UNPUBLISHED

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

THOMAS MCCLURE; TRUDY MCCLURE,
Plaintiffs-Appellants,

PLAINTIFFS' LEGAL COMMITTEE,
Intervenor,

v.

SCIENTIFIC SPINAL,
Defendant-Appellee,

and

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS; NORTH AMERICAN SPINE SOCIETY; SCOLIOSIS RESEARCH SOCIETY; ACROMED CORPORATION, Charter Number 614043; ACROMED CORPORATION, Charter Number 816942; ACROMED RESEARCH AND DEVELOPMENT CORPORATION; ACROMED SPINE RESEARCH FOUNDATION, INCORPORATED; ACROMED INCORPORATED, CHARTER NUMBER 811415; ACROMED INCORPORATED; ACROMED INCORPORATED, CHARTER NUMBER 816943; ACROMED HOLDING CORPORATION, Charter Number 811416; ACROMED CORPORATION; ACE MEDICAL COMPANY; CROSS MEDICAL PRODUCTS; DEPUY-MOTECH, INCORPORATED; HOWMEDICA, INCORPORATED; SMITH & NEPHEW

No. 99-2552

RICHARDS, INCORPORATED; SYNTHES, USA; SYNTHES NORTH AMERICA, INCORPORATED; SYNTHES, A.G. CHUR; ADVANCED SPINE FIXATION SYSTEMS, INCORPORATED; DANEK MEDICAL, INCORPORATED; SOFAMOR, INCORPORATED; SOFAMOR-DANEK GROUP, INCORPORATED; SOFAMOR, S.N.C.; NATIONAL MEDICAL SPECIALTY, INCORPORATED, a/k/a Stuart Medical Speciality, Incorporated; ADVANCED BIOSEARCH ASSOCIATES; SPINE SCIENCE ADVANCEMENT FOUNDATION; HEALTH INDUSTRY MANUFACTURER'S ASSOCIATION; ORTHOPAEDIC SURGICAL MANUFACTURERS ASSOCIATION; SPINAL IMPLANT MANUFACTURERS GROUP; ZIMMER, INCORPORATED; SYNTHES, INCORPORATED,

Defendants.

GERTRUDE KRUZE,
Plaintiff-Appellant,

PLAINTIFFS' LEGAL COMMITTEE,
Intervenor,

v.

SCIENTIFIC SPINAL,
Defendant-Appellee,

and

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS; NORTH AMERICAN SPINE SOCIETY; SCOLIOSIS RESEARCH SOCIETY; ACROMED CORPORATION, Charter Number 614043; ACROMED CORPORATION, Charter Number 816942; ACROMED RESEARCH AND DEVELOPMENT CORPORATION; ACROMED SPINE RESEARCH FOUNDATION, INCORPORATED; ACROMED INCORPORATED, CHARTER NUMBER 811415; ACROMED INCORPORATED; ACROMED INCORPORATED, CHARTER NUMBER 816943; ACROMED HOLDING CORPORATION, Charter Number 811416; ACROMED CORPORATION; ACE MEDICAL COMPANY; CROSS MEDICAL PRODUCTS; DEPUY-MOTECH, INCORPORATED; HOWMEDICA, INCORPORATED; SMITH & NEPHEW

No. 99-2553

RICHARDS, INCORPORATED; SYNTHES, USA; SYNTHES NORTH AMERICA, INCORPORATED; SYNTHES, A.G. CHUR; ADVANCED SPINE FIXATION SYSTEMS, INCORPORATED; DANEK MEDICAL, INCORPORATED; SOFAMOR, INCORPORATED; SOFAMOR-DANEK GROUP, INCORPORATED; SOFAMOR, S.N.C.; NATIONAL MEDICAL SPECIALTY, INCORPORATED, a/k/a Stuart Medical Speciality, Incorporated; ADVANCED BIOSEARCH ASSOCIATES; SPINE SCIENCE ADVANCEMENT FOUNDATION; HEALTH INDUSTRY MANUFACTURER'S ASSOCIATION; ORTHOPAEDIC SURGICAL MANUFACTURERS ASSOCIATION; SPINAL IMPLANT MANUFACTURERS GROUP; ZIMMER, INCORPORATED; SYNTHES, INCORPORATED,

Defendants.

DIANE DUDAS; MICHAEL DUDAS,
Plaintiffs-Appellants,

PLAINTIFFS' LEGAL COMMITTEE,
Intervenor,

v.

SCIENTIFIC SPINAL,
Defendant-Appellee,

and

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS; NORTH AMERICAN SPINE SOCIETY; SCOLIOSIS RESEARCH SOCIETY; ACROMED CORPORATION, Charter Number 614043; ACROMED CORPORATION, Charter Number 816942; ACROMED RESEARCH AND DEVELOPMENT CORPORATION; ACROMED SPINE RESEARCH FOUNDATION, INCORPORATED; ACROMED INCORPORATED, CHARTER NUMBER 811415; ACROMED INCORPORATED; ACROMED INCORPORATED, CHARTER NUMBER 816943; ACROMED HOLDING CORPORATION, Charter Number 811416; ACROMED CORPORATION; ACE MEDICAL COMPANY; CROSS MEDICAL PRODUCTS; DEPUY-MOTECH, INCORPORATED; HOWMEDICA, INCORPORATED; SMITH & NEPHEW

No. 99-2554

RICHARDS, INCORPORATED; SYNTHES, USA; SYNTHES NORTH AMERICA, INCORPORATED; SYNTHES, A.G. CHUR; ADVANCED SPINE FIXATION SYSTEMS, INCORPORATED; DANEK MEDICAL, INCORPORATED; SOFAMOR, INCORPORATED; SOFAMOR-DANEK GROUP, INCORPORATED; SOFAMOR, S.N.C.; NATIONAL MEDICAL SPECIALTY, INCORPORATED, a/k/a Stuart Medical Speciality, Incorporated; ADVANCED BIOSEARCH ASSOCIATES; SPINE SCIENCE ADVANCEMENT FOUNDATION; HEALTH INDUSTRY MANUFACTURER'S ASSOCIATION; ORTHOPAEDIC SURGICAL MANUFACTURERS ASSOCIATION; SPINAL IMPLANT MANUFACTURERS GROUP; ZIMMER, INCORPORATED; SYNTHES, INCORPORATED,

Defendants.

KATHLEEN BAUER; HENRY BAUER,
Plaintiffs-Appellants,

PLAINTIFFS' LEGAL COMMITTEE,
Intervenor,

v.

SCIENTIFIC SPINAL,
Defendant-Appellee,

and

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS; NORTH AMERICAN SPINE SOCIETY; SCOLIOSIS RESEARCH SOCIETY; ACROMED CORPORATION, Charter Number 614043; ACROMED CORPORATION, Charter Number 816942; ACROMED RESEARCH AND DEVELOPMENT CORPORATION; ACROMED SPINE RESEARCH FOUNDATION, INCORPORATED; ACROMED INCORPORATED, CHARTER NUMBER 811415; ACROMED INCORPORATED; ACROMED INCORPORATED, CHARTER NUMBER 816943; ACROMED HOLDING CORPORATION, Charter Number 811416; ACROMED CORPORATION; ACE MEDICAL COMPANY; CROSS MEDICAL PRODUCTS; DEPUY-MOTECH, INCORPORATED; HOWMEDICA, INCORPORATED; SMITH & NEPHEW

No. 99-2555

RICHARDS, INCORPORATED; SYNTHES NORTH AMERICA, INCORPORATED; SYNTHES, A.G. CHUR; ADVANCED SPINE FIXATION SYSTEMS, INCORPORATED; DANEK MEDICAL, INCORPORATED; SOFAMOR, INCORPORATED; SOFAMOR-DANEK GROUP, INCORPORATED; SOFAMOR, S.N.C.; NATIONAL MEDICAL SPECIALTY, INCORPORATED, a/k/a Stuart Medical Speciality, Incorporated; ADVANCED BIOSEARCH ASSOCIATES; SPINE SCIENCE ADVANCEMENT FOUNDATION; HEALTH INDUSTRY MANUFACTURER'S ASSOCIATION; ORTHOPAEDIC SURGICAL MANUFACTURERS ASSOCIATION; SPINAL IMPLANT MANUFACTURERS GROUP; ZIMMER, INCORPORATED; SYNTHES, INCORPORATED,

Defendants.

LUCIANO SORRENTINO,
Plaintiff-Appellant,

PLAINTIFFS' LEGAL COMMITTEE,
Intervenor,

v.

SCIENTIFIC SPINAL,
Defendant-Appellee,

and

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS; NORTH AMERICAN SPINE SOCIETY; SCOLIOSIS RESEARCH SOCIETY; ACROMED CORPORATION, Charter Number 614043; ACROMED CORPORATION, Charter Number 816942; ACROMED RESEARCH AND DEVELOPMENT CORPORATION; ACROMED SPINE RESEARCH FOUNDATION, INCORPORATED; ACROMED INCORPORATED, CHARTER NUMBER 811415; ACROMED INCORPORATED; ACROMED INCORPORATED, CHARTER NUMBER 816943; ACROMED HOLDING CORPORATION, Charter Number 811416; ACROMED CORPORATION; ACE MEDICAL COMPANY; CROSS MEDICAL PRODUCTS; DEPUY-MOTECH, INCORPORATED; HOWMEDICA, INCORPORATED; SMITH & NEPHEW

No. 99-2556

RICHARDS, INCORPORATED; SYNTHES, INCORPORATED; SYNTHES NORTH AMERICA, INCORPORATED; SYNTHES, A.G. CHUR; ADVANCED SPINE FIXATION SYSTEMS, INCORPORATED; DANEK MEDICAL, INCORPORATED; SOFAMOR, INCORPORATED; SOFAMOR-DANEK GROUP, INCORPORATED; SOFAMOR, S.N.C.; NATIONAL MEDICAL SPECIALTY, INCORPORATED, a/k/a Stuart Medical Speciality, Incorporated; ADVANCED BIOSEARCH ASSOCIATES; SPINE SCIENCE ADVANCEMENT FOUNDATION; HEALTH INDUSTRY MANUFACTURER'S ASSOCIATION; ORTHOPAEDIC SURGICAL MANUFACTURERS ASSOCIATION; SPINAL IMPLANT MANUFACTURERS GROUP; ZIMMER, INCORPORATED,

Defendants.

Appeals from the United States District Court
for the District of Maryland, at Baltimore.
J. Frederick Motz, Chief District Judge.
(CA-95-3867-JFM, CA-95-3868-JFM, CA-95-3869-JFM,
CA-96-404-JFM, CA-96-406-JFM)

Argued: February 26, 2001

Decided: April 25, 2001

Before WILKINS, NIEMEYER, and LUTTIG, Circuit Judges.

Affirmed by unpublished per curiam opinion.

COUNSEL

ARGUED: Andrew M. Ominsky, OMINSKY & MESSA, P.C., Philadelphia, Pennsylvania, for Appellants. James Kurt Straub, OBERMAYER, REBMANN, MAXWELL & HIPPEL, L.L.P., Philadelphia, Pennsylvania, for Appellee. **ON BRIEF:** Tara B. Dickerson, OMINSKY & MESSA, P.C., Philadelphia, Pennsylvania, for Appellants. Thomas E. Hanson, Jr., OBERMAYER, REBMANN, MAXWELL & HIPPEL, L.L.P., Philadelphia, Pennsylvania, for Appellee.

OPINION

PER CURIAM:

This product liability case, involving the use of a bone screw device, known as the "Edwards device," as an implant in spinal fusion surgery, was brought by five plaintiffs and was one of a larger group of cases consolidated in the Eastern District of Pennsylvania under multidistrict-litigation procedures for pretrial discovery. After this case was transferred from the Eastern District of Pennsylvania to the District of Maryland, Scientific Spinal Limited, the manufacturer of the Edwards device, filed a motion for summary judgment, which the district court granted. This appeal followed, and we affirm.*

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*Scientific Spinal filed a cross-appeal challenging the assessment of discovery costs in the amount of $33,646. These costs were assessed in the context of multidistrict-litigation proceedings by the Eastern District of Pennsylvania before the cases before us were transferred to the District of Maryland. By order dated September 20, 2000, we dismissed the cross-appeal based on the prevailing federal practice that orders entered in the multidistrict-litigation context be appealed to the court of appeals where the administering court sits, in this case, the Third Circuit. Accordingly, if Scientific Spinal wishes to pursue this issue, it may do so in the Third Circuit upon completion of the multidistrict phase of the proceedings or on an interlocutory basis as allowed by law. *See*, *e.g.*, Fed. R. Civ. P. 54(b).

The facts relating to each of the plaintiffs are somewhat similar, at least as relevant to our review. Thomas McClure, following a history of lower back pain of approximately 13 years that had already disabled him from working, underwent a series of three back surgeries beginning in January 1990 and concluding in December 1992. During the course of these procedures, McClure's physician, Dr. Jonas Lieponis, implanted an Edwards device to stabilize McClure's spine. Yet, McClure still suffers pain.

Kathleen Bauer, similarly having complained of pain in her lower back and legs, went to Dr. Michael McCutcheon in 1992 for treatment. She underwent surgery in 1992 after her pain did not respond to medical treatment. Again, Dr. McCutcheon installed an Edwards device. He confirmed that Bauer had a successful fusion and thus concluded that her clinical outcome was positive. About 20 months following the surgery, however, Bauer began to complain of renewed pain in her back, although radiological investigations confirmed that fusion from her original surgery was still intact. Dr. McCutcheon performed exploratory surgery on Bauer in May 1994, during which he removed the Edwards device but found no evidence of failure at the fusion site. Bauer continued to complain of low back pain even after the Edwards device was removed.

Diane Dudas suffered from back pain, dating back to 1984. She underwent back surgery during which Dr. Kenneth Kramer implanted an Edwards device in June 1990. Post surgical radiological investigations confirmed a successful fusion had occurred at the surgical site. Dudas, however, continued to suffer pain and so underwent another surgery at a different site, but she did not have the Edwards device implanted there. When Dudas' symptoms continued to deteriorate, Dr. Kramer performed exploratory surgery that confirmed complete fusion at the site where the Edwards device had been used and therefore he removed the device. However, at the site where no device had been used, fusion had not occurred.

Gertrude Kruze's chronic low back pain dates to at least 1982. Dr. Christopher Michaelson performed fusion surgery on August 12, 1992, and implanted an Edwards device. Postoperative x-rays taken in June 1993 showed a solid fusion, as did a 1994 CT scan. Two years after the surgery, however, Kruze continued to complain of back pain,

leading Dr. Michaelson to perform another operation. When Dr. Michaelson found the fusion to be solid, he removed the Edwards device from Kruze's back. Kruze nevertheless continues to complain of pain in her lower back.

Luciano Sorrentino, an Italian national, has suffered back pain since 1984. Dr. Michaelson performed a fusion surgery on Sorrentino in October 1991 and installed the Edwards device. Dr. Michaelson found that Sorrentino had achieved a good clinical result, nevertheless Sorrentino continues to suffer back pain.

These five plaintiffs sued Scientific Spinal, alleging causes of action for strict liability, fraud, fraud on the FDA, failure to warn, negligence, negligence *per se*, breach of implied warranty of merchantability, and punitive damages. Scientific Spinal filed a motion for summary judgment, on which voluminous materials were submitted by all parties. All of the treating physicians provided affidavits that they were aware of the risks of using the Edwards device and that they had knowledge of the risks which the plaintiffs claim should have been included in warnings issued to them by Scientific Spinal. Following a hearing, the district court dismissed the plaintiffs' case, concluding that on the plaintiffs' failure to warn claim, the plaintiffs' evidence "is absolutely insufficient" because the treating physicians "were fully aware of the risks" including the need that the device be extracted. In addition, with respect to all of plaintiffs' claims, the court observed that, on the evidence of causation, "there simply is none." In an effort to provide evidence of causation, the plaintiffs sought to submit further affidavits of experts, even though the time for discovery had been closed and the deadlines for filing papers relevant to the motion for summary judgment had passed. The court ruled that, even if it received the affidavits, they would fail to assist plaintiffs on the merits. But the court declined to consider the affidavits because they were untimely and failed to show that the experts could have rendered relevant opinions under the standards set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

We have reviewed the district court's rulings, the record on the summary judgment motion, and the arguments of counsel, and after our review, we agree with the district court on all of its rulings. First, it is simply unsustainable to contend that a warning required to be

given to treating physicians is defective because of a failure to warn when it is established that the physicians had knowledge of the risks that allegedly should have been included in the warning. Also, on the issue of causation, each of the plaintiffs had a lengthy history of pre-existing back pain which had been unrelieved by conservative medical treatment. Establishing the fact that the plaintiffs continued to suffer back pain in their lower back after they underwent spinal fusion surgery in which the Edwards device was implanted did not prove that the Edwards device either caused the post-surgical pain or enhanced the pain existing prior to the surgery. Finally, in excluding the late-filed experts' opinions, which we agree did not supply the necessary evidence of causation, we conclude that the district court did not abuse its discretion.

Accordingly, the judgment of the district court is

AFFIRMED.