9-8-2008

Gannon v. USA

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 07-3428

JAMIE GANNON; REBECCA GANNON,
Individually, and as husband and wife

v.

UNITED STATES OF AMERICA

WYETH HOLDINGS CORPORATION,
Intervenor Defendant in the D.C.

Jamie Gannon and Rebecca Gannon,
Appellants

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. Civil No. 03-cv-06626)
District Judge: Hon. Robert F. Kelly

Submitted Under Third Circuit LAR 34.1(a)
September 8, 2008

Before: SLOVITER, FUENTES and NYGAARD, Circuit Judges

Filed: September 8, 2008

OPINION

SLOVITER, Circuit Judge.

Jamie Gannon and his wife Rebecca filed a personal injury action against the United States under the Federal Tort Claims Act ("FTCA"), 28 U.S.C. §§ 1346(b) and 2671-2680, alleging that an oral polio vaccine ("OPV") Jamie Gannon received between 1973 and 1976 was contaminated with SV40, a simian virus found in both monkeys and humans. The Gannons claim that the government was negligent in failing to prevent Lederle Laboratories from making the OPV available to the public, and as a result, the contaminated vaccine caused Gannon to develop medulloblastoma, a type of brain cancer. The District Court entered final judgment in favor of the United States after a truncated bench trial in which it concluded that the Gannons failed to prove that SV40 causes medulloblastoma. The Gannons appeal, arguing that the District Court erred in its factual findings and in entering judgment after partial findings.

I.

Jamie Gannon was administered multiple doses of Orimune, an OPV made by Lederle Laboratories, a division of American Cyanamid, between 1973 and 1976 in Upper Darby, Pennsylvania. In November 2000, he was diagnosed with a medulloblastoma, a type of cancerous brain tumor. In March 2003, the Gannons filed a notice for damages with the proper administrative agency under the FTCA, alleging that the United States did not confirm the absence of SV40 at each stage of the manufacture of Orimune in violation of federal regulations concerning the licensing and manufacturing of

OPVs. After six months without resolution, the Gannons filed suit in the Eastern District of Pennsylvania. Both parties undertook expert discovery.

In January 2007, the District Court commenced a bench trial. Prior to the start of trial the United States had filed a motion to preclude testimony by plaintiffs' expert under the authority of Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). The Court explained to the parties that for the convenience of the witnesses (to prevent recalling the experts later in the trial), the Court would combine a Daubert hearing with the expert testimony on the issue of causation. Thus, the trial began with the Daubert examination of plaintiffs' expert, Dr. Adi Gazdar. Gazdar then presented his full testimony on the issue of causation. He testified that SV40 plays a causal role in the development of medulloblastomas, including Jamie Gannon's tumor.

The United States then presented its three expert witnesses on causation – Dr. Robert Garcea, Dr. Harald zur Hausen, and Dr. Neal Halsey. The District Court found that all three qualified as experts.

Dr. Garcea testified that SV40 has not been shown to cause medulloblastoma. Dr. zur Hausen testified similarly and added that a causal link cannot be implied based upon testing on laboratory animals. Dr. Halsey, an epidemiologist, testified that in order to determine whether a virus causes cancer, a scientist must consider both epidemiological and biological evidence. He stated that the epidemiological studies to date have suggested no causal connection between SV40 and human cancer.

Following the expert testimony, the Court denied the United States' Daubert motion. The United States then made a motion under Rule 52(c) of the Federal Rules of Civil Procedure for a judgment on partial findings. The Court granted the motion, concluding that the plaintiffs had not met their burden of proving that SV40 causes medulloblastoma and therefore could not sustain their claim against the United States.

The District Court held that plaintiffs had been fully heard on the issue of causation, and that as a result, judgment on partial findings was appropriate. Although plaintiffs argued that they had not been fully heard, the Court disagreed. It stated that Dr. Gazdar was the only causation witness for plaintiffs. The other potential plaintiffs' witnesses would have testified about OPV contamination, not causation.

Although Dr. Gazdar testified that it was his opinion that to a reasonable degree of medical certainty SV40 plays a causal role in the formation of medulloblastomas, including Jamie Gannon's tumor, the Court decided that the plaintiffs had not met their burden of proof on causation. Specifically, the Court found that Dr. Gazdar's testimony failed to satisfy the "Bradford Hill" criteria,[1] which are nine factors widely used in the scientific community to assess general causation. In addition, defense experts concluded

[1] The Bradford Hill criteria are "broadly accepted criteria for evaluating causation that have been developed by scientists such as Sir Bradford Hill." App. at 11. They are: (1) Strength of Association, (2) Consistency, (3) Specificity, (4) Temporality, (5) Biologic Gradient, (6) Plausibility, (7) Coherence, (8) Experimental Evidence, and (9) Analogy.

to a reasonable degree of medical certainty that the evidence did not support a conclusion that SV40 causes medulloblastoma. The Court found "that Dr. Gazdar failed to conduct accurate, complete and scientifically reliable testing on Mr. Gannon's medulloblastoma sample." App. at 22. Thus, plaintiffs failed to prove general and specific causation by a preponderance of the evidence.

II.

We have jurisdiction pursuant to 28 U.S.C. § 1291. We review the District Court's factual findings for clear error and its legal conclusions de novo. Rego v. ARC Water Treatment Co. of Pa., 181 F.3d 396, 400 (3d Cir. 1999).

III.

Under the FTCA, liability is determined according to the substantive law of the state in which the injury occurred, in this case Pennsylvania because that was where Gannon was vaccinated. See 28 U.S.C. § 1346(b)(1); Matsko v. United States, 372 F.3d 556, 559 (3d Cir. 2004). In order to recover on a negligence theory under Pennsylvania law, the Gannons must prove that (1) a duty existed; (2) the United States breached that duty; (3) the breach was the cause in fact of the injury; (4) the breach was the proximate cause of the duty; and (5) damages resulted from the injury. See Redland Soccer Club, Inc. v. Dep't of the Army, 55 F.3d 827, 851 (3d Cir. 1995). Therefore, the Gannons were required to prove causation, i.e., that the vaccine, if contaminated, causes medulloblastoma in general, and caused Jamie Gannon's brain tumor in particular. If

they could not so prove, they would not be able to sustain the claim against the United States.

Rule 52(c) of the Federal Rules of Civil Procedure provides:

> **(c) Judgment on Partial Findings.** If a party has been fully heard on an issue during a nonjury trial and the court finds against the party on that issue, the court may enter judgment against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue. The court may, however, decline to render any judgment until the close of the evidence. A judgment on partial findings must be supported by findings of fact and conclusions of law as required by Rule 52(a).

The plain language of Rule 52(c) states that a trial court can enter judgment after hearing evidence on only one issue, provided the party against whom judgment has been entered is fully heard.[2] Trial courts may make factual findings in this connection. See Rego, 181 F.3d at 400.

Here, the District Court found that plaintiffs were fully heard on the issue of causation because their causation expert had testified fully, and they offered no other witnesses on the issue of causation as distinct from the issue of contamination. Although Dr. Gazdar testified that SV40 causes medulloblastoma, the Court found that his opinion was not supported by the evidence produced during the bench trial. The Court relied upon the fact that all three defense experts used established scientific frameworks and

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[2] Appellants' arguments regarding former Rule 41(b) and decisions interpreting that rule have no bearing upon the plain language of current Rule 52. Appellants' position is not advanced by citation to rules and cases that no longer carry legal authority.

cited both biological and epidemiological evidence. Each of those experts opined that the evidence did not support the conclusion that SV40 causes human cancer. In addition, the Court relied upon the Institute of Medicine ("IOM") 2003 report, which concluded that "'the evidence is inadequate to accept or reject a causal relationship'" between SV40 and cancer. App. at 13 (quoting App. at 1048). Although the IOM suggested that a causal link was plausible, it stated that there must be epidemiological evidence in addition to biological evidence in order to prove causality. Even Dr. Gazdar, the plaintiffs' expert, testified that he agreed that current epidemiological evidence does not support the conclusion that SV40 causes cancer in humans.

Moreover, Dr. Gazdar could not rule out contamination in his testing, which affected the credibility of his results. He relied upon testing on rodents, which defense experts stated were not analogous to humans; even Dr. Gazdar admitted the results could not necessarily be extrapolated to humans. Finally, the Court considered each of the nine Bradford Hill criteria for causation and found that Dr. Gazdar's opinion did not meet the criteria, whereas defense experts' opinions did meet accepted scientific standards. The Court found defense experts to be credible. The Court also stated that "Dr. Gazdar failed to conduct accurate, complete and scientifically reliable testing on Mr. Gannon's medulloblastoma sample." App. at 22.

Based upon the foregoing analysis and its thorough consideration of the record evidence we cannot say that the Court clearly erred in its findings of fact or that it erred in

concluding that the Gannons had not met their burden of proof on the issue of causation.[3]

On appeal, however, the Gannons argue that they were not fully heard on the issue of causation because they wanted to offer other witnesses. They assert that they would have called Drs. Butel and Sulzinski to testify about the contamination of Orimune with SV40. The District Court found that those witnesses were not relevant to the issue of causation because their testimony would principally address the issue of contamination. Moreover, as the defense experts testified, even if the additional witnesses testified about the presence of SV40 in the tumor, such testimony would not prove that SV40 caused the tumor as the plaintiffs would have still lacked epidemiological evidence to support their causation argument. To the extent that the Gannons now complain that the District Court heard witnesses out of turn, or scheduled the trial in a particular order, that contention is unavailing. It is well-established that trial courts have broad discretion to schedule experts out of order to accommodate them and to manage the presentation of a trial. See Berroyer v. Hertz, 672 F.2d 334, 339 (3d Cir. 1982). We cannot say that the District

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[3] On appeal, the Gannons cite Smith v. German, 253 A.2d 107 (Pa. 1969), for the proposition that under Pennsylvania law the government was required to disprove causation. In Smith, the Court simply held that where there is no obvious causal relationship the parties are required to submit expert testimony. Because the defendant attempted to show a different source of causation than that proffered by the plaintiff, the defendant was required to offer expert testimony in support of that proposition. Id. at 108. Here, in contrast, the United States did not offer an alternate source of causation but merely asserted that SV40 did not cause brain tumors and offered expert testimony to that effect.

Court erred in disallowing the testimony of Drs. Butel and Sulzinski based upon its finding that the testimony would be irrelevant to the question of causation.

IV.

For the above-stated reasons, we will affirm the judgment of the District Court.