[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 10-15327

D.C. Docket No. 0:08-cv-60931-LRJ

STEPHEN HORRILLO,
as Personal Representative of the Estate of Margaret Horrillo,

Plaintiff - Appellant,

versus

COOK INCORPORATED,
d.b.a. Cook Medical,

Defendant - Appellee.

Appeal from the United States District Court
for the Southern District of Florida

(November 7, 2012)

Before WILSON, PRYOR and MARTIN, Circuit Judges.

MARTIN, Circuit Judge:

Mr. Stephen Horrillo, as the personal representative of the Estate of Ms. Margaret Horrillo, appeals the district court's grant of summary judgment in favor of Cook Incorporated in this product liability action.

I.

On May 31, 2007, Dr. Michael Rush performed an angioplasty and inserted a Formula 418 biliary stent into Ms. Horrillo's renal artery to treat her arterial stenosis.[1] The surgery was performed at Holy Cross Hospital in Fort Lauderdale, Florida. Although Dr. Rush considered the procedure a success in the hours immediately after surgery, Ms. Horrillo suffered a non-hemorrhagic stroke within twenty-four hours of the procedure, which resulted in serious injuries.

The Formula 418 biliary stent that Dr. Rush used was manufactured by Cook Incorporated. The Food and Drug Administration (FDA) had approved the stent for biliary use, but had not approved its use in renal arteries. This being the case, Cook included the following disclosures in the stent's instructions for use. First, it stated that the device was "intended for use in palliation of malignant neoplasms in the biliary tree," which is to say, treatment for cancer in the bile

[1] On a motion for summary judgment, the facts shown are viewed in the light most favorable to the nonmoving party and all inferences are drawn in favor of the nonmoving party. See Anderson v. Liberty Lobby, Inc. 477 U.S. 242, 252-55, 106 S. Ct. 2505, 2512-14 (1986).

ducts. Second, under a heading entitled, "WARNINGS," the instructions for use cautioned that "[t]he safety and effectiveness of this device for use in the vascular system have not been established."[2]

Depositions in this case suggest that it was common knowledge that biliary stents, like Cook's, were frequently used "off-label" to facilitate peripheral circulation, including in the renal arteries. In fact, Dr. Rush stated during his deposition that he had performed many angioplasty procedures and had previously used the Formula 418 biliary stent to treat arterial stenosis, to the point where he felt experienced with its off-label use.

In February 2007, the FDA contacted various medical device manufacturers, including Cook, to attend a meeting because of the extensive off-label use of biliary stents and the high rate of bad medical outcomes reported in connection with that off-label use. The FDA cited complications including "air embolism, seizure, stroke and death." For Cook, forty percent of the adverse medical incidents associated with its Formula 418 biliary stent originated in off-label use. The FDA held the meeting with the stent manufacturers, including Cook, on March 12, 2007. On October 18, 2007, Cook sent a letter to Holy Cross

[2] Cook eventually filed an application with the FDA to approve the use of the Formula 418 stent in renal arteries, but the application had not been approved at the time this lawsuit was filed.

Hospital—where Dr. Rush had performed Ms. Horrillo's surgery on May 31, 2007—warning of the risks associated with the off-label use of the biliary stent. Among the risks listed in the October 2007 letter was stroke.

II.

In January 2008, Ms. Horrillo filed a complaint against Cook in Florida state court, asserting claims for negligence, strict liability, and breach of warranty under Florida law. Cook removed the case to the District Court for the Southern District of Florida on the basis of diversity jurisdiction.

In August 2010, Cook filed a motion for summary judgment arguing that Ms. Horrillo had failed to demonstrate that Cook was the proximate cause of the harm she suffered. Relying on the learned intermediary doctrine, Cook argued that because Dr. Rush was aware of the risks associated with the angioplasty procedure, Ms. Horrillo could not demonstrate that Dr. Rush would not have used the stent if either he or Horrillo had been warned by the manufacturer of its risks.

In support of this argument, Cook cited Dr. Rush's deposition, as well as an affidavit that the doctor filed on behalf of Cook. In his deposition, Dr. Rush explained:

> I didn't think there was anything that I would be doing in her renal artery that might cause increased or an excessive risk of a stroke. The things that I might do to cause her to have a stroke, potentially,

> might be if I shut the renal artery down, occluded it completely, if she had a hypertensive spike, that is, a spike in high blood pressure, and she would bleed into her brain.
>
> That's a possibility but a remote risk, and I felt that any type of risk like that was worth the possible benefit of the procedure.

In his affidavit, Dr. Rush averred that he elected to use the device as a matter of his own clinical judgment. The magistrate judge granted Cook's motion.[3] The magistrate judge reasoned that Dr. Rush was "fully aware that [the] stent was not approved for renal use; he was familiar with the risks associated with the device's use including stroke, which he believed to be 'remote'; [and] he was immensely experienced in performing renal stenosis surgeries . . . ." Based on this, the judge held that the learned intermediary doctrine applied as a matter of law. Ms. Horrillo appealed the grant of summary judgment. After filing her notice of appeal, Ms. Horrillo passed away. We have since granted a motion to substitute her son, Mr. Stephen Horrillo, as the personal representative of her estate, pursuant to Federal Rule of Appellate Procedure 43(a)(1).

III.

This Court reviews de novo a grant of summary judgment. Fitzpatrick v. City of Atlanta, 2 F.3d 1112, 1117 (11th Cir. 1993). Summary judgment is proper

[3] The parties consented to the exercise of jurisdiction by a magistrate judge, pursuant to 28 U.S.C. § 636.

only if there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). "In reviewing a grant of summary judgment, we resolve all ambiguities and draw reasonable factual inferences from the evidence in the non-movant's favor." Layton v. DHL Express (USA), Inc., 686 F.3d 1172, 1175 (11th Cir. 2012).

Under Florida law, a manufacturer of a "dangerous commodity," such as a prescription drug or a medical device, has a duty to warn consumers of the known risks of using its product. Buckner v. Allergan Pharms., Inc., 400 So. 2d 820, 822 (Fla. 5th DCA 1981). Failure to provide that warning may render the manufacturer strictly liable for any resulting harm. Id. at 822–23. However, in the context of certain medical products, such as medical devices, the manufacturer may discharge its duty to warn by providing an adequate warning to the treating medical professional—the learned intermediary—rather than the patient. Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102, 104 (Fla. 1989); Buckner, 400 So. 2d at 822; see also Christopher v. Cutter Labs., 53 F.3d 1184, 1192 (11th Cir. 1995) (applying Florida law). This duty to warn also applies to foreseeable off-label uses of medical products. Upjohn Co. v. MacMurdo, 562 So. 2d 680, 683 (Fla. 1990). Warning the treating physician discharges the manufacturer's duty to warn because the physician "weighs the potential benefits against the dangers in

deciding whether to recommend" the product to the patient. Felix, 540 So. 2d at 104.

The learned intermediary doctrine is a corollary to the rule that a medical device manufacturer's duty to warn runs to the treating physician. Christopher, 53 F.3d at 1192. This doctrine says that "the failure of the manufacturer to provide the physician with an adequate warning of the risks associated with a [medical device] is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated." Id. Thus, even if the manufacturer breaches its duty to warn, it may nevertheless mount an affirmative defense and avoid liability by demonstrating the treating physician was otherwise aware of the particular risk associated with the medical device. See id. at 1192-93; Walls v. Armour Pharm. Co., 832 F. Supp. 1467, 1481–82 (M.D. Fla. 1993); Felix, 540 So. 2d at 105. We have interpreted this defense to mean that "the causal link between a patient's injury and the alleged failure to warn is broken" if the treating physician "had substantially the same knowledge" of the risks posed by the medical device "as an adequate warning from the manufacturer should have communicated to [the physician]." Christopher, 53 F.3d at 1192-93 (quotation marks omitted).

Here, in seeking summary judgment, Cook apparently did not dispute that it

did not, at any point prior to the May 2007 procedure, warn Dr. Rush of the risk of stroke associated with the use of its Formula 418 biliary stent in renal angioplasty procedures.[4] Instead, Cook mounted an affirmative defense under the learned intermediary doctrine by arguing that Dr. Rush had independent and adequate knowledge of the risk of stroke associated with the off-label uses of its biliary stent. Thus, the question for us on summary judgment is whether, construing all evidence in favor of Mr. Horrillo as the non-moving party, there is an issue of fact about whether Dr. Rush had substantially the same knowledge as Cook of the risk of stroke in using Cook's Formula 418 biliary stent in renal angioplasty procedures. See Christopher, 53 F.3d at 1193.

In asking us to reverse summary judgment, Mr. Horrillo argues that a question of fact exists as to whether Dr. Rush was aware of the particular risk of stroke in using the Formula 418 biliary stent in the renal artery. In response, Cook does not challenge that it was aware its biliary stent posed a risk of stroke. Indeed, the March 2007 meeting between the FDA and biliary stent manufacturers, including Cook, identified the risk of stroke in using an expandable biliary stent in

[4] While Cook offers a number of justifications for why it failed to warn Dr. Rush of the risks of using its stent in off-label procedures, these justifications are not relevant to the narrow question before us, which is whether Cook succeeds on its learned intermediary defense as a matter of law.

renal arteries, and Cook acknowledged this risk in its October 2007 warning letter. Rather, Cook argues that Dr. Rush was aware of that risk by pointing us to Dr. Rush's deposition in which he opined that the risk of stroke was "remote," and that "any type of risk like that was worth the possible benefit of the procedure." Cook also notes that Dr. Rush's decision to use the Formula 418 biliary stent was based on his own clinical judgment. According to Cook, this demonstrates, as a matter of law, that Dr. Rush had substantially the same knowledge as Cook of the risk of stroke associated with the off-label use of its Formula 418 biliary stent in renal arteries. Cook also emphasizes that Dr. Rush has twenty-seven years of experience in his field and has used hundreds of stents to treat renal stenosis.[5]

The evidence makes clear that Dr. Rush is experienced with the placement of stents to treat renal stenosis. However, the facts are ambiguous as to whether Dr. Rush had substantially the same knowledge as Cook of the particular risks posed by the use of the Formula 418 biliary stent. Mindful that Cook bears the burden of showing that Dr. Rush was aware of the risk associated with the Formula 418 biliary stent, Cutter Laboratories, 53 F.3d at 1193, and that all facts,

[5] Although Dr. Rush has less experience with the Formula 418 biliary stent, having used it "numerous times," he is "pretty experienced" with the stent.

inferences, and ambiguities are construed in favor of Mr. Horillo, see Layton, 686 F.3d at 1175, we conclude that there is a genuine issue of fact as to whether Dr. Rush was aware of the risks posed by the Formula 418 biliary stent sufficient for him to shield Cook under the learned intermediary rule.

First, we cannot conclude that Dr. Rush had substantially the same knowledge as Cook because the evidence does not indisputably show that Dr. Rush was aware of the likelihood or severity of potential complications posed by the Formula 418 biliary stent that was known to Cook after its March 2007 meeting with FDA. Cook argues that Dr. Rush must have been aware of the risk of stroke because of his education and training. While it is certainly possible that through his research and experience Dr. Rush independently learned of the serious risk of stroke described by the FDA, nothing in the record directly supports this fact. To the contrary, Dr. Rush testified that he believed the possibility of a stroke was a remote, unreasonable consideration. Although Dr. Rush is significantly experienced in his field, Mr. Horillo's expert witness, Dr. Marx, explained that "practicing physicians don't read every journal article that's published" because "it would be a full-time job."[6] As is proper at the summary judgment stage, we

[6] Dr. Marx further explained that "it is the responsibility of [the] industry that makes these products to be aware of the significant findings and give that information to physicians."

decline to speculate about what Dr. Rush did or did not know based on his education and experience. "[T]he drawing of legitimate inferences from the facts are jury functions, not those of a judge." Reeves v. Sanderson Plumbing Prods. Inc., 530 U.S. 133, 149-50, 120 S. Ct. 2097, 2110 (2000) (quotation marks omitted).

Second, Dr. Rush's general experience does not necessarily prove that he was aware of the specific risks posed by the Formula 418 biliary stent. Specifically, the differences in safety between the Formula 418 biliary stent and other stents are disputed.[7] Certainly, Cook can argue to the jury that the risks posed by the Formula 418 biliary stent were the same as other stents and therefore, Dr. Rush would know of the risks posed by the Formula 418 biliary stent from his considerable experience with other stents. However, a reasonable juror could disagree with the assertion that the Formula 418 biliary stent was just as safe as any other. For example, the stent's own label provided that "[t]he safety and effectiveness of this device for use in the vascular system have not been established." Further, Dr. Rush expressed interest in participating in trials to

[7]The record in this case includes an abundance of testifying M.D.'s and Ph.D.'s. Each party listed ten experts on their respective witness lists, and by our count, at least seven doctors were deposed. We will not attempt to summarize the testimony of each of these witnesses, but rather note that the bounty of testifying doctors and/or experts merely underscores the fact-intensive nature of the dispute with which the jury will be presented here.

prepare for Cook's FDA filing for use of the Formula 418 biliary stent in the vascular system. And finally in this regard, neither Dr. Rush's general work with stent placement, nor his specific experience with the Formula 418 biliary stent, necessarily establishes that he was aware of the risks involved with the Formula 418 stent. A reasonable juror could find that the FDA issued a warning precisely because the doctors frequently using the Formula 418 biliary stent, like Dr. Rush, were unaware of the risks and serious complications of stroke and death. Because Dr. Rush's general experience with stent placement does not necessarily mean that he had substantially the same knowledge as Cook, we conclude there are material facts in dispute which must be decided by a jury.

Third, a reasonable juror might find that Dr. Rush's knowledge that the stent carried a remote risk of stroke was not substantially similar to the FDA's serious March 2007 warning of fatal and debilitating complications, including stroke. The FDA listed a series of "serious" complications, including seizure and death. The FDA also highlighted that a substantial percentage of the reported problems associated with the use of the Formula 418 biliary stent occurred with off-label use. Again, Dr. Rush described the risk of stroke as a remote, unreasonable consideration and stated that despite the product's warning regarding off-label use, he felt "the effectiveness was probably very well established." Because Dr. Rush

was required to make sensitive judgments about the possible risks and benefits of procedures and equipment, a reasonable juror might find that such a serious FDA warning would have informed and influenced Dr. Rush's knowledge base and decision-making differently than his general belief that stents carry a remote risk of stroke.

In sum, the evidence does not indisputably inform us that Dr. Rush had substantially the same knowledge as Cook. Because a juror could reasonably conclude that Dr. Rush's education and experience with stent placement did not equate Cook's knowledge about the dangers of the off-label use of its stent, and also that Dr. Rush's belief of the remote risk of stroke contrasted with the serious warnings given to Cook in the March 2007 meeting, the evidence allows for differing interpretations. A jury should resolve this factual dispute. This is especially true insofar as Cook bears the burden in asserting this affirmative defense. Hunt v. Cromartie, 526 U.S. 541, 552, 119 S. Ct. 1545, 1552 (1999) ("Summary judgment in favor of the party with the burden of persuasion . . . is inappropriate when the evidence is susceptible of different interpretations or inferences by the trier of fact.").

IV.

In light of the dissent's position that summary judgment should also be granted on the ground that there is no evidence that the use of the Formula 418 biliary stent caused Ms. Horillo's injury, we briefly address the issue of causation now as well. The complaint alleged generally that Cook was negligent in the design, manufacture, and distribution of its stent, because, for example:

> The COOK STENT did not come with adequate warnings and instructions regarding its appropriate use, or with warnings of its dangers when used as a renal stent, or with strict instructions as to the type of procedures for which it could be appropriately used, or with adequate instructions as to how it was to be utilized under different conditions, or with sufficient warnings and instructions to promote its safe usage;
>
> The COOK STENT was a biliary stent and was negligently designed and promoted for use as a renal stent and was not approved by the FDA for "off-label" vascular use. Additionally, a similar biliary stent was recalled by the FDA on May 4, 2004. Thus defendant had knowledge of the COOK STENT's negligent design as a renal stent;

After reviewing the complaint as a whole, we conclude that Mr. Horillo has sufficiently alleged causation, in light of his alternative assertions of Cook's failure to warn; failure to instruct as to proper usage; and failure to act on its knowledge of the earlier recall of a similar biliary stent.

The dissent specifically relies on the testimony of Dr. Marx, who explained that it would be "medically improbable, if not impossible" for the stent to have caused an air embolism in the brain, because the stent was not inflated with air and

the renal artery does not flow directly to the brain. However, even accepting Dr. Marx's opinion as uncontested, that testimony would not prevent a reasonable juror from finding that the Formula 418 biliary stent caused a stroke for a reason other than an air embolism. Indeed, Dr. Marx testified that the stroke was probably not caused by an air embolism, but by low blood pressure which resulted from the placement of the stent. He explained that "the placement of the Formula 418 biliary stent in the renal artery . . . caused a destabilization of the hemodynamics of the kidneys" because after the stent placement, the kidneys, which regulate blood pressure, received a different amount of blood than they were accustomed to getting. We are certainly aware that Dr. Marx's theory that a drop in blood pressure caused the stroke is contested by yet another expert–Dr. Meyers. However, and again with regard to this issue as well, we conclude that this type of dispute among experts about the cause of Ms. Horrillo's stroke falls precisely into the province of the jury.

V.

For these reasons, we REVERSE the magistrate judge's grant of summary judgment and REMAND for further proceedings consistent with this opinion.

PRYOR, Circuit Judge, dissenting:

I would affirm the summary judgment in favor of Cook. The majority concludes that the record is "ambiguous as to whether Dr. Rush had substantially the same knowledge as Cook of the particular risks posed by the use of the Formula 418 biliary stent." ante at 9. The majority believes that a reasonable juror could conclude that "Dr. Rush's education and experience with stent placement did not equate Cook's knowledge about the dangers of the off-label use of its stent." Id. at 13

The problem with the majority opinion is that the record, construed in the light most favorable to Horrillo, establishes that the "particular risk of stroke" associated with the Formula 418 stent is no different from the ordinary risk involved in any stenting procedure. Dr. Rush was aware of this risk independent of any warning by Cook because he had conducted hundreds of renal angioplasties with various kinds of stents and affirmed that he knew there was a risk of stroke involved with the procedure. Dr. Rush has practiced as an interventional radiologist for over 25 years and has conducted 20 years of protocol research for the Food and Drug Administration, including research on vascular stents. Dr. Rush had ample means to gain knowledge of the risk of stroke associated with stenting procedures independent of any warning by Cook.

A review of the testimony by Dr. Rush, particularly in the light of the testimony of Horrillo's expert witness, Dr. Marx, makes clear that Dr. Rush possessed the same knowledge of the risk of stroke that any warning specific to the Formula 418 stent would have provided him. The testimony of Dr. Marx establishes that the "particular risks of stroke in using the Formula 418 biliary stent in the renal artery" represents the risk involved in any stenting procedure. An experienced interventional radiologist like Dr. Rush would have known about this risk. Dr. Marx was explicitly asked whether there was anything unique about the Formula 418 stent that could cause Horrillo's stroke and answered that there was not:

> Q. Okay. Was there anything in particular about the Formula 418 Biliary Stent as opposed to any other biliary stent that produced her stroke?
> ….
> A. No.
> Q. Okay. So there's nothing about our stent in particular, it was the procedure that was involved that is — you're focusing on, am I correct in thinking that?
> A. Correct.

Dr. Marx testified that the risk of stroke came from blood pressure fluctuation caused by increased blood flow to the kidney or embolism in the kidney caused by emboli formed when the stent broke up the arteriosclerotic vascular disease. Dr. Marx's testimony establishes that this ordinary risk would be known by any interventional radiologist performing a renal stent. As Dr. Marx testified, risks

from fluctuations in blood pressure after renal stenting are "not something that would not be known and understood by medical practitioners." Although Dr. Marx faulted Cook for not disclosing information about embolic risks to stenting, he admitted that radiologists, "[i]n general[,] . . . accept minor embolic phenomena everywhere in the body except in the brain in general." He admitted that, even after looking through all the medical charts, depositions, and medical articles that Horrillo provided him, nothing persuaded him that the risk of embolization in the kidneys was more than "minimal."

Because Dr. Marx's testimony establishes, without dispute, that the "particular risk of stroke in using the Formula 418 biliary stent in the renal artery" is the same risk involved in any stenting procedure, Horrillo is reduced to arguing that there is an issue of fact as to whether Dr. Rush understood the general risks of renal stenting, but there is no genuine issue of material fact that Dr. Rush understood the general risks of renal stenting. Dr. Rush testified that he knew that the ways the procedure could cause Horrillo "to have a stroke, potentially, might be if I shut the renal artery down, occluded it completely, if she had a hypertensive spike, that is, a spike in high blood pressure, and she would bleed into her brain. That's a possibility but a remote risk, and I felt that any type of risk like that was worth the possible benefit of the procedure." Dr. Rush undoubtedly knew that there could be an increased flow of blood to the kidney because that was the entire

reason for implanting the stent. Dr. Marx also testified that radiologists are aware that any time they break up an atherosclerotic plaque, there is a risk of embolization. Dr. Rush testified that the purpose of the angioplasty is to "push the atherosclerotic disease, the hardening[,] out to open up the vessel." As Dr. Marx explained, embolization of some of this atherosclerotic disease is a common, well-known phenomenon with minimal risks to a patient. After we construe all ambiguities and factual inferences in favor of Horrillo, there is no genuine issue of material fact as to whether Dr. Rush was aware of the "particular risk of stroke" associated with the Formula 418 stent because that risk is no different from the ordinary risk involved in any stenting procedure.

I would also affirm the summary judgment in favor of Cook because there is no evidence of a causal connection between the use of the Formula 418 stent and Horrillo's injury under the theory Horrillo offers. When we review a summary judgment, we can affirm "on any legal ground, regardless of the grounds addressed and relied upon by the district court." Cuddeback v. Fla. Bd. of Educ., 381 F.3d 1230, 1235 (11th Cir. 2004). Horrillo alleges that the Formula 418 stent likely caused an air embolism because the stent used a balloon that could leak air into the artery that could travel to the brain and cause a stroke. Horrillo's complaint states only one theory of causation: that the Formula 418 stent caused air to enter Ms. Horrillo's artery, which led to her stroke:

> The COOK STENT was negligently manufactured in that when it is implanted for vascular use, air may be introduced into the patient via the stent system causing serious complications, including seizure and stroke.
> ….
> [T]he stent was misused in that when the stent is implanted for vascular use, air may be introduced into the patient via the stent system causing serious complications, including seizure and stroke.
> ….
> The COOK STENT was negligently labeled regarding its correct or appropriate usage, in that when it is implanted for vascular use, air may be introduced into the patient via the stent system causing serious complications, including seizure and stroke.

There is no evidence to support this theory of causation because, as Dr. Marx testified, it would be "medically improbable, if not impossible," to get an air embolism in the brain from a renal artery stent of this design. The majority quotes part of paragraph 11 of Horrillo's complaint, but that part says nothing—not one word—about an alternative theory of causation.

An air embolism in this situation is "medically improbable, if not impossible" for two reasons. First, the balloon on the Formula 418 stent is inflated with a saline solution, not air. Second, the blood in the renal artery does not flow directly to the brain but instead flows to the kidney and down into the legs, making it "medically improbable, if not impossible, to get an embolus from a renal artery stenting embolic event to go to the brain." And Horrillo's surviving son never amended his complaint to reflect a different theory of causation. See Bryant v. Jones, 575 F.3d 1281, 1308 (11th Cir. 2009) ("[A]bsent extraordinary

circumstances, legal theories and arguments not raised squarely before the district court cannot be broached for the first time on appeal.").

We should affirm the summary judgment in favor of Cook. Although I would affirm the summary judgment in favor of Cook based on the learned intermediary doctrine, I would also alternatively affirm based on the absence of evidence to support the theory of causation offered by Horrillo. I respectfully dissent from the majority opinion that reverses the summary judgment in favor of Cook.