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UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF KENTUCKY  
LOUISVILLE DIVISION  
CIVIL ACTION NO. 3:11-CV-00450-TBR

**BRIAN SADLER and MICHELLE SADLER,  
Individually, and On Behalf of Their Minor  
Child BREANNA SADLER**

**v.**

**ADVANCED BIONICS, LLC**

**JURY INSTRUCTIONS**

## INTRODUCTION

Members of the jury, it is now time for me to instruct you about the law that you must follow in deciding this case. I will start by explaining your duties and the general rules that apply in every civil case. Then I will explain the elements, or parts, of the claims in question.

You have two main duties as a juror. The first is to decide what the facts are from the evidence that you saw and heard here in court. Deciding what the facts are is your job, not mine, and nothing that I have said or done during this trial was meant to influence your decision about the facts in any way.

Your second duty is to take the law that I give you, apply it to the facts, and decide if the plaintiffs have proved their case against the defendant by a preponderance of the evidence. It is my job to instruct you about the law, and you are bound by the oath you took at the beginning of the trial to follow the instructions that I give you, even if you personally disagree with them. This includes the instructions that I gave you during the trial, and these instructions now. All the instructions are important, and you should consider them together as a whole.

The attorneys for the plaintiffs and defendant may have talked about the law during their arguments. But if what they said is different from what I say, you must follow what I say. What I say about the law controls.

Perform these duties fairly. Do not let any bias, sympathy, or prejudice that you may feel toward one side or the other influence your decision in any way. In deciding this case, you should consider it as a dispute between persons of equal standing in the community and holding the same or similar stations in life. All persons, including

corporations and other organizations, stand equal before the law, and are to be treated as equals.

Upon retiring to the jury room, you will select one juror to act as your foreperson. The foreperson will preside over your deliberations and will be your spokesperson here in Court. You will take these instructions to the jury room, and when you have reached a unanimous agreement, you will have your foreperson fill in, date, and sign your answers.

Once you start deliberating, do not talk to the jury officer, or to me, or to anyone else except each other about the case. If you have any questions or messages, you must write them down on a piece of paper, sign them, and give them to the jury officer. The officer will give them to me, and I will respond as soon as I can. I may have to talk to the parties about what you have asked, so it may take some time to get back to you. Any questions or messages normally should be sent to me through your foreperson.

One more thing about messages. Do not ever write down or tell anyone outside the jury room how you stand on your votes. That should stay secret until you are finished.

Your verdict or answer to any question must be unanimous. That is, all ten (10) members of the jury must agree on any answer to the question and on the verdict.

It is your duty as jurors to consult with one another and to deliberate with a view to reaching an agreement, if you can do so without violence to individual judgment. You must each decide the case for yourself, but only after an impartial consideration of the evidence of the case with your fellow jurors. In the course of your deliberations, do not hesitate to reexamine your own views and change your opinion, if you are

convinced it is erroneous. But do not surrender your honest conviction as to the weight or effect of the evidence solely because of the opinion of your fellow jurors or for the mere purpose of returning a verdict.

## **INSTRUCTION NO. 1**

### **Weighing the Evidence; Credibility of Witnesses**

You should use common sense in weighing the evidence and consider the evidence in light of your own observations in life. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion.

In our lives, we often look at one fact and conclude from it that another fact exists. In law we call this an “inference.” A jury is allowed to make reasonable inferences. Any inference you make must be based on the evidence in the case.

Another part of your job as jurors is to decide how credible or believable each witness was. This is your job, not mine. It is up to you to decide if a witness’s testimony was believable and how much weight you think it deserves. You are free to believe everything that a witness said, or only part of it, or none of it at all. But you should act reasonably and carefully in making these decisions. You may consider other things that you think shed some light on the witness’s believability. Use your common sense and your everyday experience in dealing with other people. Then decide what testimony you believe and how much weight you think it deserves. The weight of the evidence does not necessarily depend upon the number of witnesses who testify for either side.

## **INSTRUCTION NO. 2**

### **FDA form 483s**

You have heard evidence regarding FDA reports called “form 483s.” These documents list observations made by the FDA representatives during the inspection of Advanced Bionics. They are inspectional observations and do not represent a final Agency determination regarding Advanced Bionics compliance.

### **INSTRUCTION NO. 3**

#### **Deposition Testimony**

During the trial, certain testimony was presented to you by videotaped depositions or by depositions read to you. You should give this testimony the same weight and consideration you would give it had the witnesses appeared and testified here in court.

## **INSTRUCTION NO. 4**

### **Expert Witnesses**

The rules of evidence ordinarily do not permit witnesses to testify as to opinions or conclusions. “Expert witnesses” are an exception to this rule. Witnesses who, by education and experience, have become experts in some art, science, profession, or calling, may state their opinions as to relevant and material matters in which they profess to be an expert, and may also state their reasons for the opinion.

You should consider each expert opinion received in evidence in this case, and give it such weight as you may think it deserves. If you should decide that the opinion of an expert witness is not based upon sufficient education and experience or if you should conclude that the reasons given in support of the opinion are not sound, or if you feel that it is outweighed by the other evidence, you may disregard the opinion entirely.



## **INSTRUCTION NO. 5**

### **Juror Notes**

Some of you have taken notes during the trial. An individual juror may use notes to refresh his or her memory of evidence presented at trial, but the notes should not be relied upon as definitive fact or as evidence. Juror notes have no greater weight than memory, and note-aided and non-aided memory are of equal significance. Jurors should not be influenced by another juror's notes.

## **INSTRUCTION NO. 6**

### **Burden of Proof and “Preponderance of the Evidence”**

The burden is upon the Plaintiffs to prove every essential element of their claims by a “preponderance of the evidence.”

The term “preponderance of the evidence” is used many times in these instructions and deserves some additional explanation. To establish by the “preponderance of the evidence” means to prove that something is more likely so than it is not so. In other words, a preponderance of the evidence in this case means such evidence as, when considered and compared to that opposed to it, has more convincing force, and produces in your mind a belief that what is sought to be proved is more likely true than not true. In determining whether any fact in issue has been proved by a preponderance of the evidence in the case, you may, unless otherwise instructed, consider the testimony of all witnesses, regardless of who may have called them, and all exhibits received in evidence, regardless of who may have produced them.

The preponderance-of-the-evidence standard does not apply to the issue of punitive damages. I will discuss the higher burden the Plaintiffs must meet with regard to punitive damages later in these instructions.

## INSTRUCTION NO. 7

### Strict Products Liability

Plaintiffs claim that Defendant Advanced Bionics' cochlear implant device implanted into Plaintiff Breanna Sadler was unreasonably dangerous because of a defect in the design and/or manufacture of that device.

A product is "unreasonably dangerous" if it creates such a risk of injury or death that an ordinarily prudent company engaged in the design or manufacture of similar products, being fully aware of the risk, would not have put it on the market.

You will find for the Plaintiffs and against the Defendant, Advanced Bionics, if you are satisfied that the Plaintiffs have proved by a preponderance of the evidence each of the following:

(1) The cochlear implant, as designed or manufactured by Advanced Bionics, was defective and unreasonably dangerous either because:

(a) Advanced Bionics failed to manufacture the implant in compliance with the PreMarket Application (PMA) Supplement #30 approved by the Food and Drug Administration;

*OR*

(b) Advanced Bionics failed to test the implant in compliance with 21 C.F.R. § 820.30(g), which requires that a device's design be validated under actual or simulated use conditions;

*AND*

(2) The defect in the design or manufacture of the cochlear implant was a substantial factor in causing Plaintiffs' injuries.

“Substantial factor,” as used in this and all the following instructions, means an event or occurrence that caused or was responsible for an injury as opposed to an event or occurrence that only had an insignificant or negligible effect. That is, an act or failure to act must play a significant part in bringing about or actually causing the injury, and the injury must have been the direct result or reasonably probable consequence of the act or omission. The law recognizes that a substantial factor need not be the sole cause of any injury but may be one of other substantial factors.

Please proceed to Verdict Form No. 1. When you have completed Verdict Form No. 1, please proceed to Instruction No. 8.

## INSTRUCTION NO. 8

### Negligence

Plaintiffs claim that Defendant Advanced Bionics was negligent in its design and manufacture of Plaintiff Breanna Sadler's Advanced Bionics cochlear implant.

A person is "negligent" when the person fails to exercise ordinary care. "Ordinary care" as applied to Defendant Advanced Bionics means such care as the jury would expect an ordinarily prudent company in the same type of business to exercise under similar circumstances.

You will find for the Plaintiffs and against Defendant Advanced Bionics if you are satisfied that the Plaintiffs have proved by a preponderance of the evidence each of the following:

(1) Advanced Bionics failed to exercise the care expected of an ordinarily prudent manufacturer of cochlear implant devices under similar circumstances because Advanced Bionics either:

(a) failed to manufacture the implant in compliance with the PreMarket Application (PMA) Supplement #30 approved by the Food and Drug Administration;

*OR*

(b) failed to test the implant in compliance with 21 C.F.R. § 820.30(g), which requires that a device's design be validated under actual or simulated use conditions;

*AND*

(2) Advanced Bionics' failure to exercise such care was a substantial factor in causing the Plaintiffs' injuries.

Please proceed to Verdict Form No. 2. If your answer is "YES" under either this Instruction or Instruction No. 7, please proceed to Instruction No. 9 after you have

completed Verdict Form. No. 2. If your answer is "NO" under both this Instruction and Instruction No. 7, your verdict is complete, please return to the Courtroom.

## INSTRUCTION NO. 9

### Compensatory Damages

If you decided in favor of Plaintiffs under Instruction No. 7 and/or Instruction No. 8, then you must determine the amount that is fair compensation for all of the Plaintiffs' damages. These damages are called compensatory damages. The purpose of compensatory damages is to make the Plaintiffs whole—that is, to compensate the Plaintiffs for the damages that they have suffered.

In this case, Plaintiffs are seeking compensatory damages in an unspecified amount for Plaintiff Breanna Sadler's physical injury and pain and suffering, both mental and physical, to date. Plaintiffs are also seeking compensatory damages in specified amounts for Plaintiff Breanna Sadler's medical expenses, for the Plaintiffs' travel expenses and *per diem*, and for Plaintiff Brian Sadler's lost wages.

You may award compensatory damages only for injuries that the Plaintiffs proved were caused directly by the Defendant's allegedly wrongful conduct. The damages that you award must be fair compensation for all of the Plaintiffs' damages, no more and no less. Compensatory damages are not allowed as punishment and cannot be imposed or increased to penalize the Defendant. You should not award compensatory damages for speculative injuries, but only for those injuries which the Plaintiffs have actually suffered.

If you decide to award compensatory damages, you should be guided by dispassionate common sense. Computing damages may be difficult, but you must not let

that difficulty lead you to engage in arbitrary guesswork. On the other hand, the law does not require that the Plaintiffs prove the amount of their losses with mathematical precision, but only with as much definiteness and accuracy as the circumstances permit.

If you find for the Plaintiffs you should compensate Plaintiff Breanna Sadler for any bodily injury and any resulting pain and suffering, either mental or physical, to date. No evidence of the value of such intangible things as mental or physical pain and suffering has been or need be introduced. In that respect, it is not the value you are trying to determine, but an amount that will fairly compensate the Plaintiffs for the damages they have suffered. There is no exact standard for fixing the compensation to be awarded on account of such elements of damage. Any such award should be fair and just in light of the evidence.

Please enter the amount of your verdict for compensatory damages, if any, on Verdict Form No. 3.

When you have completed Verdict Form No. 3, proceed to Instruction No. 10.



## **INSTRUCTION NO. 10**

### **Punitive Damages**

If you find in favor of the Plaintiffs under Instruction No. 7 and/or Instruction No. 8, then, in addition to any compensatory damages to which you find the Plaintiffs entitled under Instruction No. 9, you may, but are not required to, award the Plaintiffs an additional amount as punitive damages. You should consider the purposes of punitive damages in considering whether to award them. The purposes of punitive damages are to punish the Defendant for conduct that is outrageous because of the Defendant's alleged reckless indifference toward the Plaintiffs and to deter the Defendant and others like it from doing similar things in the future, or both.

You may only award punitive damages if you find, by clear and convincing evidence, that Defendant Advanced Bionics acted with reckless disregard for the lives, safety, or property of others, including the Plaintiffs. "Clear and convincing evidence" is evidence that produces in your mind a firm belief or conviction as to the matter at issue. Clear and convincing evidence involves a greater degree of persuasion than is necessary to meet the preponderance of the evidence standard; however, this standard does not require proof to an absolute certainty.

Whether to award the Plaintiffs punitive damages is within your sound discretion. That is, if you find that the legal requirements for punitive damages are satisfied, then you may decide to award punitive damages, or you may decide not to award them.

Your discretion to determine and award an amount, if any, of punitive damages is limited to the following factors:

- (1) the harm to the Plaintiffs, as measured by the compensatory damages you have awarded under Instruction No. 9, caused by Defendant Advanced Bionics' conduct or failure to comply with its duties; and
- (2) the degree, if any, to which you find from the evidence that the Plaintiffs have proved, by clear and convincing evidence, that Defendant Advanced Bionics' conduct or failure to comply with its duties was reprehensible.

In considering whether Defendant Advanced Bionics' conduct or failure to comply with its duties was "reprehensible," you may only consider the following factors:

- (a) whether the harm caused was physical as opposed to economic;
- (b) the degree to which Advanced Bionics' conduct evinced an indifference to, or a reckless disregard of, the health and safety of others;
- (c) the degree to which Advanced Bionics' conduct involved repeated actions as opposed to an isolated incident;
- (d) the likelihood that serious harm would arise from Advanced Bionics' conduct;
- (e) the degree of Advanced Bionics' awareness of that likelihood;
- (f) the profitability of the conduct to Advanced Bionics;
- (g) the duration of the conduct and any concealment of it by Advanced Bionics;
- (h) the likelihood that Advanced Bionics would repeat the conduct if punitive damages were not awarded; and
- (i) any actions by Advanced Bionics to remedy the conduct once it became known to Advanced Bionics.

In determining reprehensibility, you may consider evidence of actual harm to persons other than the Plaintiffs in deciding whether the conduct that harmed the Plaintiffs also posed a substantial risk of harm to others. However, you may not use punitive damages to punish the Defendant directly on account of harms it is alleged to have caused on persons other than the Plaintiffs.

Please enter the amount of your verdict for punitive damages, if any, which relates to the Plaintiffs' claims, on Verdict Form No. 4.

When you have completed Verdict Form No. 4, your verdict is complete, please return to the Courtroom.