

**UNPUBLISHED**

**UNITED STATES COURT OF APPEALS**

**FOR THE FOURTH CIRCUIT**

THERESA L. FITZGERALD; JOHN  
PATRICK FITZGERALD, JR.,  
Plaintiffs-Appellants,

v.

SMITH & NEPHEW, INCORPORATED,  
Defendant-Appellee,

SMITH & NEPHEW PLC; BURNETT  
MEDICAL COMPANY, INCORPORATED;  
T. G. MEDICAL, INCORPORATED;  
LARRY GROSS & ASSOCIATES,  
INCORPORATED; HERRINGTON AND  
ASSOCIATES, INCORPORATED;  
ORTHOPEDIC SYSTEMS, INCORPORATED;  
DUSTY SULLIVAN CORPORATION;

No. 00-1145

ABRAHAM ROGOZINSKI; CHAIM  
ROGOZINSKI; SAM ROGOZINSKI; JAMES  
WALT SIMMONS; WILLIAM WATTERS,  
III; G. LEE CROSS; GARTH RUSSELL;  
AMERICAN ACADEMY OF ORTHOPEDIC  
SURGEONS; NORTH AMERICAN SPINE  
SOCIETY; SCOLIOSIS RESEARCH  
SOCIETY; COLUMBIA REGIONAL  
HOSPITAL; JACKSONVILLE MEMORIAL  
MEDICAL CENTER; GEORGIA BAPTIST  
HOSPITAL; ST. LUKE'S EPISCOPAL  
HOSPITAL; MASSACHUSETTS GENERAL  
HOSPITAL; SAN ANTONIO REGIONAL  
HOSPITAL, AKA HUMANA; ACROMED  
CORPORATION, CHARTER NUMBER  
614043; ACROMED CORPORATION;

ACROMED CORPORATION, CHARTER NUMBER 816942; ACROMED RESEARCH AND DEVELOPMENT CORPORATION; ACROMED SPINE RESEARCH FOUNDATION, INCORPORATED; ACROMED, INCORPORATED, CHARTER NUMBER 811415; ACROMED INCORPORATED, CHARTER NUMBER 816943; ACROMED HOLDING CORPORATION, CHARTER NUMBER 811416; ACE MEDICAL COMPANY; ADVANCED SPINE FIXATION SYSTEMS, INCORPORATED; CROSS MEDICAL PRODUCTS; DEPUY-MOTECH, INCORPORATED; HOWMEDICA, INCORPORATED; SCIENTIFIC SPINAL; SYNTHES (U.S.A.); SYNTHES NORTH AMERICA, INCORPORATED; SYNTHES, A.G. CHUR; DANEK MEDICAL, INCORPORATED; SOFAMOR, INCORPORATED; SOFAMOR-DANEK GROUP, INCORPORATED; SOFAMOR, S.N.C.; NATIONAL MEDICAL SPECIALTY, INCORPORATED, AKA STUART MEDICAL SPECIALTY, INCORPORATED; ADVANCED BIOSEARCH ASSOCIATES; SPINAL SCIENCE ADVANCEMENT FOUNDATION; HEALTH INDUSTRY MANUFACTURER'S ASSOCIATION; ORTHOPEDIC SURGICAL MANUFACTURERS ASSOCIATION; SPINAL IMPLANT MANUFACTURERS GROUP; ZIMMER, INCORPORATED,  
Defendants.

Appeal from the United States District Court  
for the District of Maryland, at Baltimore.  
J. Frederick Motz, Chief District Judge.  
(CA-95-3870-Y)

Argued: September 27, 2000

Decided: June 12, 2001

Before WILLIAMS, Circuit Judge,  
HAMILTON, Senior Circuit Judge, and  
Robert E. PAYNE, United States District Judge for the  
Eastern District of Virginia, sitting by designation.

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Affirmed by unpublished per curiam opinion.

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#### **COUNSEL**

**ARGUED:** Frederick Steven Longer, LEVIN, FISHBEIN, SEDRAN & BERMAN, Philadelphia, Pennsylvania, for Appellants. Terri Steinhilber, HOGAN & HARTSON, L.L.P., Washington, D.C., for Appellee. **ON BRIEF:** Arnold Levin, Scott Levensten, LEVIN, FISHBEIN, SEDRAN & BERMAN, Philadelphia, Pennsylvania; Steven M. Pavsner, JOSEPH, GREENWALD & LAAKE, Greenbelt, Maryland, for Appellants. James B. Irwin, Nathan T. Gisclair, Jr., MONTGOMERY, BARNETT, BROWN, READ, HAMMOND & MINTZ, L.L.P., New Orleans, Louisiana, for Appellee.

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Unpublished opinions are not binding precedent in this circuit. See Local Rule 36(c).

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## OPINION

### PER CURIAM:

This is an appeal from an order of the district court granting summary judgment in favor of Smith & Nephew, Incorporated ("S&N"), the manufacturer of an allegedly defective medical device referred to as the Rogozinski Spinal Rod System ("Rogozinski System") which was implanted in Theresa Fitzgerald in 1993 and explanted in 1996. The district court granted summary judgment because, after it precluded, as unreliable, the testimony of Mrs. Fitzgerald's only expert witness on the subject of causation, there was no evidence on which a jury reasonably could find that the medical device had caused Mrs. Fitzgerald's injury. We affirm.<sup>1</sup>

### I.

Mrs. Fitzgerald has a long history of back problems dating back to 1970 when, at the age of 19, she was diagnosed with defects in the configuration of her lumbar spine. The medical history is documented in the record and is not disputed. To assess the district court's decision, it is necessary to appreciate the medical background against which the district court precluded the expert testimony as unreliable.

In December 1970, Mrs. Fitzgerald had the first of six lumbar spine surgeries, an interlaminar exploration and foraminotomy at the L4 level of her spine. J.A. 1420. However, that surgery did not relieve her symptoms (generalized back pain, which radiated into both legs). Id. Therefore, a second surgery ensued in July 1971, another foraminotomy, accompanied by an attempted fusion at the L4-L5 and L5-S1 levels of the spine. J.A. 213, 1420-21. According to Mrs. Fitzgerald, the second surgery was successful and her back pain subsided.

By 1988, however, Mrs. Fitzgerald began to again experience low back pain, accompanied by bladder problems, constipation and numb-

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<sup>1</sup> Mr. Fitzgerald's claim is for loss of consortium and depends on the same causation evidence as that offered by Mrs. Fitzgerald to support her claims. For the sake of simplicity, we will refer hereafter only to Mrs. Fitzgerald.

ness in both legs. J.A. 1422. A CAT scan revealed developmental abnormalities and degenerative changes at the L4-L5 and L5-S1 levels of Mrs. Fitzgerald's spine. Mrs. Fitzgerald fell in 1989 and she began thereafter to suffer neck pains. J.A. 1364. In January 1990, Mrs. Fitzgerald reported pain and tingling in her arms and, later in the month, she reported numbness and pain over the entire left side of her body. J.A. 1423, 1426. A CT scan revealed that Mrs. Fitzgerald's brain was normal, but it also disclosed disc difficulties. J.A. 1427. Later, Mrs. Fitzgerald was diagnosed with cervical disc disease and, in October 1990, underwent fusion surgery on her neck. J.A. 1430-35. About five weeks later, she began to complain of frequent urination and again reported discomfort in both legs. J.A. 1436-38.

Subsequently, in February 1991, Mrs. Fitzgerald continued to report bladder problems as well as tingling in her legs. J.A. 1444-45. Additionally, she continued to complain of lower back pain for which no objective cause was uncovered, notwithstanding extensive testing. In May 1991, Dr. Tolner, Mrs. Fitzgerald's treating physician, cataloged her reports of leg and back pain for the three preceding years, observed that those reports were unsupported by objective neurological findings and confessed still to be "quite at a loss to explain this patient's symptoms." J.A. 1448. Hence, Dr. Tolner referred Mrs. Fitzgerald to Dr. Randy Davis, an orthopedic surgeon.

Shortly thereafter, but also in May 1991, Dr. Davis examined Mrs. Fitzgerald, reviewed her medical history, and reached the conclusion that Mrs. Fitzgerald likely had a nonunion of the spine at L4-L5 or a pseudarthrosis there. J.A. 1449. Dr. Davis recommended rehabilitation therapy and advised Mrs. Fitzgerald that, if the rehabilitation therapy was unsuccessful, she might consider surgery to explore the fusion that had been accomplished in 1991, a surgical procedure to which Dr. Davis ascribed a 40% chance of improving Mrs. Fitzgerald's situation and a 10% chance of making it worse. J.A. 1449-50. At about the same time, Mrs. Fitzgerald consulted Dr. Barry who also recommended physical therapy. J.A. 1451-52.

Mrs. Fitzgerald, however, reported that physical therapy made her worse. J.A. 1455. She complained that she could not walk without pain and determined to proceed with surgery. After consulting again with Dr. Davis, who emphasized that he was pessimistic about the

benefit of surgery, Mrs. Fitzgerald elected to proceed with the surgical alternative and, on August 1, 1991, Drs. Davis and Tolner performed Mrs. Fitzgerald's next surgery, this time a revision lumbar laminectomy with extended foraminotomies and an L4-L5 fusion. J.A. 1455, 1456-57. They also implanted a bone growth stimulator to assist the process of fusion. J.A. 1456-57. Mrs. Fitzgerald initially reported significant improvement, and she was discharged from neurological care in December 1991. J.A. 1458. However, in February 1992, she had surgery to remove the bone growth stimulator.

A month later, in March 1992, Mrs. Fitzgerald again complained that the back pain had returned and that it significantly limited her activities. J.A. 1459. Dr. Davis expressed the opinion that she might have pseudarthrosis, but advised against further surgery because it would involve the use of plates and screws to stabilize her spine. J.A. 1460. Mrs. Fitzgerald returned to Dr. Davis in September 1992, reporting that she could no longer live with her severe and debilitating pain and that she wanted once again to consider surgical options. J.A. 1461. In November 1992, Mrs. Fitzgerald told Dr. Barry that she wanted to have surgery but that she did not want to return to Dr. Davis because she had "lost repore [sic] with him." J.A. 1462.

Dr. Barry informed Mrs. Fitzgerald, as had Dr. Davis sometime before, that further relief would require implanting the Rogozinski System. Dr. Barry's records reflect that he informed Mrs. Fitzgerald that there was "significant risk of damage to nerve roots from placement of pedicle screws possibly requiring the need to go back and remove the screws." J.A. 1462. Dr. Barry also recorded that Mrs. Fitzgerald "understands that even with the instrumentation there was no guarantee that the fusion would take and that the instrumentation itself would not hold up without a solid fusion." Id.<sup>2</sup> Mrs. Fitzgerald's next surgery, implantation of the Rogozinski System, was performed on January 21, 1993 to fuse the spine at the L4-L5 level. J.A. 1417-19.

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<sup>2</sup> Dr. Tolner corroborated this information, although Mrs. Fitzgerald now contends that neither doctor warned her of the experimental nature of the Rogozinski System. J.A. 1464.

Immediately after that surgery, Mrs. Fitzgerald reported improvement; and, on a follow-up visit in May 1993, she had no back or leg pain, and she reportedly was "very pleased" with the result of the surgery. J.A. 1469. That circumstance did not last long, and, by July 1993, Mrs. Fitzgerald complained of "some bizarre symptoms in her arms and legs" as well as headaches, weakness, short term memory loss, and difficulty judging distances. J.A. 1469-70.

Dr. Barry examined Mrs. Fitzgerald in September 1993 and observed, through x-rays, that there was a solid fusion at L4-L5 "with no change in the excellent position of the fixation hardware." J.A. 1472. Like Mrs. Fitzgerald's family doctor, Dr. Barry thought that perhaps her difficulties were psychiatric or psychological in origin and suggested exploring that alternative for treatment. Id.

In May 1994, another doctor diagnosed Mrs. Fitzgerald with fibromyalgia, J.A. 1476, a form of nonarticular rheumatism which is said to cause pain or stiffness in the lower back, neck, shoulders, arms, hands, knees, thighs, legs and feet. J.A. 1476. Later in 1994, Dr. Hennessey, a neurosurgeon, suggested that the Rogozinski System could be related to Mrs. Fitzgerald's recurring back pain and asked whether she wanted to remove it. J.A. 1474. Although Mrs. Fitzgerald refused to proceed with that course in 1994, she did have the Rogozinski System removed on August 8, 1996 after she had learned about pending multidistrict litigation involving the use of bone screws. J.A. 1479-80, 85. Dr. James Murphy performed the explant of the Rogozinski System and confirmed that, at the time, there was a solid fusion of L4-L5. J.A. 1479-80.

For a brief period after explantation of the Rogozinski System occurred, Mrs. Fitzgerald experienced relief. However, by October 1996, she again complained of "constant excruciating pain," of numbness and weakness, cervical pain, and reported that her level of activity had significantly decreased. J.A. 1414. Her complaints of cervical pain persisted into December 1997, at which time she also reported suffering from neck, arm and posterior iliac spine pain and twitching and numbness in both legs. J.A. 1416. In April 1998, nearly two years after explanation of the Rogozinski System, Mrs. Fitzgerald still complained of headaches, neck and arm pain, "chronic pain with her back and [was] severely limited in her activities." J.A. 1415.

## II.

Mrs. Fitzgerald instituted this action on October 10, 1996 and, pursuant to 28 U.S.C. § 1407, it was transferred to the multidistrict litigation pending in the United States District Court for the Eastern District of Pennsylvania. On May 28, 1999, after Judge Bechtle, the MDL judge, had resolved a goodly number of issues, the action was remanded for disposition on its merits.

The claims left for resolution on remand that remain the subject of this appeal are those of strict liability in tort, negligence in the design, manufacture, testing and marketing of the Rogozinski System and the alleged breach of the warranty of merchantability. <sup>3</sup> The Amended Complaint alleges that the assertedly defective Rogozinski System caused various injuries to Mrs. Fitzgerald's spine and neural system. Mrs. Fitzgerald's brief on appeal charges that her "symptoms increased dramatically upon the implantation of S&N's defective device and decreased significantly upon its explanation." Appellants' Opening Brief at 16. Dr. Norman M. Krause was designated to present Mrs. Fitzgerald's only evidence on the issue of causation.

Dr. Krause is a general orthopedic surgeon who does not specialize in spine surgery and who is expert neither in spinal instrumentation nor in the Rogozinski System. Although S&N asserted Dr. Krause's lack of qualifications as a ground for precluding his testimony, the district court found it unnecessary to confront that issue. It is undis-

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<sup>3</sup> The Amended Complaint asserted various claims of, and related to, fraud on the FDA. The Plaintiff argued on appeal that, in light of the "but for" proximate causation doctrine available under Maryland law, the mere implantation of the Rogozinski System would permit her claims of fraud on the FDA to proceed without the need for expert testimony. However, after oral argument in this case, the Plaintiff rightly acknowledged that the recent decision of the Supreme Court of the United States in Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 121 S. Ct. 1012 (2001), precludes her claims of fraud on, and related to, the FDA. In Buckman, the Supreme Court held that a state law action based on fraud on the FDA is preempted by the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C.A. § 360e(b)(1)(A, B). Hence, the causation argument respecting those claims is moot and we do not further consider it.

puted, however, that Dr. Krause did not examine Mrs. Fitzgerald, did not speak with her or with her treating physicians, did not review her deposition testimony and never reviewed any x-rays of Mrs. Fitzgerald's spine. J.A. 496, 581. And, it is agreed that Dr. Krause's opinion was reached, and his report prepared, based on a review of medical records. J.A. 483, 486, 496. On that basis, Dr. Krause expressed an opinion, to a reasonable degree of medical certainty, as follows:

I feel that Ms. Fitzgerald's back and leg problems were made substantially worse by the instrumentation with the Rogozinski frame in 1993. This, being a very bulky foreign body, as reflected in Dr. Alexander's defect report, caused increased tissue scarring, fibrosis, nerve root entrapment and exacerbation of her medical condition. Based on the records reviewed, I am able to rule out other potential causes of Ms. Fitzgerald's pain such as disc herniation, osteomyelitis, etc. This opinion is substantiated by the fact that her symptoms got markedly worse, including increasing leg pain, right foot drop and bowel and bladder problems directly after the 1993 surgery. The fact that Ms. Fitzgerald felt significantly better and was able to resume many of her activities of daily living starting immediately after the removal of this hardware further substantiates this assertion. The fact that, at the time of the 1996 surgery, Dr. Murphy found that several of the screws were loose and his diagnosis was retain painful hardware [sic] further substantiates this opinion.

J.A. 646. The district court concluded that "[i]n reaching his conclusions, Dr. Krause purportedly performed a differential diagnosis" which, citing Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999), the district court correctly identified as "a standard scientific technique of identifying the cause of a medical problem by eliminating the likely cause[s] until the most probable one is isolated." J.A. 1369. The district court also observed that:

In and of itself differential diagnosis certainly is a "method and procedure of science." However, in order for conclusions drawn from a differential diagnosis to be admissible, the diagnosis must be conducted with "intellectual vigor [sic]." Kumho Tire Co. v. Carmichael, 119 S. Ct. 1167, 1176

(1999). Its underlying integrity requires professional thoroughness, and it must at least "take serious account of other potential causes." Westberry, 178 F.3d at 265. Dr. Krause's diagnosis does not hold up under these standards.

Id.

The district court further correctly observed that "[w]here a plaintiff has a complicated and troubled medical history, any reliable causation testimony based on temporal relationship must be based upon complete and accurate facts,"<sup>4</sup> and concluded that Dr. Krause's opinions were based upon "only a portion of Ms. Fitzgerald's partial medical history." Id. That was because Dr. Krause failed to review most, if not all, of Ms. Fitzgerald's medical records before 1991, notwithstanding that Mrs. Fitzgerald had complained of similar back problems since 1970. As a further ground, the district court rightly found that Dr. Krause had not considered Mrs. Fitzgerald's medical records after 1996, notwithstanding that the same kind of symptoms she had expressed for years before implantation had returned after the explanation of the Rogozinski System in 1996. The district court held that those deficiencies rendered Dr. Krause's opinion scientifically unreliable considering that Dr. Krause had not examined Mrs. Fitzgerald, had not talked with her or her treating physicians about her pre-1991 or post-1996 back pain and related symptoms, and had not read her deposition in which she had discussed those matters. J.A. 1370. In the district court's opinion, the approach taken by Dr. Krause "prevented him from becoming knowledgeable about material facts that were essential to his differential diagnosis" (the reported bladder problems and excruciating pain before the 1993 implantation and the presence of the same kind of "constant, excruciating pain" after the 1996 explant procedure). Thereupon, the district court held that application of the differential diagnosis method by Dr. Krause was unreliable on the facts of record respecting Mrs. Fitzgerald's long and complicated medical history of back pain, which, in essentially the same form, pre-

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<sup>4</sup> Id. (citing Heller v. Shaw Industries, Inc., 167 F.3d 146 (3d Cir. 1999)).

dated and post-dated implantation, and the subsequent explantation, of the Rogozinski System. J.A. 1370-71.5

III.

We review the decision precluding Dr. Krause's opinion testimony for abuse of discretion. See General Electric Co. v. Joiner, 522 U.S. 136 (1997). Where, as here, the plaintiff's claim is based on the worsening of pain and other symptoms which have been manifest for years before the allegedly causative event and which continue after that event in largely the same form, where the record discloses a lengthy and complex medical history, and where the expert's opinion is made without reference to significant parts of the plaintiff's medical history both before and after the event that is alleged to have caused aggravation of a pre-existing injury, we cannot say that the district court abused its discretion in foreclosing, as unreliable, an opinion which assertedly employed an otherwise standard method and procedure of medical science. There being no other evidence of causation, the district court did not err in granting summary judgment on all of the plaintiff's claims because, on each claim, the plaintiff relied only on the opinion of Dr. Krause to establish causation. Therefore, on this record and for the reasons stated by the district court in Fitzgerald v. Smith & Nephew Richards, Inc., Civil No. JFM-95-3870 (D. Md. Dec. 30, 1999), we affirm the decisions to exclude the testimony of Dr. Krause and to grant summary judgment on the issue of causation. The judgment of the district court is

AFFIRMED.

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5 The district court considered Dr. Krause's methodology to have been unreliable for the additional reason that he "failed to rule out what could have been another cause of Ms. Fitzgerald's condition -- her prior four foraminotomies." J.A. 1371. That failure was particularly problematic, in the view of the district court, considering that Dr. Krause testified at deposition that "Ms. Fitzgerald's tingling, numbness, and pain in the legs could be the result of scarring from multiple foraminotomies." Id. (citing Krause dep. at 125-26).