United States Court of Appeals
For the First Circuit

No. 09-1079

ALBERT ANAYA-BURGOS,

Plaintiff, Appellant,

v.

DR. EDUARDO M. LASALVIA-PRISCO; PHARMABLOOD, INC.,

Defendants, Appellees,

JOSÉ MURATTI-SEPÚLVEDA; DR. RUBÉN OTERO-LÓPEZ; FÉLIX COTTO-ORTIZ; PHARMABLOOD MEDICAL CENTER, INC.,

Defendants.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

[Hon. José Antonio Fusté, U.S. District Judge]

Before

Torruella, Selya, and Lipez,
Circuit Judges.

Manuel San Juan, with whom Law Offices of Manuel San Juan, José F. Velázquez-Ortiz, and Velázquez Law Offices, PSC, were on brief for appellant.

John E. Bergendahl, with whom Law Offices of John E. Bergendahl, was on brief for appellees Dr. Lasalvia-Prisco and Pharmablood, Inc.

June 9, 2010

TORRUELLA, Circuit Judge. Plaintiff-appellant Albert Anaya-Burgos ("Anaya") filed a complaint against Dr. Eduardo Lasalvia-Prisco ("Dr. Lasalvia") and other Defendants-appellees alleging that the death of his wife, Juana Ramos ("Ramos"), occurred as a result of Defendants' negligent acts and omissions by inducing her to purchase their supposed "cancer vaccine" treatment and forego conventional cancer treatments. The case was tried to a jury, which found for Plaintiff, awarding $500,000 in compensatory damages. At Defendants' motion, the court granted them judgment as a matter of law, setting aside the jury verdict and dismissing the complaint. For the reasons below, we overturn the grant of judgment as a matter of law and reinstate the jury verdict for Plaintiff.

I. Facts and Procedural History[1]

A. Cancer Diagnosis Treatment at Pharmablood

In April 2003, Plaintiff's wife, Ramos, was diagnosed with breast cancer. She consulted a surgeon who recommended a radical mastectomy. She sought a second opinion from another surgeon in early May of 2003, who also recommended a mastectomy. Subsequently, Ramos was referred to an oncologist, Dr. Rizek, who examined her for the first time on May 23, 2003. While Ramos had

[1] We recite the facts in the light most favorable to the jury verdict. Granfield v. CSX Transp., Inc., 597 F.3d 474, 482 (1st Cir. 2010) (citing Cigna Ins. Co. v. Oy Saunatec, Ltd., 241 F.3d 1, 8 (1st Cir. 2001)).

initially been diagnosed with a form of cancer called "invasive duct carcinoma," Dr. Rizek's diagnosis was of "inflammatory breast cancer," a type of cancer that tends to progress much faster than Ramos's earlier diagnosis. There was expert testimony at trial to the effect that someone diagnosed with inflammatory breast cancer could die within six to twelve months without adequate treatment. Dr. Rizek recommended to Ramos that she begin chemotherapy on June 6, 2003.[2] Although Ramos never began the chemotherapy treatments, Anaya testified that Ramos agreed to proceed with chemotherapy. According to Anaya, Ramos did not begin chemotherapy on the scheduled date because she was never notified that she had been approved for coverage by her insurance carrier.[3]

According to Anaya, Ramos had always been interested in a "natural" lifestyle, and regularly visited individuals who recommended various vitamin and other natural substances to her. She continued those visits after she was diagnosed with cancer.[4]

At some point after visiting Dr. Rizek but before July 10, 2003, Ramos and Anaya became aware of Dr. Lasalvia's

---

[2] At trial, Plaintiff's expert testified that "[m]ost people nowadays would use chemotherapy before doing a mastectomy, [but] some people continue to use mastectomy if the tumor is too big and to give the chemotherapy after the surgery rather than before."

[3] Evidence was presented at trial that Ramos's insurer had approved the treatments as of June 6, 2003, but no evidence was presented that this was ever communicated to Ramos or Anaya.

[4] Plaintiff's expert testified that vitamins have not been shown to have any effect on cancer treatment.

company, Pharmablood, through a radio program. Anaya testified that he and Ramos heard a radio program that announced that Dr. Lasalvia, an Uruguayan doctor, had developed a new "cancer vaccine" that was available at the San Juan Bautista Hospital.[5]

A Pharmablood commercial that aired in October 2003 was introduced at trial and touted Pharmablood as a "novel alternative to cancer patients in Puerto Rico." A "Dr. Sylvia Cucci" explained in the commercial that the procedure was "comfortable" and "effective" and that it was an "FDA approved protocol." A "Dr. Rubén Otero" was also heard in the commercial explaining that "terminal patients that were told that perhaps their life expectancy was six months or less . . . were offered the Pharmablood immunotherapy and . . . in 42% of the population treated, it was noticed there was an increase, not only in life expectancy, but also a great improvement in the quality of life itself."

On July 10, 2003, Anaya and Ramos visited Pharmablood at the San Juan Bautista Hospital and met Dr. Lasalvia as well as other Pharmablood personnel. According to Anaya, Dr. Lasalvia examined Ramos and told her that his treatment could "cure" her. Anaya testified that after hearing this, Ramos made the decision to

---

[5] Pharmablood had rented office space in the first floor of the San Juan Bautista Hospital, a well-regarded hospital in Caguas, Puerto Rico. While Pharmablood was not formally affiliated with the Hospital, there was testimony that the set-up gave the appearance of affiliation.

go with the Pharmablood treatment and forego other treatments. Anaya also explained that Pharmablood personnel told him and Ramos that their medical plan would eventually cover the treatments, but that they first had to make payments up front.[6] All told, Anaya and Ramos paid around $10,000 out-of-pocket for the Pharmablood treatments.

At Pharmablood, Ramos signed an informed consent form which stated that the Pharmablood cancer vaccine's risks were "minimal inflammation or pain in the areas of the blood extraction" and that it was reasonable to expect up to a one-hundred percent improvement in the survival rate of forty percent in the patients who were administered the vaccine treatment. Ramos began treatments with Pharmablood shortly after signing the consent form.

On June 29, 2004, after almost one year of regular treatments with Pharmablood, Ramos was hospitalized at the Auxilio Mutuo Cancer Center since she was having difficulty breathing. Expert testimony at trial revealed that at this point in time her cancer had progressed so far that all Ramos could receive was palliative chemotherapy, to extend her life but not to attempt to cure her. The chemotherapy failed to work; Ramos continued to

---

[6] The jury also was shown a separate form signed by Ramos which states that by signing she understood that the services provided by the Pharmablood Medical Center were not currently covered by insurance companies. However, because this case is here following a jury verdict in Plaintiff's favor, we credit Anaya's testimony about what he and Ramos were told by Pharmablood.

deteriorate, and eventually died on July 30, 2004, "with her lungs full of tumors."

B. Expert Testimony at Trial

1. Breach of the Standard of Care

At trial, Anaya's expert, Dr. Cabanillas, testified that Dr. Lasalvia's medical license had been revoked in Hawaii. Dr. Cabanillas testified that the Pharmablood treatments were "illegal,"[7] that they were never approved by the Food and Drug Administration ("FDA"), and that this was not mentioned in any of the Pharmablood literature he reviewed.[8] Dr. Cabanillas also explained that the medical papers Dr. Lasalvia had written about the Pharmablood treatment were published in what were, in his professional opinion, very poor journals. Dr. Cabanillas went on to criticize the studies published in these papers, stating that the design of the studies was very poor and that there were basic scientific reliability tests that were not performed. He stated: "I don't know how the papers were published, not even in journals of low quality. I wouldn't have accepted a paper like that."

---

[7] The district judge allowed this to be put on the record but Dr. Cabanillas did not explain further what he meant by this. It appears that he was referring to a criminal investigation against Pharmablood and its officers.

[8] Dr. Cabanillas also testified that none of the literature claimed that Pharmablood was a "cure" for cancer and that instead the literature referred to it as another "tool" in the fight against cancer.

With regard to the forty percent or greater improvement mentioned in both the advertisement watched by the jury and the informed consent form signed by Ramos, Dr. Cabanillas testified that "there was, basically, no statistical analysis of the results [in Dr. Lasalvia's studies] to be able to convince anyone that there's a 40 percent improvement."

Dr. Cabanillas also testified regarding Ramos's medical records from the Pharmablood Cancer Center. He testified that it appeared that Dr. Lasalvia did not do a physical examination of Ramos because there were no notes of such an examination in the records, something which Dr. Cabanillas testified was surprising because he would have expected it of a doctor. Dr. Cabanillas also testified that as part of her treatment, Dr. Lasalvia gave Ramos two chemotherapy drugs. However, according to Dr. Cabanillas, those drugs were administered at such low doses that they could not have helped to decrease Ramos's cancer, and that the particular drug combination used was abandoned decades ago and fell below the standard of care. Ramos was also given a third drug at Pharmablood: Tamoxifen. According to Dr. Cabanillas's testimony, Tamoxifen was a drug that in the past had been thought to help a patient in Ramos's condition. However, a 2001 medical study showed that this drug would have no effect on a patient such as Ramos and should not have been used on her. Dr. Cabanillas testified that

the fact that Ramos was given this drug fell below the standard of care.

2. Causation

Dr. Cabanillas testified that none of the notations in the Pharmablood records indicated that Ramos had rejected traditional treatment. When asked if the Pharmablood treatment had caused her death, Dr. Cabanillas responded that Ramos had "lost an opportunity." Explaining further, Dr. Cabanillas testified that if Ramos had been given a treatment that comported with the standard of care instead of the Pharmablood treatment, she would have had a fifty percent chance of being alive for five years or longer.[9] Instead, Ramos died just over a year after beginning the Pharmablood treatments.

C. Anaya's Testimony on Causation

Multiple times at trial, Anaya was asked whether Ramos had rejected traditional treatments for her cancer since she failed to start chemotherapy or get surgery as recommended by some of the

---

[9] The jury also heard the following exchange:

> Q: If she had made a decision to reject chemo, reject surgery, and reject radiation, nothing that Dr. Lasalvia did caused her death; correct?
> A: That's correct.

(emphasis added). The district court used this exchange as a reason for granting judgment as a matter of law in favor of the Defendants. However, this exchange begs the question of when and why Ramos rejected traditional forms of treatment in favor of Pharmablood.

doctors she saw. Anaya testified unequivocally that "[Ramos] never ruled anything out;" "she was willing to have any treatment;" "I don't believe she rejected chemotherapy," and that she did not rule out surgery. Anaya testified that Ramos was willing to go through chemotherapy or surgery, but that she also wanted to explore all her options. After discovering Pharmablood's treatment at the San Juan Bautista Hospital and speaking with Dr. Lasalvia, however, Anaya testified that Ramos discarded chemotherapy and surgery as options to treat her cancer.[10] Anaya testified that because of its location on the first floor of the San Juan Bautista Hospital, the literature in the waiting room describing the patents that were pending for the technology, and the representations that Dr. Lasalvia made that his treatment would "cure" Ramos's cancer, he and his wife proceeded to pay over $10,000 to Pharmablood for their "cancer vaccine."

[10] A medical report from the time when Ramos sought medical care for difficulty breathing was also read into evidence. In summarizing the patient's history, the report stated that Ramos had previously refused to be under standard care and had sought treatment under Dr. Lasalvia. The district court made much of these notations as evidence that Ramos had rejected traditional forms of treatment. But this was the opinion of the doctor who wrote the medical report, and it did not state whether the "rejection" occurred before or after Ramos met Dr. Lasalvia or learned of the Pharmablood "vaccine." The jury was entitled to credit other testimony presented to the effect that Ramos had not in fact rejected "traditional" treatment until at least after meeting Dr. Lasalvia.

D. Procedural History

After the conclusion of Plaintiff's presentation of evidence, Defendants moved for judgment as a matter of law, alleging that "there was nothing that Dr. Lasalvia did to cause [Ramos's] death" because she had "refused standard medical treatment." The district court denied the motion and Defendants rested their case without putting on any evidence. The case was submitted to the jury which found for Plaintiff and awarded him $500,000 in damages.

Subsequently, Defendants renewed their motion for judgment as a matter of law, and this time the district court granted it, overturning the jury verdict and concluding as a matter of law that "Lasalvia's quackery was not the cause of Juana Ramos's demise" and that instead "her own election of medical remedies and the devastating nature of the disease caused her death."

II. Discussion

We review de novo the district court's grant of judgment as a matter of law. J.R. v. Gloria, 593 F.3d 73, 78 (1st Cir. 2010). We will not approve of a district court's ruling setting aside the jury verdict unless "the evidence was so strongly and overwhelmingly inconsistent with the verdict that no reasonable jury could have returned [it]." Forgie-Buccioni v. Hannaford Bros., Inc., 413 F.3d 175, 181 (1st Cir. 2005) (internal quotation marks omitted).

Under Puerto Rico law, to establish a prima facie case for medical malpractice the plaintiff must show that (1) defendant owed plaintiff a duty; (2) defendant breached that duty; and (3) there was "a sufficient causal nexus between the breach and some resultant harm." Martínez-Serrano v. Quality Health Servs. of Puerto Rico, Inc., 568 F.3d 278, 285 (1st Cir. 2009).

> The "adequate causation" doctrine governs in Puerto Rico to determine legal causation between the negligent act or omission and the harm. According to this doctrine, not any condition without which a result would not have occurred is a cause, but that which would ordinarily produce it according to experience. Pursuant to this doctrine, the issue to be addressed is whether the materialization of the harm was to be expected in the normal course of events or if, on the contrary, it cannot be calculated.

Sepúlveda de Arrieta v. Barreto, No. RE-90-41, 1994 WL 908876 (P.R. Dec. 23, 1994) (internal citations and quotation marks omitted). These concepts are very similar to proximate cause, id., and like proximate cause, "the touchstone is foreseeability: [conduct results in] liability if, and to the extent that, a foreseeable risk of harm materializes." Swift v. United States, 866 F.2d 507, 510 (1st Cir. 1989).

On appeal, Defendants do not contest that Dr. Lasalvia owed a duty of care to Ramos. Dr. Lasalvia was an oncologist practicing in rented space at the San Juan Bautista Hospital. Ramos went to see him to care for her cancer and he represented to her that she would receive an FDA-approved treatment that improved

the survival of forty percent of patients who took it. Even more, according to uncontroverted testimony at trial, Dr. Lasalvia himself told Ramos and Anaya that his treatment could "cure" her of cancer.

There is also no question that a reasonable jury could have found that Dr. Lasalvia breached his duty in numerous ways. There was uncontroverted expert testimony that Dr. Lasalvia's treatment was not FDA-approved, despite advertisements claiming otherwise, and that the kind and quantity of drugs given to Ramos violated the standard of care. There was also uncontroverted expert testimony that the medical papers Dr. Lasalvia published on the Pharmablood treatment were published in sub-standard journals and lacked basic scientific research methodology. The jury also heard Plaintiff's testimony that Dr. Lasalvia promised Plaintiff and Ramos that his treatment would "cure" her.

Finally, the informed consent form could be considered a breach of duty in and of itself. According to unrebutted expert testimony, the form that Ramos signed only explained that the risks involved minimal inflammation or pain in the site of the blood extraction. In the "benefits and probabilities of success" section, the form stated that it was reasonable to expect an improvement in the survival rate of forty percent of the patients who receive the Pharmablood treatment and also said that the prolongation of life could be more than one-hundred percent of the

average person.[11] Plaintiff's expert testified that these improvement figures had no basis whatsoever.[12] In addition, Plaintiff's expert testified that contrary to standard practice in the oncology field, the informed consent form did not reflect the approval of any institution. See, e.g., Sepúlveda de Arrieta, 1994 WL 908876 (P.R. 1994) ("Applied to the present case, the issue to be addressed is whether in the normal course of events [the defendant doctor] had to foresee that the lack of pertinent information would lead [the patient] to take a different decision than the one she would have taken if she had been suitably informed."); Cruz Avilés v. Bella Vista Hosp., Inc., 112 F. Supp. 2d 200, 202 (D. P.R. 2000) (finding that "under Puerto Rico law a patient suing for lack of informed consent does not need to prove a separate negligent act, other than the lack of informed consent.").

Defendants urge us to affirm the district court's reversal of the jury verdict because, based on the evidence presented, a reasonable jury could not have concluded that Plaintiff met his burden to show that Defendants sufficiently caused Plaintiff's harm under Puerto Rico law. We disagree.

---

[11] Plaintiff's expert explained that it was not clear what was meant by this.

[12] Defendants do not contest the issue of breach on appeal.

We begin at the beginning, making clear that the harm complained of in this case was, as Plaintiff's expert testified, the opportunity that Ramos lost because Defendants induced her to choose the Pharmablood treatment instead of traditional methods. In order to be found liable, that "lost opportunity" harm needed to have been sufficiently foreseeable to Defendants. We find that there was sufficient evidence of a causal nexus between Defendants' multiple breaches of duty and Ramos's untimely death.

Anaya testified at trial that Ramos only decided to forego chemotherapy and surgery after meeting Dr. Lasalvia. Anaya's expert, Dr. Cabanillas, testified that there was no indication in the Pharmablood records that Ramos had ruled out chemotherapy or surgery.[13] Defendants point to evidence that allegedly contradicted that testimony. They point to the fact that Ramos went to three different doctors after her cancer diagnosis and did not show up for chemotherapy after an appointment had been scheduled. They also point to a notation in a medical record which stated that Ramos had rejected chemotherapy and other traditional treatments. The physician who wrote those notes saw Ramos over a

[13] The district court's opinion seems to suggest otherwise, apparently referring to the Pharmablood intake form which stated that Ramos had not taken chemotherapy and had never taken it, and that she was "on a natural diet." At trial, Defendants attempted to elicit testimony from Dr. Cabanillas that the hand-written Pharmablood records stated Ramos had "refused" chemotherapy and surgery. Nevertheless, Dr. Cabanillas testified that he did not understand that is what the records said.

year after she began seeing Dr. Lasalvia and receiving the Pharmablood treatments. The notation was made by the physician who saw Ramos after she sought treatment for difficulty breathing.

Defendants are correct that there was evidence on the record that Ramos was determined not to submit herself to chemotherapy or surgery for her cancer. However, there was also evidence to the contrary. Specifically, the jury heard Anaya's testimony that Ramos had never ruled anything out until she met with Dr. Lasalvia, and that the reason she missed the chemotherapy appointment was because no one notified her that her insurance was going to cover it. That testimony was uncontroverted -- the fact that the insurance company paid for all other treatments does not undermine Anaya's testimony -- and the jury was entitled to believe Anaya and his expert over the other evidence.

Defendants also point to the signed informed consent form as evidence that Ramos knowingly rejected all forms of traditional medical treatment. The form stated that the Pharmablood treatments were meant to be undertaken by patients for whom chemotherapy and/or surgery had failed, was not possible, or had been rejected. But, Anaya testified that Dr. Lasalvia told him and Ramos that his treatment would "cure" Ramos and that she rejected other possible treatments based on his representations. Defendants also point to the payment form, which stated that Pharmablood treatments were not covered by health insurance, arguing that this should have clued in

Ramos and Anaya to the fact that this was an experimental treatment. However, Plaintiff's expert testified that he did not see anything in Pharmablood's literature that explained that this was an experimental treatment; indeed, the evidence presented showed that Defendants were advertising the treatment as FDA-approved, and that they were misleadingly operating out of the San Juan Bautista Hospital. Anaya also testified that Pharmablood personnel explained that the insurance coverage issues were temporary, and that they would only have to pay up-front for a little while, and would later be reimbursed. Furthermore, the informed consent form itself claimed that forty percent of patients experienced improved quality and length of life, and that some experienced up to a one-hundred percent improvement. The jury was entitled to credit Anaya's testimony that Defendants' statements and (mis)representations induced Ramos to reject other treatments in favor of Pharmablood.

We find that Plaintiff put forth sufficient evidence, including expert testimony, from which a reasonable jury could have concluded -- and did conclude -- that Defendants' breach of the standard of care towards Ramos caused her untimely death by inducing Ramos to choose the Pharmablood treatment with promises that it would cure her. That is, a reasonable jury could have found that due to Dr. Lasalvia's intervention and misrepresentations about the viability of the Pharmablood treatment

and its success rate, continued "treatment" of Ramos during an entire year in which her cancer was continually progressing, and the failure by Defendants to investigate and/or to advise Ramos as to the spread of her cancer, Ramos was induced to forego traditional treatments. From the evidence presented at trial, a reasonable jury could have found that it was foreseeable to Dr. Lasalvia that by advertising and inducing Ramos to receive and pay for his "cancer vaccine," Ramos would forego conventional medical treatment. The jury could reasonably infer that Dr. Lasalvia, an oncologist himself, was aware of the effectiveness of conventional treatment, and the consequences of foregoing it in favor of his "vaccine."

Defendants urge a number of other theories, all in the guise of lack of causation. We dispose of them quickly. At trial, Defendants attempted to elicit evidence showing that Ramos and Anaya had gone to college and were educated, presumably in an attempt to convince the jury that they should not have believed in Dr. Lasalvia's "vaccine" and instead should have returned to their other doctors. Defendants also cite a number of cases where other courts have held that a patient's failure to return to her physician for follow-up care can be the sole cause or contributing cause of her injury, and thus bar or limit her right to recover damages. Those arguments are inapposite. Defendants did not raise the issue of comparative negligence before or during trial, and

they did not request a comparative negligence instruction, all of which were options available under Puerto Rico law. P.R. Laws Ann. tit. 31, § 5141. That Ramos or Plaintiff might have been negligent in believing Dr. Lasalvia's "quackery" could have certainly been believed by a jury, but in this case it was not. Defendants did not request an instruction assigning comparative blame for the harm and they have thus waived this argument. Phav v. Trueblood, Inc., 915 F.2d 764, 769 (1st Cir. 1990).

III. Conclusion

Finding, as we do, that there was sufficient evidence for a reasonable jury to find Defendants guilty of medical malpractice, we reinstate the jury verdict in its entirety. We thus vacate the district court's entry of judgment for Defendants and remand the case to the district court to enter judgment on the jury verdict.

Vacated and Remanded. Costs in favor of the Plaintiff.