UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
AT LOUISVILLE

CIVIL ACTION NO. 3:11-CV-00450-H

BRIAN AND MICHELLE SADLER PLAINTIFFS
Individually and on behalf of their
Minor child, B.S.

V.

ADVANCED BIONICS, INC. DEFENDANT

MEMORANDUM OPINION AND ORDER

This is a medical negligence and products liability case arising out of Plaintiffs' injuries that resulted from the malfunctioning of a cochlear implant manufactured by Defendant, Advanced Bionics. In previous Orders, the Court dismissed some causes of action on preemption grounds and ruled on some motions *in limine* filed by both parties. The Court now addresses three important motions *in limine* relating to the admissibility of certain documents. Specifically, the Court will rule on part of Plaintiffs' Motion to Deem Documents Admissible (DN 93); Defendant's Motion *in Limine* Number 4: to exclude evidence of FDA Form 483s, Warning Letter and related communications (DN 115) ("Motion Number 4"); and Defendant's Motion *in Limine* Number 3: to exclude reference to FDA civil monetary penalty action ("CMP") and related documents (DN 109)("Motion Number 3"). For the reasons stated herein, the Court will sustain in part and deny in part Plaintiffs' Motion to Deem Documents Admissible, reserving part of that motion for later consideration. Further, the Court will sustain in part and deny in part Motion Number 4, and will sustain Motion Number 3.

I.

The first two motions are the easiest to resolve. Plaintiffs moved to deem some thirty documents admissible for trial (DN 93).[1] Advanced Bionics moved to deem some of the same documents inadmissible in a separate motion (DN 115). The Court will address the admissibility of those documents that are the subject of both motions.

In 2001, the federal Food and Drug Administration ("FDA") issued a Form 483 Report finding deficiencies in Advanced Bionics' supplemental reports relating to prior generations of Advanced Bionics cochlear implant ("2001 Form 483"). In September 2004, following an FDA inspection of Advanced Bionics facilities, the FDA issued a Form 483 listing 23 observations mostly relating to moisture issues ("2004 Form 483"). The 2004 Form 483 pertained to the HiRes 90k, but mis-diagnosed the cause of the moisture problems, claiming that moisture was being sealed into the device during its manufacture. In 2005, the FDA issued a Warning Letter to Advanced Bionics identifying 15 alleged deviations from FDA regulatory requirements supposedly in response to Advanced Bionics' failure to respond adequately to the 2004 Form 483 ("2005 Warning Letter"). In February 2007, the FDA issued another Form 483 to Advanced Bionics ("2007 Form 483") arising out of Advanced Bionics' 2006 recall of its HiRes 90k devices with AstroSeal feedthrus ("Vendor B HiRes 90k"). In the 2007 Form 483, the FDA correctly cites a leak in the device's feedthru as the cause of the excess moisture. The Court finds the 2004 Form 483, 2005 Warning Letter and 2007 Form 483 admissible, while the 2001 Form 483 is inadmissible.

[1] In Response to Plaintiffs' Motion, Advanced Bionics conceded to the admissibility of certain documents. Accordingly, the Court sustains Plaintiffs' motion as to those documents, assuming Plaintiffs provide proper foundation for the evidence. These documents are the July 2003 FDA Conditions of Approval for the Hi Res 90k, the 2004 Pernicka report for Device No. 200064, the 2004 Pernicka Report for Device No. 201084, the 2004 Trip Report to Pernicka Lab in Colorado, and the Failure Analysis Report for Device No. 308051.

Advanced Bionics argues that these four documents are irrelevant under Fed. R. Evid. 401. The Court agrees that the 2001 Form 483 is irrelevant, because the FDA issued the report eighteen months before Advanced Bionics received FDA approval for the HiRes 90k. The report concerned earlier generations of the cochlear implant, which are not at issue in this case. Moreover, the 2001 Form 483 noted deficiencies in Advanced Bionics' supplementation obligations, but the Court has already determined that the Federal Food Drug and Cosmetic Act, and particularly the Medical Device Amendment to that legislation, preempts claims based upon Advanced Bionics' failure to obtain a PMA Supplement for the Vendor B HiRes 90k and other supplementation requirements. Therefore, the contents of the 2001 Form 483 are not relevant to any issue presently before the Court.

However, the Court finds that the 2004 Form 483, 2005 Warning Letter, and 2007 Form 483 are relevant. The forms and letter are a product of FDA investigations of Advanced Bionics' facilities and products, relate to the HiRes 90k, and reveal issues in Advanced Bionics' manufacturing practices that caused excessive moisture levels in these cochlear implants. That the FDA based the 2004 Form 483 and 2005 Warning Letter upon a mis-diagnosis of the hermeticity issue is important and a fact that Advanced Bionics is free to emphasize at trial, but the information contained within these documents show evidence of Advanced Bionics' notice of moisture problems with the HiRes 90k. Therefore, the documents are relevant.

Advanced Bionics argues that these documents are inadmissible hearsay. These documents are hearsay, but admissible under the public records exception to the hearsay rule located in Fed. R. Evid. 803(8). This rule provides that records of a public office that set out "a matter observed while under a legal duty to report" or "factual findings from a legally authorized investigation" are

excepted from the hearsay prohibition if these documents are sufficiently trustworthy. Fed. R. Evid. 803(8). These documents report factual findings[2] and matters observed under the FDA's investigatory authority. While courts are divided on the admissibility of evaluative reports under this exception, the Advisory Committee notes to this rule encourage courts to admit this evidence unless "sufficient negative factors are present." Fed. R. Evid. 408 advisory committee's notes. These negative factors are (1) the timeliness of the investigation, (2) the special skill or experience of the official, (3) whether a hearing was held, and (4) possible motivational problems. *Id.* The Court finds that only one of these factors–holding a hearing–weighs against the trustworthiness of these documents. However, when balanced with the other three factors, the trustworthiness indicators are sufficient to support admissibility of the evidence. FDA officials conducted the investigation themselves as a neutral party with motivations to protect public health and safety. Therefore, the Court finds these documents sufficiently reliable to be excepted from the hearsay rule.

The Court concludes that 2004 Form 483, 2005 Warning Letter, and 2007 Form 483 contain the reliable observations of the federal agency in charge of regulating medical device manufacturing, so the jury should afford the documents a certain weight. Though undue prejudice is possible, Advanced Bionics will have ample opportunity to show that the statements in the documents are mere observations. Moreover, the Court will issue a cautionary instruction at trial that can temper any undue weight as to opinions contained in the Form 483s.

[2] Advanced Bionics makes a strong argument for inadmissibility under the principle that legal conclusions are not permitted under Fed. R. Evid. 803(8). After a review of the relevant evidence, the Court finds that most of the content of these documents comes in the form of observations and factual findings. However, if Advanced Bionics maintains that specific sections of these documents go beyond mere observations into the realm of legal conclusions, the Court will entertain an objection to those specific sections. At this time, however, the Court makes no comment as to whether legal conclusions are admissible under Fed. R. Evid. 803(8).

Advanced Bionics' character evidence argument, while creative, is not persuasive. Accordingly, the Court finds the 2001 Form 483 inadmissible as irrelevant, and the 2004 Form 483, 2005 Warning Letter, and 2007 Form 483 admissible.[3]

II.

Turning to Defendant's Motion Number 3, on November 6, 2011, the FDA filed a complaint against Advanced Bionics and its two co-CEOs, Jeffrey Greiner and Al Mann, for shipping 74 HiRes 90k devices without first submitting a PMA Supplement for those devices or receiving FDA approval for the device with AstroSeal feedthrus. On March 17, 2008, the FDA amended the complaint to release Al Mann as a defendant and add allegations that Advanced Bionics failed to sufficiently evaluate and select AstroSeal as a component manufacturer and adequately validate and test devices with AstroSeal feedthrus. Later, the FDA submitted a second amended complaint in which it dropped the claims added in the first amended complaint. In 2008, the parties settled the case. Advanced Bionics paid $1.1million and Jeffrey Greiner paid $75,000 in the settlement, but made no admission of liability. In Motion Number 3, Advanced Bionics seeks to exclude all evidence of or reference to the CMP, including the original and two amended complaints, answers, settlement agreement, and press releases.

The Court sustains Defendant's motion for several reasons. First, the Court finds the original and first amended complaints inadmissible, because they do not represent the FDA's final determination as to Advanced Bionics' alleged liability in the CMP. That there is a second amended complaint shows that the FDA's two preliminary complaints were abandoned for purposes of the

[3] Advanced Bionics' motion also sought to exclude "related communications". However, Advanced Bionics failed to identify the related communications. Therefore, Advanced Bionics should submit any specific arguments as to the admissibility of related communications for further consideration.

CMP. In light of the fact that the FDA only pursued the CMP on the second amended complaint, the two preceding complaints are irrelevant to the CMP itself and do not "possess[] sufficient probative value to justify receiving it in evidence." Fed. R. Evid. 401 advisory committee's note.

Second, the fact of settlement, the nature of the settlement, and the settlement agreement itself are inadmissible under Fed. R. Evid. 408 for purposes of proving liability or validity of the claims. Rule 408 prohibits evidence of "furnishing, promising, or offering–or accepting, promising to accept, or offering to accept–a valuable consideration in compromising or attempting to compromise the claim" and "conduct or a statement made during compromise negotiations about the claim" for purposes of proving or disproving "the validity or amount of a disputed claim or to impeach by a prior inconsistent statement." Fed. R. Evid. 408(a). The committee notes make clear that the rule applies to completed compromises, and that the term validity is intended to encompass liability. Fed. R. Evid. 408 advisory committee's notes. The settlement evidence is inadmissible to prove Advanced Bionics' liability.

Plaintiffs contend that they will introduce this evidence for other purposes, which Fed. R. Evid. 408(b) permits. Specifically, Plaintiffs seek to introduce this evidence for three purposes: to prove witness bias, to negate a contention of undue delay, and to show notice that Advanced Bionics' conduct was wrongful, that Advanced Bionics acted in bad fath, and of Advanced Bionics' intent. Plaintiffs present no definitive situation in which the evidence concerning the settlement can prove witness bias, and neither party has argued undue delay. Moreover, the FDA filed its complaint for the CMP in 2007, two years after Advanced Bionics manufactured Plaintiffs' HiRes 90k and one year after surgeons implanted Plaintiff B.S. with her HiRes 90k. Therefore, this evidence could not give notice of anything relevant to this suit. Accordingly, this evidence is

inadmissible, except to the extent that Plaintiffs use this evidence for permissible purposes of proving witness bias or negating allegations of undue delay.

Finally, evidence of the CMP and documents submitted therein, are inadmissible under Fed. R. Evid. 402 and 403, because this evidence is irrelevant to the present case and would be unduly prejudicial. Evidence is relevant where "it has any tendency to make a fact more or less probable than it would be without the evidence." Fed. R. Evid. 401(a). The evidence contained in the second amended complaint and the answers filed in the CMP do not satisfy this standard. Plaintiffs claim that this evidence is relevant for four reasons. First, Plaintiffs allege that this evidence shows that Advanced Bionics had notice of problems and flaws in the company's compliance with the FDA regulations. However, notice is an inapposite argument here, because the CMP post-dated the manufacture and implantation of Plaintiffs' cochlear implant. Second, Plaintiffs contend that the CMP shows the extent and nature of Advanced Bionics' conduct. However, the statements made in civil complaints are mere allegations, and have not been validated by any authority, including the FDA itself. The second amended complaint and answers also pertain to those claims this Court already preempted, and therefore, the relevance of any reliable substance in this evidence is marginal at best to any surviving claims.

This evidence could be deemed admissible in certain circumstances where Advanced Bionics opens the door to introduction of the CMP. However, the two situations Plaintiffs proffer to support the relevance of this evidence do not justify a judicial determination that Advanced Bionics opened the door. Plaintiffs assert that where Advanced Bionics argues that the FDA offered an incorrect opinion as to the source of the excessive moisture accumulation and where Advanced Bionics pursues the learned intermediary doctrine, Advanced Bionics opens the door to the admissibility of

the CMP evidence. Essentially, Plaintiffs argue that if Advanced Bionics offers one FDA opinion, this opens the door to all FDA opinions, and if Advanced Bionics presents evidence about what hazards doctors knew at the time of B.S.'s surgery, this opens the door to what the United States government knew around this time. Plaintiffs are attempting to apply a narrow evidentiary principle too broadly. Moreover, these arguments do not support the relevancy argument. As such, the evidence does not tend to make any material fact more or less likely.

If the Court admitted this evidence, however, the jury may accord undue weight to the evidence. Because the FDA, a federal government agency, wrote the complaint, the jury may weigh the allegations as something more definitive than mere assertions. Advanced Bionics would then be forced to devote time to explaining the actual meaning and effect of allegations in complaints, explanations that are of no real consequence to the present case.

In sum, the Court finds that any evidence pertaining to the CMP irrelevant and in violation of Fed. R. Evid 401, 402, 403, and 408. Accordingly, this evidence is inadmissible.

Being otherwise sufficiently advised,

IT IS HEREBY ORDERED that Defendant's Motion *in Limine* Number 4 is SUSTAINED in part and DENIED in part. Accordingly, the 2004 Form 483, 2005 Warning Letter, and 2007 Form 483 are admissible, and the 2001 Form 483 is inadmissible.

IT IS FURTHER ORDERED that Plaintiffs' Motion to Deem Documents Admissible is SUSTAINED in part, DENIED in part, and the remaining sections reserved for further consideration, consistent with this Opinion.

IT IS FURTHER ORDERED that Defendant's Motion *in Limine* Number 3 is SUSTAINED and reference to and evidence of the Civil Monetary Penalty action, including the original and

amended complaints, answers, and settlement agreement, are inadmissible as described in this Opinion.

John G. Heyburn II, Judge
United States District Court

March 26, 2013

cc: Counsel of Record