

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>SANDRA TAYLOR, ET AL.</b>	<b>:</b>	<b>CIVIL ACTION</b>
	<b>:</b>	
<b>v.</b>	<b>:</b>	<b>95-7232</b>
	<b>:</b>	
<b>DANEK MEDICAL, INC., ET AL.</b>	<b>:</b>	

**MEMORANDUM**

**Broderick, J**

**May 10, 1999**

This is a bone screw case. Plaintiff Sandra Taylor and her husband claim damages arising out of the implantation of the Cotrel-Dubousset (“CD”) system in Mrs. Taylor’s spine during surgery on April 10, 1992. Defendants Danek Medical, Inc., Sofamor S.N.C., Sofamor-Danek and Sofamor Inc. (collectively “Sofamor”) are the manufacturers of the CD device. Defendant Youngwood Medical Specialties, Inc. f/k/a National Medical Speciality, Inc., f/k/a Stuart Medical Speciality, Inc. (“Youngwood”) is the distributor.

Presently before the Court are several motions by the parties: Defendant Sofamor’s motion to preclude the testimony of Plaintiff’s medical causation expert Dr. Madgy Shady (Docket Number 82 ); Defendant Sofamor and Defendant Youngwood’s joint motion to preclude the testimony of Plaintiff’s expert Dr. Harold Alexander (Docket Number 113); and Defendant Sofamor’s and Defendant Youngwood’s motions for reconsideration of summary judgment (Docket numbers 103 and 106 ). For the reasons stated below, this Court will deny Defendant Sofamor’s motion to preclude the testimony of Plaintiff’s medical causation expert Dr. Madgy Shady and deny Defendant Sofamor and Defendant Youngwood’s joint motion to preclude the testimony of Plaintiff’s expert Dr. Harold Alexander. Defendant Sofamor’s and

Defendant Youngwood's motions for reconsideration of summary judgment will be denied, and this Court's December 29, 1998 Memorandum and Order shall remain in full force and effect.

***Dr. Shady***

Rule 702 of the Federal Rules of Evidence provides: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." The United States Supreme Court's "trilogy" of cases governing the admissibility of scientific and other expert testimony: Daubert v. Merrell Dow Pharm. Inc., 509 U.S. 579 (1993); General Electric Co. v. Joiner, 522 U.S. 136 (1997); and Kumho Tire Co. v. Carmichael, 119 S.Ct. 1167 (1999), provide guidance in clarifying the "gatekeeping" function of District Courts. District Courts must ensure that testimony from a qualified expert is both relevant and reliable in order for it to be presented to a jury. See Daubert 509 U.S. 579 (1993).

The first requirement of Rule 702 is that the expert be qualified. Defendants contend that Dr. Shady is not qualified to testify as an expert in this case because he is a neurologist who specializes in trauma and has never performed a spinal fusion procedure. However, the Third Circuit has held that an expert can be qualified using a broad range of knowledge, skills and training. In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741 (3d Cir. 1994) ("Paoli II"). The Third Circuit has "eschewed imposing overly rigorous requirements of expertise and [has] been satisfied with more generalized qualifications." Id. at 741.

Dr. Shady holds two medical degrees from Mansoura University, in Mansoura Egypt, the

most recent being a master's in general surgery completed in 1981. Beginning in 1978, Dr. Shady completed several neurosurgery residencies and fellowships at hospitals in Egypt, Canada, and the United States. He has spoken on lumbar disk disease and has written on lumbar disk protrusion. Dr. Shady is certified by the American Board of Neurological Surgery. Since 1991, Dr. Shady has been an Assistant Professor of Neurosurgery at the State University of New York at Stony Brook.

The Court finds Dr. Shady's training and experience qualify him to offer his expert opinion on the issue of medical causation. Without going into a protracted analysis of his credentials, publications and the nature of his responsibilities as Assistant Professor of Neurosurgery at the State University of New York at Stony Brook, Dr. Shady's curriculum vitae and expert reports reflect his experience with issues related to lower back pain. Defendants' focus on Dr. Shady's credentials and his relative lack of experience with procedures involving pedicle screw fixation and bone fusion are issues properly evaluated by a jury. This Court finds Dr. Shady qualified to testify, as set forth in his reports, that Plaintiff's increased back pain was caused by the CD pedicle screw instrumentation.

The second requirement of Rule 702 is that the expert's opinions are reliable. Daubert holds that an expert's opinion must be based on "methods and procedures of science" rather than on "subjective belief or unsupported speculation." 509 U.S. at 590. With respect to this requirement, the Third Circuit has cautioned that the reliability requirement "must not be used as tool by which the court excludes all questionably reliable evidence." Paoli II, 35 F.3d at 745.

Dr. Shady formed his opinions after examining Mrs. Taylor's medical records. These records contained the results of physical exams performed by other physicians, and medical

histories compiled by other physicians. In his reports, Dr. Shady reviews Mrs. Taylor's records and opines with a reasonable degree of medical certainty that the CD device with pedicle screw instrumentation was the cause of Mrs. Taylor's increased pain.

The Court recognizes that Defendants have pointed out areas in Dr. Shady's methodology which they consider weaknesses, but these criticisms do not render his proposed testimony so fundamentally unsupported that they could not help the fact finder. Similarly, Defendants' contentions that Dr. Shady did not review all of the relevant medical records goes to the weight of his testimony, rather than the admissibility. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are traditional and appropriate means of attacking shaky but admissible evidence." Daubert, 509 U.S. at 596.

Finally, Rule 702 requires that the testimony must assist the trier of fact. This is referred to as the "fit" requirement. Paoli II, 35 F.3d at 743. Once again, the Third Circuit has advised that "the standard is not that high." Id. at 745. Dr. Shady's opinions that Mrs. Taylor's injuries were due to irritation of soft tissue, nerve root irritation, scarring and fibrosis caused by the CD device with pedicle screw instrumentation can assist the fact finder and his opinions "fit" the facts of the case.

Accordingly, because the Court finds that Dr. Shady is qualified to testify as an expert and that his methodologies and conclusions are sufficiently reliable under Daubert and its progeny, the Defendants' Motion will be denied.

***Dr. Alexander***

Plaintiff offers Harold Alexander, Ph.D., as an expert in the field of orthopedic

bioengineering, to give “opinions concerning the risks posed by orthopedic devices and the adequacy of testing to determine the safety and effectiveness of such devices in clinical use.” Judge Bechtle, as the transferee court for the federal multi-district litigation in bone screw cases, has already ruled on a Daubert challenge to Dr. Alexander. In an opinion which applied to all of the federal bone screw cases, including this case, Judge Bechtle found that Dr. Alexander is qualified to testify “on matters concerning orthopedic bioengineering and its related disciplines” including “biomechanics, biomaterial, biomechanical engineering, and design and analysis of device research.” In re Orthopedic Bone Screw Prod. Liab. Litig., 1997 WL 39583 (E.D.Pa. Jan. 23, 1997).

Judge Bechtle found Dr. Alexander is an expert in orthopedic bioengineering and its related disciplines, including “biomechanics, biomaterials, biomechanical engineering, and design and analysis of device research.” Judge Bechtle noted that biomechanical engineering is the study of “how a device should be designed and constructed.” Id. at \*1 fn.4. Moreover, Judge Bechtle noted that “[d]esign and analysis of device research is the study of ‘the proper design and implementation of studies to determine the existence, nature and magnitude of potential risks and benefits associated with various device designs and the extent to which those risks and benefits are realized in clinical practice.’” Id. at \*1 fn 5. Therefore, pursuant to Judge Bechtle’s order, opinions regarding the adequacy of clinical product testing fall into the disciplines of orthopedic bioengineering, including biomechanical engineering and design and analysis of device research.

Moreover, Judge Bechtle recognized that “determinations concerning which of Dr. Alexander’s opinions are subject to inclusion or exclusion are more appropriately made by the ultimate trial court after remand.” Id. at \* 6. This Court finds it is in the interests of justice to

consider the opinions contained in Dr. Alexander's more recent, case-specific report dated November 18, 1998. Based on Dr. Alexander's case specific report and the curriculum vitae attached to it, this Court finds that Dr. Alexander is qualified to testify as an expert and that his methodologies and conclusions are sufficiently reliable under Daubert and its progeny.

As noted above, the first requirement of Rule 702 is that the expert be qualified, using a broad range of knowledge, skills and training. See Paoli II, 35 F.3d at 741. Dr. Alexander has three decades of experience in the fields of biomechanics and biomaterials. He holds a bachelor of science degree in aeronautics and astronautics and both a master's degree and Ph.D. in applied mechanics. For approximately 10 years, Dr. Alexander was the Director of the Department of Bioengineering at the Hospital for Joint Diseases Orthopaedic Institute. He has developed both implantable and non-implantable medical devices, and has performed or monitored all of the steps in bring a new product to clinical use.

Dr. Alexander is currently a Professor of Orthopaedic Surgery at the New York University School of Medicine, a Grant Professor of Biomedical Engineering at the Department of Mechanical Engineering of the City College of New York, and an Adjunct Professor of Biomedical Engineering at the New Jersey Institute of Technology. As a result of these experiences, Dr. Alexander has analyzed hundreds of situations where device failure has occurred and the resulting injury to the patient must be assessed and treated. Moreover, Dr. Alexander has experience on institutional review boards, which are responsible for supervising the conduct of clinical trials conducted pursuant to investigational device exemptions issued by the FDA. He has therefore gained knowledge of the requirements placed on a manufacturer by government regulation and the responsibilities placed on a manufacturer in assuring the safety

and efficacy of implantable medical devices.

Based on these extensive qualifications, Dr. Alexander is qualified as an expert in the field of orthopedic bioengineering and related disciplines, including biomechanics, biomaterial, biomechanical engineering, and design and analysis of device research. This includes how a device should be designed and constructed, as well as the proper design and implementation of studies to determine the existence, nature and magnitude of potential risks and benefits associated with various device designs and the extent to which those risks and benefits are realized in clinical practice.

As noted above, the second requirement of Rule 702 is that the expert's opinions are reliable. Once again, the Judge Bechtel has already determined that "[b]ecause Dr. Alexander brings his expertise in orthopedic bioengineering to bear on his opinions regarding the alleged risks of orthopedic screws, the court finds that the opinions he offers that fall within the realm of orthopedic bioengineering satisfy Rule 702's reliability requirement." 1997 WL 39583 at \*5. After an independent evaluation of Dr. Alexander's methodology, this Court likewise finds that Dr. Alexander's proposed testimony is sufficiently reliable to satisfy Rule 702.

Finally, Rule 702 requires that the testimony must assist the trier of fact, and "fit" the issues in the case. See Paoli II, 35 F.3d at 743. Dr. Alexander's opinions regarding the risks of pedicle screw fixation and the hazards and dangers of the CD device can assist the fact finder and his opinions "fit" the facts of the case. For example, Dr. Alexander opines that the Defendants:

did not follow appropriate product development procedures prior to the general introduction of the Cortel-Dubouset (CD) Spinal System. They did not demonstrate the safety and efficacy of the product through appropriate clinical testing to validate its [sic] design rationale. Since there are always significant risks associated with the long term implantation of foreign materials into the

human body, it must be assumed that an untested device is unsafe until it is proven to be safe through appropriate clinical testing. In the absence of this clinical data and a subsequent risk versus benefit assessment, the Sofamor-Danek Group introduced an unproven, and therefore unsafe product, into the stream of commerce. Sandra Taylor has experienced complications that are consistent with the potential risks associated with the use of the CD Spinal System.

Alexander Report, November 18, 1998 at p. 2. On page 8 of his report, Dr. Alexander states:

“Many orthopaedic surgeons did not heed FDA’s warning that these forms of spinal fixation were not proved safe and effective . . . They used these devices outside of controlled clinical studies without informing their patients of their experimental nature. . . . In spite of . . . restrictions, device manufacturers openly provided their products for pedicle fixation and encouraged orthopaedic surgeons to use them in that way.”

Finally, Dr. Alexander has also stated, on page 9 of his report:

Pedicle screw fixation involves placement of screws within the pedicles of the vertebrae. These screws are then attached to a “construct” of plates or rods which, in theory, eliminates or limits motion at the joint between the vertebrae sought to be fused. Given the anatomy and physiology of the spine, the use of screws in this manner creates a unique hazard for patients. The relatively small diameter of the pedicle and the relatively large outer diameter of the pedicle screws necessary for adequate strength, together with the irregular and unpredictable contours and course of the pedicle, make it extremely difficult for even the most experienced and skilled surgeon to reliably place the screws within the pedicle without breach or violating at least some portion of the external walls of the pedicle. The variability and unpredictability of the pedicle anatomy is even more pronounced in the deformed, diseased, or injured spine, thereby increasing the likelihood of screw misplacement under such conditions.

Dr. Alexander’s opinions regarding the risks of pedicle screw fixation and the hazards and dangers of the CD device can assist the fact finder and his opinions “fit” the facts of the case.

Accordingly, because the Court finds that Dr. Alexander is qualified to testify as an

expert and that his methodologies and conclusions are sufficiently reliable under Daubert and its progeny, the Defendants' Motion will be denied.

***For Reconsideration***

By memorandum and order dated December 29, 1998, this Court granted in part and denied in part Defendants' motions for summary judgment. Defendants subsequently filed a motion for reconsideration of the Court's Order denying Defendants' motions for summary judgment on Plaintiff's negligence per se claim in count VII and negligent failure to obtain proper regulatory clearances and negligent design claims in count VIII.

The Court has reconsidered its December 29, 1998 Memorandum and Opinion. In light of the discussion of proposed testimony of Dr. Shady and Dr. Alexander, outlined above, the Court finds no justiciable reason to amend or alter its Memorandum or Order, and said December 29, 1998 Order shall remain in full force and effect.

An appropriate Order follows.

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<b>DANEK MEDICAL, INC., ET AL.</b>	<b>:</b>	

**ORDER**

**AND NOW**, this 10th day of May, 1999; for the reasons stated in the memorandum filed on this date; **IT IS ORDERED**:

1. Defendant Sofamor's motion to preclude the testimony of Plaintiff's medical causation expert Dr. Madgy Shady (Docket Number 82) is **DENIED**;
2. Defendant Sofamor and Defendant Youngwood's joint motion to preclude the testimony of Plaintiff's expert Dr. Harold Alexander (Docket Number 113) is **DENIED**;
3. Defendant Sofamor's and Defendant Youngwood's motions for reconsideration of summary judgment (Docket numbers 103 and 106 ) are **DENIED**.

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RAYMOND J. BRODERICK, J