger Corp., 116 F.R.D. 507, 510 (E.D. Pa. 1987)). As such, any documents purportedly privileged should be at least produced to the extent that the documents contain facts underlying any such opinion or recommendation.

CONCLUSION

For the reasons set forth above, the documents sought are not protected by an applicable privilege that is recognized in the state of Tennessee. As such, the documents listed in Advanced Bionic's privilege log as protected by the Critical Self-Evaluation privilege should be produced. Further, to the extent other responsive documents to Request for Production No. 26 are being withheld pursuant to the Critical Self-Evaluation Privilege, those documents should be produced, as well.

WHEREFORE, PREMISES CONSIDERED, Plaintiffs, Terra Johnson, Individually and as next of friend and mother of Tamario Miller, a minor, and Christine Purchase, Individually and as next of friend and mother of Clyce ("Chase") Purchase Weatherly, a minor, respectfully request that this Court enter an Order compelling the Defendant, Advanced Bionics, LLC to produce all documents currently listed on the Defendants' Privilege Log as protected by the critical self-evaluation privilege, as well as others responsive to Request for Production No. 26.

Respectfully submitted,

GLASSMAN, EDWARDS, WADE
& WYATT, P.C.

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(File No. 07-213 & 08-158T)

CERTIFICATE OF SERVICE

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