United States Court of Appeals
Fifth Circuit
F I L E D
March 14, 2006
Charles R. Fulbruge III
Clerk

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 04-30202

DANELL GOMEZ and MARTIN GOMEZ,

Plaintiffs-Appellants,

versus

ST. JUDE MEDICAL DAIG DIVISION INC., formerly known as Daig Corporation; KENSEY-NASH CORPORATION; TYCO INTERNATIONAL; WYETH, formerly known as American Home Products Corporation; TYCO HEALTH CARE GROUP LP, formerly known as Kendall Company,

Defendants-Appellees.

Appeal from the United States District Court
for the Eastern District of Louisiana

Before KING and DAVIS, Circuit Judges, and ROSENTHAL, District Judge.[*]

LEE H. ROSENTHAL, District Judge:

In March 1999, Danell Gomez had a surgical catheterization to treat a blockage in an artery leading to her left arm. When the procedure was complete, the surgeon used a medical device known as an Angio-Seal to close the hole he had made in Gomez's femoral artery to access the blockage. The Angio-Seal deposits a small plug of collagen on the outside of the artery wall at the puncture site. The collagen plug quickly causes a clot that stops the bleeding. The Angio-Seal includes an "anchor" intended to keep any of the collagen from

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[*] District Judge for the Southern District of Texas, sitting by designation.

traveling to the inside of the artery, where it can cause a clot in the bloodstream. Gomez alleges that the Angio-Seal worked improperly in her case, allowing collagen to travel to the inside of her artery and cause a large blockage that had to be surgically removed. She attributes her subsequent nine surgeries and persistent leg pain and weakness to the defective Angio-Seal.

Gomez sued the manufacturer of the Angio-Seal under the Louisiana Product Liability Act, seeking actual and punitive damages. Gomez's husband joined in the suit seeking loss of consortium damages. The district judge granted summary judgment as to Gomez's state-law design and marketing claims on the basis of federal preemption. The parties tried the manufacturing defect claim to a jury. At the close of the evidence, the district judge granted defendants' motion for judgment as a matter of law under Rule 50(a) of the Federal Rules of Civil Procedure. Gomez appealed.

We affirm the preemption determination, reverse the Rule 50 order, and remand to the district court. The reasons are explained below.

I. Factual and Procedural Background

In 1999, Danell Gomez, then forty-four years old, saw her doctor complaining about numbness and tingling in her left arm and hand. (Tr. at 399, 789). An arteriogram indicated a blockage in the right subclavian artery in Gomez's chest. Her doctor referred her to Dr. Christopher White, an interventional cardiologist—defined as one who "performs procedures such as angioplasties and stents"—at the Ochsner Clinic in New Orleans. (Tr. at 778).

Dr. White performed surgery to relieve the blockage and repair the artery. Dr. White followed a standard procedure and accessed the subclavian artery through the right femoral artery in the groin area, where the blood vessels are close to the skin. Dr. White inserted a catheter through the opening he made in the femoral artery, passed the catheter to the

subclavian artery, and inserted a balloon to open the blockage. The balloon did not have the desired effect, requiring insertion of a stent, which was successful. Dr. White then withdrew the catheter and other equipment through the femoral artery, leaving an opening that had to be treated to stop the bleeding.

The evidence at trial described two common approaches to closing such an opening. One approach is to use manual compression, applying pressure to the puncture area until a clot forms and the bleeding stops. This approach can be uncomfortable for the patient because of the pressure and because the patient must stay still for a long period—six to eight hours—to avoid disrupting the clot. Complications such as prolonged bleeding and pseudoaneurysms can result. The other approach is to use one of the recently-developed puncture-closing devices, such as the Angio-Seal. The Angio-Seal operates by placing a small plug of collagen on the outside of the artery wall to close the puncture site. Other devices operate with a stitch or glue applied to the site. Dr. White and the Ochsner Clinic had been involved in clinical studies leading to the FDA's approval of the Angio-Seal and Dr. White preferred it to other puncture-closing devices and to manual compression. Dr. White testified that the use of closure devices like the Angio-Seal make the postoperation procedure easier, faster, and less expensive for both the doctor and patient. Because both closure devices and manual compression have approximately the same rate of complications—although the complications are different—one approach is not inherently more or less safe than the other.

The Angio-Seal consists of a guidewire, a carrier tube, a bypass tube, a bovine collagen plug, and a T-shaped biodegradable polymer anchor. The Angio-Seal specifications require that when the device is packaged for shipping, the T-shaped anchor must be in a vertical position within the bypass tube, neither extending beyond the end of the tube nor

inserted deeply within it. The bypass tube protects the anchor from damage during shipping and during surgery. When the doctor inserts the Angio-Seal into the patient, the Angio-Seal anchor must pass through a silicon hemostasis valve, which prevents the patient's blood from flowing back through the artery opening during the surgery. When the Angio-Seal is inserted into a patient, the bypass tube—not the anchor—pushes open the hemostasis valve, the anchor is inserted into the artery, and the collagen plug is deposited on the outside of the artery wall.

During a surgery such as the one performed on Gomez, the surgeon enters the femoral artery through a catheter. When the doctor has completed the procedure and is ready to remove the catheter and close the entry wound using an Angio-Seal, the surgeon first inserts the guidewire through the catheter that is already inside the patient's femoral artery. The catheter is then removed. The surgeon then inserts the Angio-Seal device, using the bypass tube to push through and open the hemostasis valve before the anchor is released from the bypass tube. The anchor is supposed to swivel ninety degrees once it is out of the bypass tube, allowing the surgeon to pull the anchor flat, or flush, against the inner wall of the artery. The surgeon cannot see the anchor, but relies on the tension felt when the suture is pulled and the anchor is drawn perpendicular to, and flush against, the interior artery wall. The surgeon then tamps the collagen plug attached to the suture on the outer artery wall, causing rapid clotting at the puncture site. The anchor prevents the collagen from getting into the inner portion of the artery, the patient's bloodstream. If collagen enters the bloodstream, the intended benefit of the Angio-Seal—rapid clotting—can instead cause severe harm. Several medical witnesses testified that if collagen is introduced into a patient's bloodstream, significant complications can result. Dr. White, Gomez's treating doctor, described possible complications as including death, heart attack, stroke, bleeding, infection,

limb loss, and "embolization," which he described as the "breaking off [of] bits and pieces of plaque in the artery [that] can go downstream and cause problems in toes and fingers and [cause] stroke as well." (Tr. at 787). All the witnesses agreed that humans have collagen in their bodies, but only in the outer artery walls, not inside the arteries.

Dr. White did not experience any problem in using the Angio-Seal on Gomez on March 12, 1999. The records show that the bleeding at the access puncture site stopped with "no complications." (Tr. at 792–93). After routine postsurgical monitoring showed no problems, Dr. White discharged Gomez.

Less than two days after her surgery, Gomez experienced extreme pain in her right leg. She returned to Dr. White approximately two weeks later, complaining of pain in the right groin and thigh when she walked. Dr. White arranged for an ultrasound, which showed a 70 % narrowing of the artery at the point he had entered it for the surgery. Dr. White advised either an angioplasty or surgery to correct the narrowing. Dr. White testified at trial that he believed scarring from the collagen plug caused a clot on the outer femoral artery wall, which externally compressed and narrowed the artery. (Tr. at 856).

Gomez did not quickly obtain the treatment Dr. White recommended. Instead, she decided that she wanted a doctor closer to her home. She consulted Dr. Diana Gilmore, a cardiovascular surgeon, who referred her to Dr. Anthony Morales, an interventional cardiologist. Gomez's leg pain persisted during this period. On April 22, 1999, Dr. Morales performed an arteriogram, which indicated a 99% blockage in Gomez's right femoral artery. (Tr. at 404–06). Dr. Morales tried but failed to clear the blockage using a catheter. He testified that when he tried moving the catheter through the blockage he felt like he was "hitting concrete." He recommended surgery, which Dr. Gilmore performed on April 29, 1999.

Dr. Gilmore testified that she found a single embolus, or mass, *inside* Gomez's right femoral artery. She emphasized that the mass was not on the *outside* compressing the artery wall, as Dr. White opined, but inside the artery itself, in the area known as the luma. The mass was so large that it was pressing against the inside wall of the artery, known as the intima. (Tr. at 753–54). Dr. Jerry Hudson, a pathologist, examined the mass and determined that it consisted of suture material and collagen. (Tr. at 454–55). Dr. Hudson tested the mass for the presence of Type IV (human) collagen, which he found, but did not test for the Type I (bovine) collagen used in the Angio-Seal. (Tr. at 457).

Gomez continued to experience pain in her right leg and medical tests revealed diminished blood flow. Gomez has seen a number of doctors, including a hematologist/oncologist, who ruled out clotting disease as the cause of Gomez's problems. To treat the pain associated with clotting in her leg, Gomez saw a neurologist, who prescribed several drugs. Through May 3, 2000, Gomez has undergone nine surgical procedures, including seven catheterizations. Gomez has missed significant time at work and will likely need additional medical procedures and drugs to treat pain and weakness in her right leg.

On March 11, 2000, Gomez sued the Angio-Seal designer and manufacturer in federal court. Gomez asserted causes of action under the Louisiana Product Liability Act, LA. REV. STAT. ANN. §§ 9:2800.57(A) & (C) (West 1997), for unreasonably dangerous design, failure to warn of the dangers of the Angio-Seal, failure to warn the public of the dangers that the Angio-Seal posed for individuals with small blood vessels, failure to train medical personnel to use the Angio-Seal properly, lack of informed consent, breach of express warranty, redhibition, failure to communicate to the medical community the possibility of complications discovered after the FDA approval process ended, failure to train physicians

to address complications caused by the Angio-Seal, and failure to manufacture the device in accordance with FDA specifications.

Kensey Nash Corporation developed the Angio-Seal and obtained the approval of the Federal Food and Drug Administration through the premarket approval (PMA) procedure under the Medical Device Amendments to the Food, Drug, and Cosmetics Act, 29 U.S.C. § 360k(a). Kensey Nash Corporation licensed the rights to the device to American Home Products Corporation. In 1995, an American Home Products subsidiary, Quinton Instrument Company, was designated as the device manufacturer. The Food and Drug Administration approved Quinton's manufacturing and quality procedures on September 26, 1996. In 1998, American Home sold the rights to the device to Tyco International, which sold and marketed the Angio-Seal through its affiliate, the Kendall Company LP, n/k/a Tyco Healthcare Group LP ("Kendall"). Because Kendall was the only entity that owned and manufactured the Angio-Seal when the device used in Gomez's procedure was manufactured and sold, the district court dismissed the other defendants.

The district court granted summary judgment in Kendall's favor as to all Gomez's claims except manufacturing defect, on the basis that the Federal Medical Device Amendments preempted the Louisiana product liability statute. The district court initially granted summary judgment to Kendall on the manufacturing defect claim, but granted Gomez's Rule 59 motion after submission of previously-unavailable documents from the FDA demonstrated genuine issues of fact material to determining whether the Angio-Seal was made in accordance with the FDA-approved specifications. The district court convened a jury trial for the manufacturing defect claim. At trial, Gomez claimed that the Angio-Seal was defectively manufactured because the anchor extended past the bypass tube and did not sit fully within the tube as the specifications required. Gomez argued, and presented

witnesses who testified that, such a "positive extension" was a defect in the Angio-Seal. These witnesses, whose qualifications under Rules 701 and 702 of the Federal Rules of Evidence are not challenged, explained that this extension led to an improper position of the anchor inside Gomez's femoral artery when Dr. White used the Angio-Seal. Because the anchor did not sit flush against the interior artery wall, it did not perform its intended function of preventing the collagen from getting to the inside of the artery. As a result, Gomez asserted, collagen did enter her bloodstream and caused the blockage and subsequent circulatory problems in her leg.

Gomez relied on circumstantial evidence of defect and causation. The evidence included information that the Angio-Seals sent to the Ochsner Clinic, including the one used in Gomez's surgery, came from two manufacturing lots. Predistribution tests showed a two percent incidence of positive anchor extensions in the lot that supplied most of the Angio-Seals sent to the Ochsner Clinic. Gomez also presented evidence that FDA adverse-incident reports filed between November 1998 and April 1999 showed that six of the Angio-Seals in the reports came from the same two lots that had supplied the Ochsner Clinic, and three of those six resulted in occlusions, or blockages, in the patients.

At the close of the evidence, Kendall moved for judgment as a matter of law under Rule 50(a), contending that the evidence was insufficient to show either a defect in the Angio-Seal or that it caused the clot in Gomez's femoral artery. The district court granted the motion. Gomez timely appealed. Gomez contends that the district court committed error in finding that federal law preempted her state-law claims for defective design, failure to warn, breach of express warranty, negligence in training and consent forms, and redhibition. Gomez also challenges the district court's grant of Kendall's motion for judgment as a matter of law on the manufacturing-defect claim. Gomez also appeals from the district court's

order, entered after final judgment and after she filed her notice of appeal, requiring Gomez to pay certain deposition fees. Finally, Gomez claims that the district court erred in a number of discovery and evidentiary rulings and asks this court to assign the case to a new judge on remand.

We affirm the district court's preemption decision, reverse the Rule 50 order, remand for additional proceedings, and deny all additional relief as either moot or unwarranted.

II. The Standards of Review

This court reviews an award of summary judgment *de novo*, using the familiar standard. *Royal Ins. Co. of America v. Hartford Underwriters Ins. Co.*, 391 F.3d 639, 642 (5th Cir. 2004); FED. R. CIV. P. 56. Discovery and evidentiary rulings are reviewed under a deferential abuse of discretion standard. *See Freudensprung v. Offshore Technical Servs., Inc.*, 379 F.3d 327, 347 (5th Cir. 2004); *Rubinstein v. Adm'rs of the Tulane Educ. Fund*, 218 F.3d 392, 397 (5th Cir. 2000). This court reviews a district court's ruling on a motion for judgment as a matter of law *de novo*, applying the same standard as the district court. *Piotrowski v. City of Houston*, 237 F.3d 567, 576 n.9 (5th Cir. 2001) (citing *Rutherford v. Harris County, Tex.*, 197 F.3d 173, 178 (5th Cir. 1999)). "The district court properly grants a motion for judgment as a matter of law only if the facts and inferences point so strongly in favor of one party that reasonable minds could not disagree." *Id.* "In ruling on a rule 50 motion based upon the sufficiency of the evidence, we 'consider all of the evidence—not just that evidence which supports the non-mover's case—but in the light and with all reasonable inferences most favorable to the party opposed to the motion.' " *Info. Commc'n Corp. v. Unisys Corp.*, 181 F.3d 629, 633 (5th Cir. 1999) (quoting *Boeing Co. v. Shipman*, 411 F.2d 365, 374 (5th Cir. 1969) (en banc)) (additional citations omitted). In evaluating the Rule 50

motion, the district court cannot assess the credibility of witnesses or weigh the evidence. *Reeves v. Sanderson Plumbing Prod.*, 530 U.S. 133, 150 (2000).

III. Preemption

The district court held that the Medical Device Amendments of 1976, 21 U.S.C. §§ 360c–l, to the Food, Drug and Cosmetic Act preempted Gomez's state-law claims that despite compliance with FDA requirements, the Angio-Seal was defectively designed, defectively manufactured, and defectively marketed. The district court dismissed the claims for failure to warn, breach of express warranty, negligence regarding training and consent forms, strict liability, unreasonably dangerous *per se*, and negligence. This circuit's decisions in *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001), and *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993), control this issue. Because the Angio-Seal was subject to the FDA's "rigorous" PMA procedure, we agree with the district court that these state-law claims are preempted.

The Medical Device Amendments of 1976 classify medical devices into three categories based on the potential risk to the public. 21 U.S.C. § 360c(a)(1)(A)–(C); *Lohr v. Medtronic, Inc.*, 518 U.S. 470, 476 (1996). "Devices that present no unreasonable risk of illness or injury are designated Class I and are subject only to minimal regulation by 'general controls.'" *Lohr*, 518 U.S. at 476–77 (citing 21 U.S.C. § 360c(a)(1)(A)). "Devices that are potentially more harmful are designated Class II" and must comply with a set of regulations coined "special controls." *Lohr*, 518 U.S. at 477 (citing 21 U.S.C. § 360c(a)(1)(B)). Devices that present "a potential unreasonable risk of illness or injury" or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" are designated Class III. 21 U.S.C. § 360c(a)(1)(C). The Angio-Seal is a Class III medical device.

Before a Class III device may be put on the market, the manufacturer must give the FDA "reasonable assurance" that the device is both safe and effective. 21 U.S.C. § 360e(d)(2). A manufacturer provides "reasonable assurance" through the PMA process. The PMA process requires the manufacturer to "submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Lohr*, 518 U.S. at 477. Significantly, the FDA's involvement with the devices continues even after the PMA is complete. *See, e.g.*, 21 C.F.R. § 814.80 (prohibiting the production or labeling of any device in a manner inconsistent with any conditions of approval specified in the approval order); 21 C.F.R. § 814.3a(d) (requiring an applicant to submit a supplemental application setting forth any proposed changes for FDA approval before implementing any changes).

Congress provided two exceptions to the PMA process. First, a grandfather clause permits medical devices marketed before passage of the amendments to remain unless and until the FDA initiates and completes the PMA process. *See Lohr*, 518 U.S. at 21; C.F.R. at 478 (citing 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1)). Second, devices that are "substantially equivalent" to a preexisting medical device are exempt from the PMA process and instead subject to a streamlined approval process. *See Lohr*, 518 U.S. at 492–94 (describing the significant differences between the PMA and the "substantially similar" process under § 510(k));[1] 21 U.S.C. § 360e(b)(1)(B).

The Supremacy Clause of the Constitution prohibits state laws from conflicting with federal law. U.S. CONST. art. VI, cl. 2. A "state law that conflicts with federal law is without effect." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). "In view of the

[1] The procedure used to determine whether a device is "substantially equivalent" to a preexisting medical device is often referred to as the "§ 510(k)" process, named after the number of the section in the original act. *Lohr*, 518 U.S. at 478.

historic importance of federalism in these areas, the states' police powers relating to public health and safety are not preempted by federal law unless Congress' intent to do so is clearly expressed." *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000) (citing *Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985)). When Congress enacts a specific preemption provision, that provision determines the preemptive effect of the statute. *Cipollone*, 505 U.S. at 517.

The express preemption provision in the Medical Device Amendments governs the extent to which it preempts state law. It states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The FDA has promulgated regulations to assist courts in interpreting this section, which states in part as follows:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act.

21 C.F.R. § 808.1(d); *see also id.* at 808.1(d)(1)–(10) (listing examples).

This circuit has held that the PMA process "preempts state tort causes of action to the extent that they relate to safety, effectiveness, or other MDA requirements" if the state-law claims impose "substantive requirements" different from or inconsistent with the federal law. *Martin*, 254 F.3d at 584. In *Martin*, this circuit examined its earlier preemption

analysis in *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993) in light of the Supreme Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). Both *Stamps* and *Martin* involved Class III medical devices subject to the PMA process; *Lohr* involved a device that was subject to the less-demanding § 510(k) notification process. In *Martin*, the court reaffirmed *Stamps* and held that the PMA requirements preempted Texas state product-liability claims arising from a Class III medical device, including claims of defective design, failure to warn, and inadequate labeling, because those claims related to areas specifically covered in the PMA process and sought to impose requirements that were "different from and, indeed, conflict with" the results of the PMA process. *Martin*, 254 F.3d at 584.

This circuit, and all but one of the appellate courts considering the issue, require a district court to look through the general duties imposed by the state-law causes of action and consider the effect a successful lawsuit asserting those causes of action would have and determine whether they threaten the federal PMA process requirements. *See, e.g.*, *Horn v. Thoratec Corp.*, 376 F.3d 163, 172–73 (3d Cir. 2004) (same); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 799 (8th Cir. 2001) (en banc); *Kemp*, 231 F.3d at 230, 236; *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913–15 (7th Cir. 1997); *Papike v. Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir. 1997); *but see Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1377 (11th Cir. 1999) (holding that § 360k(a) does not preempt common-law claims involving PMA-approved devices). This court and the other courts of appeals (save the Eleventh Circuit) recognize that the FDA, through the PMA process, has imposed a set of specific regulations on medical devices and their manufacturers that preempt state-law claims relating to the same areas and seeking to impose different requirements. Through the decisions made in the PMA process, the federal government has "weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those

competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." *Papike*, 107 F.3d at 741 (quoting *Lohr*, 518 U.S. at 501). That conclusion is entitled to preemptive effect.

Because the Angio-Seal went through the PMA process, the cases discussing medical devices subject to the less-demanding "substantially equivalent" process are not helpful. *Compare Martin*, 254 F.3d at 584 ("[T]he fact that the § 501(k) process did not preempt state causes of action in *Lohr* does not indicate that the PMA process cannot preempt state tort causes of action.") *with Reeves v. Acromed Corp.*, 103 F.3d 442, 447 (5th Cir. 1997) ("[T]he 'substantial equivalence' provision did not preempt Reeves' unreasonably dangerous *per se* claim."). The *Martin*/*Lohr* test applies to products liability claims against PMA-approved devices such as the Angio-Seal. The district court correctly analyzed Gomez's claims to determine whether the state-law duties enforced by the causes of action she asserted would threaten the federal duties imposed under the PMA process.

Gomez alleged strict liability defective design and negligent design causes of action under Louisiana law. To prevail on her "unreasonably dangerous in design" claim, Gomez had to prove that: (1) "[t]here existed an alternative design for the product that was capable of preventing the claimant's damage"; and (2) "[t]he likelihood that the product's design would cause the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product. An adequate warning about a product shall be considered in evaluating the likelihood of damage when the manufacturer has used reasonable care to provide the adequate warning to users and handlers of the product." LA. REV. STAT. ANN. § 2800.56 (West 1997). The FDA studied the Angio-Seal design through

the PMA process and approved it. To permit a jury to second-guess the Angio-Seal design by applying the Louisiana statutory standard for unreasonably dangerous design would risk interference with the federally-approved design standards and criteria. The district court judge correctly found that federal law preempted this state-law challenge to the design of the Class III FDA-approved Angio-Seal.[2] *Accord Horn*, 376 F.3d at 176; *Martin*, 254 F.3d at 584–85; *Papike*, 107 F.3d at 741–42.

Gomez also alleged state-law causes of action for failure to warn and failure to train, including a claim that because Kendall's clinical studies underrepresented women, it failed to give adequate warnings of risks more likely to occur in women as a result of generally smaller blood vessels. *See* LA. REV. STAT. ANN. § 2800.57 (listing elements of inadequate warning claims). Gomez claimed that Kendall provided inadequate warnings; that Kendall should have been required to provide more specific information about the Angio-Seal; that the consent forms should have required a physician to obtain a patient's specific, informed consent to the use of the Angio-Seal before its use; and that the material Kendall supplied to train in the use of the Angio-Seal were inadequate. Gomez also sought recovery under a theory of redhibition, which is Louisiana's equivalent to a breach of implied warranty claim. *See* LA. REV. STAT. ANN. § 2520 (West 1997).

The FDA approved Kendall's warnings and instructions for physicians contained in the Instructions for Use ("IFU") through the PMA process. That process required the FDA to approve clinical studies and evaluate the results, to specify the labeling requirements, and

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[2] Courts have permitted state law-based actions claiming that a defendant failed to build a medical device in compliance with PMA-approved design specifications. *See Martin*, 254 F.3d at 582 n.8 ("However, common law duties that incorporate the PMA process, such as the general duty to take due care to comply with the PMA process and labeling or manufacturing, will never contain specific requirements that are additional to or different from federal requirements. Therefore, claims based on those duties are not preempted.") (citing *Lohr*, 518 U.S. at 495). The district court permitted such a claim to go forward in this case, a decision Kendall did not appeal.

and approve the label that issued. The FDA also approved the "Patient Guide" used to provide information and warnings to patients, again through the PMA process. Kendall's training requirements were also subjected to, and approved in, the PMA process. To permit a jury to decide Gomez's claims that the information, warnings, and training material the FDA required and approved through the PMA process were inadequate under state law would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations on Kendall. The district judge correctly found that Gomez's state-law claims that Kendall's labeling, warning, information, and training were inadequate or incomplete are preempted. *Accord Horn*, 376 F.3d at 176; *Martin*, 254 F.3d at 584–85; *Stamps*, 984 F.2d at 1422; *Mitchell*, 126 F.3d at 913–14; *Papike*, 107 F.3d at 741–42.

Gomez argues that it is inappropriate to apply preemption to her warranty claims to the extent she based them on a later-acquired knowledge theory. Gomez argues that even if Kendall did not know the potential problems Angio-Seal presented for patients like her when the device received FDA approval, it later learned more information about those risks but failed to provide that information in updated warnings for patients and physicians. This argument fails to overcome preemption. Medical device manufacturers such as Kendall have ongoing obligations to report experience with the device to the FDA, and the FDA has plenary authority to amend the regulations and requirements it imposed relating to the device, up to and including removing it from the market. At the end of the PMA process leading to approval, the FDA issues conditions of approval requiring the manufacturer to meet ongoing reporting and other obligations. *See* 21 C.F.R. § 814.80; 21 C.F.R. § 814.3a(d). The record shows that after the FDA approved the Angio-Seal, Kendall submitted a proposed change to the warning label recognizing risk for patients with smaller veins, particularly females, and recommending additional procedures to mitigate this risk. Gomez's state-law claims related

to Kendall's alleged failure to provide information obtained after the FDA approved the Angio-Seal risk the same interference with the federal regulatory scheme as her other claims and are preempted.

Gomez also claimed that Kendall breached express warranties imposed under Louisiana law relating to the Angio-Seal. The Seventh Circuit has noted that express warranties, which "arise[s] from the representations of the parties and are made as the basis of the bargain between them" may "not necessarily interfere with the operation of the PMA, and therefore" may not be preempted. *Mitchell*, 126 F.3d at 915. Both parties agree that the Angio-Seal's express warranty was part of the IFU, which is itself part of the PMA process. This fact does not resolve the issue, however, because a lawsuit that simply parallels or enforces the federal regulatory requirements without "threatening" or interfering with them is not preempted. *See Lohr*, 518 U.S. at 495.

The Louisiana law governing claims of breach of express warranty reads,

> A product is unreasonably dangerous when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use the product and the claimant's damage was proximately caused because the express warranty was untrue.

LA. REV. STAT. ANN. § 9:2800.58 (West 1997). The district court held that the breach of warranty claim was preempted because "the warranty is intertwined with the FDA's standards concerning the device's design, testing, intended use, manufacturing methods, performance standards and labeling." (R. at 595). Unlike the alleged breach of express warranty at issue in *Mitchell*, the Louisiana statute goes beyond merely enforcing the federal requirements. The last part of the Louisiana provision requires proof that "the express warranty was untrue." LA. REV. STAT. ANN. § 9:2800.58. A jury hearing Gomez's state-law breach of express warranty claim would have to decide whether Kendall's representations

about the Angio-Seal were true. Because those representations—including the label, warnings, and IFU—were approved by the FDA through the PMA process, the duties arising under the Louisiana breach of warranty statute relate to, and are potentially inconsistent with, the federal regulatory scheme. The claim is preempted. *Accord Baker v. Medtronic, Inc.*, No. 2:99-CV-1355, 2002 WL 485013, at *8 (S.D. Ohio Mar. 28, 2002) ("[E]xpress representations are subject to comprehensive FDA regulation.") (citing *Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1100 (6th Cir. 1997)).

Gomez also alleged several negligence-based state-law claims, including claims of negligence *per se*. The district court denied Kendall's motion for summary judgment that federal law preempted Gomez's state-law defective manufacturing claim. That statute requires a plaintiff to show that: (1) defendant is a manufacturer of the product; (2) the product proximately caused the plaintiff's damage; (3) the damaging characteristic of the product rendered it "unreasonably dangerous"; and (4) the plaintiff's damage arose from a reasonably anticipated use of the product. LA. REV. STAT. ANN. § 2800.54 (West 1997); *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 261 (5th Cir. 2002). Gomez's claims that Kendall deviated from the FDA-approved specifications in manufacturing the Angio-Seal used in her surgery survived summary judgment.

The district court properly granted summary judgment on Gomez's negligence claims that were based on aspects of the Angio-Seals's design, manufacture, and marketing that complied with the FDA-approved requirements. No negligence claims can be maintained as to devices that complied with the FDA requirements because success on those claims requires a showing that the FDA requirements themselves were deficient. These claims cannot be presented to a jury because, if successful, they would be inconsistent with the federal regulatory requirements. The district judge properly limited Gomez's negligence

claims to a claim that the Angio-Seal used in her surgery was defectively manufactured because it did not comply with the FDA-approved specifications. *Cf. Mitchell*, 126 F.3d at 913 ("The Mitchells' negligence claims must be considered preempted to the extent that they allege that Collagen was negligent despite its adherence to the standards required by the FDA in its PMA for this specific product."). The district court's summary judgment ruling that Gomez's other state law-based claims were preempted by the MDA is affirmed.

IV. Rule 50

To prevail on a manufacturing defect claim under Louisiana law, the plaintiff must show that when the product left the manufacturer's control, it "deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." LA. REV. STAT. ANN. § 9:2800.55 (West 1997). At the close of the evidence, the district court granted Kendall's Rule 50 motion on the ground that Gomez had failed to present evidence from which a reasonable jury could conclude that the Angio-Seal used in her surgery was defective, or that the alleged defect caused her injuries. To prevail on appeal, Gomez must point to record evidence that could have supported a finding in her favor on defect and causation. In reviewing the record, we must draw all reasonable inferences and resolve all conflicting evidence in favor of Gomez and refrain from weighing the evidence or making credibility determinations. *Reeves*, 530 U.S. at 150.

A. The Evidence of Defect

After Gomez's surgery, the hospital destroyed Angio-Seal as medical waste. Gomez had to rely on circumstantial evidence to prove that the Angio-Seal used on her was defective. As the district court properly noted, however, the law does not distinguish between circumstantial and direct evidence. *See, e.g., Holland v. United States*, 348 U.S.

121, 140 (1954) (noting that circumstantial evidence "is intrinsically no different" than direct evidence). On a Rule 50 motion, the district judge could neither weigh the evidence presented nor make credibility determinations about it. *See Ellis v. Weasler Eng'g, Inc.*, 258 F.3d 326, 337 (5th Cir. 2001) (citing *Reeves*, 530 U.S. at 150) (additional citations omitted)). After a thorough review of the record, we find that Gomez met her standard for defeating the Rule 50 motion as it related to defect.

Dr. Seth Bilazarian, an interventional cardiologist, Dr. John Eidt, a vascular surgeon, and Dr. Steven Jones, a biomechanical engineer, testified about the Angio-Seal and how it worked to stop bleeding at a puncture site used to access the bloodstream in a catheterization procedure. All gave testimony that supported an inference that a positive extension of the anchor in relation to the bypass tube violated the FDA manufacturing specification, made the device defective, and that the device used on Gomez in March 1999 contained this defect.

Dr. Bilazarian testified that he had extensive experience in using Angio-Seals. He testified as to why he concluded that in Gomez's case, the anchor did not perform its intended function of keeping collagen from the inside of the artery. The pathology report showed that the mass removed from Gomez's right femoral artery contained fragments of suture material and collagen. Dr. Bilazarian testified that both came from the Angio-Seal: the suture is used to attach the anchor to the collagen plug; and Gomez's own collagen would not be found inside her blood vessel, but only in the artery wall itself. (Tr. at 169, 172). The contents of the mass supported an inference that the Angio-Seal anchor did not operate properly. Bilazarian testified that the pathology report was consistent with collagen causing a clot to form *inside* Gomez's artery, instead of on the outside artery wall. (*See id.* at 173). Dr. Bilazarian testified that the medical records showed no evidence of other conditions, such as a clotting disorder, that could explain the clot on the inside of the artery. Dr.

Bilazarian also testified that the medical records showed no evidence of causes for a collagen deposit inside the artery wall—such as a separation or dissection of the artery walls when the Angio-Seal was used—other than the improper operation of the Angio-Seal anchor.

The district court relied on a statement incorrectly attributed to Dr. Bilazarian in granting Kendall's Rule 50 motion. The district court stated that Dr. Bilazarian had testified that if he saw an Angio-Seal with the anchor extending past the bypass tube, he would simply tap it back into place and use it. The district court found this statement supported his conclusion that there was insufficient evidence of defect to allow the case to go to the jury. The record reveals that Dr. Bilazarian, along with other witnesses, testified that if he saw such an extension, he would not push the anchor back inside the tube and would discard it. (Tr. at 189).

Dr. John Eidt also testified that he would discard an Angio-Seal with a positive anchor extension and explained why:

> When you push [the bracket through the hemostasis valve], it's kind of like going through barroom doors, you kind of have to push them open to get through.
>
> I think there is—while the risk is that as you push the device through this sort of rubber seal, that if the extension, if the anchor is sticking out the end of the device it could malposition, it could cause it to rotate or change its relationship to the device so that when you do pull on it, when you get it in the artery instead of it being aligned the way it's supposed to, it's misaligned.

(Tr. at 319, 308–09).

Dr. Jones, the biomechanical engineer, explained that the hemostasis valve—the barroom doors—are made of silicon, a sticky viscous material harder than the plastic of the anchor. The bypass tube is intended to push through the hemostasis valve, while the anchor remains in the tube's protective sheath. Dr. Jones testified that if the anchor extended past the bypass tube and was the part of the Angio-Seal pushing through the hemostasis valve, the

anchor could be damaged and mispositioned inside the artery. In its proper position, the anchor is flat against the inner artery wall. If it is damaged when inserted into the artery, it could be positioned at an angle to the artery wall instead of flush against it. When the surgeon uses the tamping tube to tamp the Angio-Seal collagen plug, an angled anchor could allow collagen to be tamped down into the artery itself. Dr. Eidt testified that he could move a positively-extended anchor back into the bypass tube. He was not asked, and did not testify, that he would do so before using the device on a patient.

Kendall argued that Gomez presented insufficient evidence that this deviation—an anchor extending beyond the bypass tube—was present in the Angio-Seal used in her surgery or that it was a defect. The evidence showed that the Angio-Seal specifications called for the anchor to be fully within the bypass tube, no more than .05 inches away from the end of that tube. (Tr. at 516). Dr. Jones testified that an "anchor extension" is on the list of "major defects" for the Angio-Seal. The evidence at trial showed that the devices supplied to the Ochsner Clinic came from two lots, 100804 and 100858. Kendall followed required protocol and tested 100 randomly-selected Angio-Seals from each of these lots before releasing them for shipment. The tests showed that in one of the lots, 2 % of the devices tested had positive anchor extensions that were "nonconforming." Jones testified that FDA-approved quality assurance inspections require an entire lot to be discarded if a random test of devices within the lot reveal a defect in 1 out of 1,000 devices (a defect rate of 0.01%). Lot number 100804 had two defective Angio-Seals within the 100 samples: one with an anchor extension of 0.13 inches and one with an anchor extension of 0.14 inches. (Tr. at 483). Lot number 100858 also had two Angio-Seals within the 100 samples with deviations in the anchor position, but this lot had negative, not positive, anchor extensions. The record showed that the bulk of the devices supplied to the Ochsner Clinic came from lot number

100804, which had a 2 % incidence of positive anchor extensions. (Tr. at 282, 328, 491–92; Ex. 46).

The testimony supported an inference that the lot supplying the majority of the devices shipped to the Ochsner Clinic during the relevant period had a positive anchor extension rate of 1 out of 50 devices, or 2%, well in excess of the FDA standards requiring disposal of the entire lot. Jones testified that a company releasing a lot with such a high incidence of noncomforming devices is "pretty much guaranteed [to] send[ ] out devices that exceed that specification." (Tr. at 483).

Under Kendall's FDA-required procedures, "[a] record of a nonconformance . . . requires quarantine of the discrepant material, review, and disposition by the Material Review Board, and a preventive action response by a designated individual." (*Id.*). Tamara Yount, the Kendall Quality Assurance and Regulatory Affairs directors when Kendall released the two lots at issue, corroborated much of Dr. Jones's testimony about the specifications in the two lots that were the source of the Angio-Seals sent to the Ochsner Clinic. Yount remembered the two lots with the anchor extensions and testified that these were the only two lots that had such deviations. (Tr. at 641–43).

Yount served on the Material Review Board that reviewed the deviations from manufacturing specifications and authorized the release of the devices. A Material Review Board cannot authorize release of noncomforming devices unless it determines that the deviation will have "no clinical effect." (Tr. at 668). In her testimony, Yount conceded that the positive anchor extensions were not in compliance with the specifications. (Tr. at 656). Yount testified that the Material Review Board determined that the positive anchor extensions would have no clinical effect on how the Angio-Seals operated. (Tr. at 650). Yount admitted that the Board conducted no regular meetings and did not meet on this issue;

kept no minutes; and performed no tests to determine the potential effects of a positive anchor extension in human surgical procedures.

Yount's testimony showed that after Kendall discovered the anchor extension problem, it determined the likely cause. The employees placing Angio-Seals in packages were putting the devices too close to the package sealer bars, which could cause the tubes to be pushed back when the package was sealed. Kendall retrained its employees to avoid this problem. Yount agreed with Gomez's witnesses that the purpose of requiring the anchor to be inside the bypass tube is to have the bypass tube push past the hemostasis valve. Yount's testimony did not show that the Material Review Board specifically considered the effect of having the anchor, rather than the tube, push open the valve.

The jury heard testimony from witnesses, including Dr. Bilazarian, Dr. Eidt, and Dr. Jones, that the anchor could be damaged if it extended beyond the bypass tube and had to push past the hemostasis valve. (Tr. at 650, 668–72). Kendall emphasizes that Dr. Christopher White, Gomez's treating physician and the only witness who actually observed the Angio-Seal used, did not record any indication of a positive anchor extension and had no recollection that he had ever seen one. Medical witnesses who had also used Angio-Seals testified that a physician might not notice an anchor extension in preparing to use the device at the end of a surgical procedure. (Tr. at 325). The fact that Dr. White disagreed with some of Gomez's expert and fact witnesses, however, or that there were inconsistencies in some of the testimony of the witnesses Gomez called, does not support granting the Rule 50 motion. The evidence could support an inference that the Angio-Seal used on Gomez had a positive anchor extension and that this condition was a defect. Gomez presented sufficient evidence to have the jury weigh it and make the credibility judgments necessary to resolve any conflicts. *Accord Ellis*, 258 F.3d at 337–38.

B. The Evidence of Causation

Gomez was not required to eliminate every possible alternative cause of her injuries to raise an inference that a defective Angio-Seal caused her injuries. Instead, under Louisiana law, Gomez had to eliminate alternative causes with "reasonable certainty." *Pipitone*, 288 F.3d at 243 n.5 (applying Louisiana law); *Wheat v. Pfizer, Inc.*, 31 F.3d 340, 342–43 (5th Cir. 1994) (same).

As noted, Dr. Bilazarian, Dr. Eidt, and Dr. Jones testified that the anchor prevents the collagen used in the Angio-Seal from moving to the inside of the artery. They testified that a positive anchor extension on the Angio-Seal used on Gomez could have caused the anchor to be pushed out of position when it passed through the hemostasis valve into Gomez's artery and not sit flush against the inner artery wall. Dr. Jones testified that a positive anchor extension could cause the Angio-Seal anchor to "stick into the wall of the artery" instead of lining up flush against the artery wall. (Tr. at 522). Once the anchor is stuck against the artery wall, and the surgeon goes to "tamp the collagen down, there is room, there is a space there for collagen to get into the artery and, of course, come into contact with the blood." (*Id.*). Jones and other witnesses testified that an angled or improperly-positioned anchor could allow collagen from the Angio-Seal plug to escape into the artery itself. (*Id.*). Such testimony, if found credible, could support an inference that the positive-anchor defect in the Angio-Seal caused Gomez's injuries.

Dr. Bilazarian and Dr. Eidt testified about the medical evidence supporting the conclusion that collagen from the Angio-Seal caused the blood clot to form in Gomez's femoral artery after the March 1999 surgery. Dr. Gilmore performed the surgery to relieve a 99 % blockage from Gomez's femoral artery one month after her initial surgery. The jury heard Dr. Gilmore's testimony that the mass she removed from Gomez was inside the

femoral artery. (Tr. at 753). Dr. Gilmore testified that she agreed with the pathology report, which stated that the injury and the extracted lump were consistent with a "collagen plug." (Tr. at 754). The pathology report also showed suture fragments inside Gomez's artery. (*See* Testimony of Dr. Jerry Hudson, Tr. at 455–56).

Dr. Bilazarian and other medical witnesses rejected alternative causes for the presence of collagen inside Gomez's artery. They testified that artery dissection or physician error were unlikely explanations for the presence of collagen and suture fragments inside the artery. Dr. Bilazarian examined the report from Dr. Gilmore and could not think of any alternative as to "how . . . that stuff [parts of the Angio-Seal] was in there and shouldn't have been in there." (*Id.*). Dr. Bilazarian and other medical witnesses, including Dr. White, testified that they could eliminate other causes for the formation of the blood clots, such as a tendency to form clots or Gomez's history of smoking. (Tr. at 181–82, 195–96, 577, 726, 848). Dr. White conceded that Gomez's injuries were not caused by preexisting plaque in her right femoral artery, an artery dissection, or vasospasm. (Tr. at 842–45). Dr. Bilazarian also provided testimony from which the jury could have concluded that the injuries did not result from a vasospasm. (*See* Tr. at 186).

Kendall argued that there was no evidence that the collagen found inside Gomez's femoral artery was bovine collagen, the substance used in the Angio-Seal. The pathologist did not screen for bovine collagen, only human. As a result, there was no evidence that collagen inside Gomez's bloodstream was, or was not, bovine. Kendall contends that this contributed to Gomez's failure to meet her burden of proof that the Angio-Seal was defective or caused her injuries. Because Angio-Seal contains bovine collagen, a definitive result one way or the other would have provided significant evidence. The lack of that evidence required Gomez to demonstrate defect and causation through other evidence. Gomez

introduced evidence that there should not have been any collagen inside her bloodstream at all. She introduced evidence eliminating causes for the presence of collagen inside her femoral artery other than the failure of the Angio-Seal's anchor to prevent that from occurring.

Kendall presented evidence that an external clot pressing on the artery from the outside caused the femoral artery narrowing. Dr. White testified that a recognized complication of a properly-manufactured and deployed Angio-Seal is that the collagen will cause a large clot to form on the outside of the artery wall, which can compress and narrow the artery. This conflicted with Gomez's evidence that a clot inside the artery caused her femoral artery narrowing because the Angio-Seal's anchor failed to prevent the externally-deposited collagen from coming inside the artery itself. The jury should have resolved this conflicting evidence as to causation. Gomez did not, as Kendall asserts, simply rely on the fact that she suffered injuries after the surgery and blame it on the use of a medical device no longer available for inspection. *Cf. Todd v. State*, 699 So. 2d 35, 43 (La. 1997) ("Proof which establishes only possibility, speculation, or unsupported probability does not suffice to establish a claim.") (citing *Coon v. Placid Oil Co.*, 493 So. 2d 1236 (La. App. 3 Cir. 1996)). As with the defect issue, Kendall put forward substantial conflicting testimony and evidence, but under the Rule 50 standard, the court must draw all reasonable inferences in favor of the nonmoving party, Gomez, and may not weigh the evidence or the credibility of the witnesses. The district court erred in granting the Rule 50 motion on the basis of insufficient evidence as to causation.

C. Remand

Gomez asks this court to interpret Rule 50 to forbid a judge from granting a motion for judgment as a matter of law after the evidence is concluded, to prevent the necessity of

retrial in the event the district judge is later reversed. Gomez asks this court to require a district judge to withhold judgment on the Rule 50 motion, submit the case to the jury, and then rule on the motion only if the jury returns with a plaintiff's verdict. We decline to impose such a rule. It may be prudent to allow the jury to consider a case before ruling on a Rule 50 motion, but the language of Rule 50 does not require making this an inflexible requirement. *See, e.g.*, *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 126 S. Ct. 980, 988 (2006) (citing and quoting with approval 9A CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE & PROCEDURE § 2533, at 319 (2d ed. 1995)); *McPhillamy v. Brown & Root, Inc.*, 810 F.2d 529, 533 (5th Cir. 1987) ("In reserving judgment here, the district court was following a practice we have described as highly desirable and salutary.") (internal citations and quotations omitted). It is not necessary to create such a requirement to resolve this case. The record shows that Gomez introduced sufficient evidence of defect and causation to allow the jury to resolve her manufacturing defect claim. The district court's order granting Kendall's Rule 50 motion is reversed and the case is remanded for a new trial.

Gomez makes a number of challenges to the district court's evidentiary and discovery rulings. The challenges primarily focus on the district judge's refusal to allow Gomez to discover or introduce into evidence information about the design, warnings, labels, instructions, training materials, and other information based on the preemption ruling, and about lots besides the two that were the source of the Angio-Seal used on Gomez. Because we have affirmed the district judge's dismissal of Gomez's claims except the defective manufacturing claim based on the theory that Kendall deviated from the FDA-approved manufacturing specifications, we find these general limits on discovery and admission of evidence appropriate. The evidence that the two lots that supplied the Ochsner Clinic's Angio-Seals during the relevant period were the only lots with positive anchor extensions

provides support for the district judge's refusal to allow evidence about Angio-Seals that came from other lots. We need not address Gomez's objection to the district court's postjudgment award of costs, which is vacated in light of this ruling.

Gomez asks this court to use its supervisory power to reassign this case to a different district court judge on remand. 28 U.S.C. § 2106; *United States v. Williams*, 400 F.3d 277, 283 (5th Cir. 2005) (per curiam). The record provides no support for this step. A federal judge should not preside over a case if "his impartiality might reasonably be questioned." 28 U.S.C. § 455(a). In evaluating disqualification under section 455, the question is whether the court is biased against a party, not whether the court is annoyed with the party's counsel. *See United States v. Andrews*, 390 F.3d 840, 851 (5th Cir. 2004) (removing and reassigning to a different judge where the trial judge exhibited "brazen antagonism" to both the controlling law and the defendant during sentencing); *Henderson v. Dep't of Pub. Safety & Corr.*, 901 F.2d 1288, 1296 (5th Cir. 1990) ("In order for bias against an attorney to require disqualification of the trial judge, it must be of a continuing and personal nature.") (internal citations omitted).

Our review of the record indicates no grounds for reassignment on remand. The district judge was obviously annoyed with counsel at times, but not without reason; the record reveals that Gomez's counsel failed to comply with the district court's rules and even the pretrial order. The record also shows that the district judge's frustration was not limited to one side, but at different times extended to counsel for both parties. The court took care to instruct the jury that any indication of his own feelings should play no role in their decisionmaking process. And the record shows that the judge displayed neither bias nor favoritism in ruling on motions and objections. As expected in a complex, aggressively tried case, both sides received favorable and unfavorable rulings from the district court. Gomez

has failed to demonstrate bias against her. Her request for reassignment to a different district judge on remand is denied.

V. Conclusion

The district court's preemption decision is affirmed. The district court's Rule 50 order is reversed and the case is remanded for a new trial on the issue of whether the Angio-Seal was defective as a result of Kendall's failure to manufacture the product in accordance with the FDA-approved specifications and whether that defect caused Gomez's injuries. The Gomezes' additional requests for relief are denied.

AFFIRMED IN PART; REVERSED IN PART; AND REMANDED. ALL OUTSTANDING MOTIONS DENIED AS MOOT.