JISRF Editorial Comments

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"Kransk ASR® Jury Award"

I believe we have the best of all world opportunities here in the United States but there are times when I wonder about our justice system. The Kransk ASR judicial hearing has highlighted the recent problems of metal-on-metal bearings.[1] Wear generated debris from bearings of total hip arthroplasties and resurfacing arthroplasties can cause considerable tissue destruction and bone necrosis causing long-term patient disability. The metal ions may also be disseminated systemically within the patient's body.

The recent decision of the jury to award $8,338,000 in compensation damages for a revised ASR metal-on-metal bearing hip seems to be excessively punitive, even though the jury found that DePuy adequately warned of the risks associated with their use of this device. Kransky's lawyers had asked jurors for $338,000 in economic damages, $5 million in economic damages for pain and suffering, and up to $179 million in punitive damages. No punitive damages were awarded, so it is reasonable to question the additional $3 million beyond the asking compensation for pain and suffering.

Since the jury awarded higher than requested compensation for pain and suffering one has to ask was this decision the act of an overly sympathetic jury especially in light of a comment made by a juror after the verdict "I wanted punitive damages."[1]

Elective surgery is not without inherent risks. The question of who is ultimately accountable for a failed surgery that requires replacement surgery of a potentially deficient implant remains an open debate. Should the surgeon be held responsible as he is the final decision maker on which type of implant he will use in the patient's best interest? Should the hospital have an active role in the implant choice and what of the insurance company who is the payer for the device and the surgical procedure? The FDA is the august body which regulates the use of devices and allows the implant to be sold on the market and used to improve patients' hip pain and function once they have been deemed to be effective and safe for use in patients.

In addition lets not forget the patient who electively decides on surgery and may not follow surgeon instructions on related physical activities. There is no single decision maker who justifiably is solely responsible in this process.

What role should our legal system play when we (the orthopedic community) make honest mistakes when striving to advance technology that has the potential to benefit patients? Problems with a variety of bearing materials have arisen. Some are specifically related to the material properties, others to the design of the implant as well as surgical error. In my opinion this is an industry that has taken care to self-regulate and is aided by the Continuing Medical Education (CME) system. As we are about to begin the 2013 American Academy of Orthopedic Surgeons Annual Meeting in Chicago IL, we will see papers and lectures on design and technical problems associated with total joint surgery. All delegates attend to learn and stay current in an ever-changing environment. Why? So they can provide the best possible care for their patients.

The legal argument against the ASR hip system was that the design was defective. Have we seen poorly designed devices that have come to market? No designer, bioengineer, or product company knowingly marketed a design deficient implant. It is extremely difficult to anticipate all the potential failure modes that can affect the performance of a new device. In my 42 years as a member of the orthopedic community and as a designer of total joints (14 patents), I am well aware of the burden of trying to anticipate failure modes, while at the same time striving to advance patient outcomes. The benefit of hindsight is a luxury.

Regrettably it is the patient that bears the brunt of a flawed implant and they should be properly compensated for their pain, loss, and possible permanent curtailment of their chosen lifestyle. In this particular case the restive process of preventing

the jury from hearing testimonies may have been critical to the final conclusion of the hearings. The jury did not have the benefit of the details about the FDA's review in the evaluation and clearance of the ASR device. Why would such a critical part of the process of the analysis of a new device be denied to the jurors? We are aware that to bring a new device to market there remains a rigorous process in place before any product can be sold or implanted.

It is my understanding that DePuy will appeal. I am not suggesting that DePuy should not be held liable, but it would be in the best interests of all parties concerned that all the facts be argued and debated in the courts. Only then can the merits of this case be fully appreciated and decisions rendered.

What have we, the orthopedic community, learned from the recent legal arguments? We should note that implant manufacturers involved in patient care should uphold the highest quality and integrity not only in device testing, but also in post-market evaluation of their products. Is the FDA 510K pathway (of a substantive equivalent) adequate given that minor alterations of device design may radically alter the clinical outcome? Perhaps there should be a controlled exposure of a new device into the market to allow for the careful monitoring of failures of any device over time. To this end, there is a real requirement for a national joint registry. We all understand and appreciate that it remains a privilege to care for patients and that we are all accountable.

It appears to me that the jury may have put punitive damages in a compensatory verdict and the court should consider using its power to reduce it to the reasonable amount.

I have discussed this verdict with legal healthcare experts who have agreed with my observations and opinions. However, this Editorial Comment is made by me and does not represent the opinion of the Reconstructive Review Editorial Board or the Board of Trustees, or Clinical Surgical Advisors for The Joint Implant Surgery & Research Foundation.

Compensatory Damages[2]

Compensatory damages provide a plaintiff with the monetary amount necessary to replace what was lost, and nothing more. In order to be awarded compensatory damages, the plaintiff must prove that he or she has suffered a legally recognizable harm that is compensable by a certain amount of money that can be objectively determined by a judge or jury.

Punitive Damages[3]

Monetary compensation awarded to an injured party that goes beyond that which is necessary to compensate the individual for losses and that is intended to punish the wrongdoer.

Reference:

1. Orthopaedics This Week - Monday, March 11, 2013
2. http://legal-dictionary.thefreedictionary.com/Compensatory+Damages
3. http://legal-dictionary.thefreedictionary.com/punitive+damages