[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 19-13087

D.C. Docket No. 1:18-cv-05648-WMR

KAREN LEIGH HUBBARD,
MICHAEL L. HUBBARD,

Plaintiffs - Appellants,

versus

BAYER HEALTHCARE PHARMACEUTICALS INC.,
BAYER PHARMA AG,

Defendants - Appellees,

TEVA PHARMACEUTICALS USA INC.,

Defendant.

Appeal from the United States District Court
for the Northern District of Georgia

(December 22, 2020)

Before GRANT and MARCUS, Circuit Judges, and AXON,[*] District Judge.

MARCUS, Circuit Judge:

This tragic case began when Karen Hubbard suffered a catastrophic stroke. The stroke left her paralyzed and her cognitive functions severely impaired. Her oral contraceptive, Beyaz--a drug known to increase the risk of blood clots that can cause strokes--may have been to blame. We must decide whether Karen Hubbard and her husband Michael Hubbard have adduced sufficient evidence to survive summary judgment on their claims against the manufacturers of Beyaz, Bayer Pharma AG and Bayer HealthCare Pharmaceuticals Inc. (together, "Bayer"), for failing to provide an adequate warning of the risk of stroke.

We hold they have not. Georgia's learned intermediary doctrine controls this diversity jurisdiction case. That doctrine imposes on prescription drug manufacturers a duty to adequately warn physicians, rather than patients, of the risks their products pose. But a plaintiff claiming a manufacturer's warning was inadequate bears the burden of establishing that an improved warning would have caused her doctor not to prescribe her the drug in question. The Hubbards have not met this burden. The prescribing physician testified unambiguously that even with the benefit of the most up-to-date risk information about Beyaz, he considers his

[*] Honorable Annemarie Axon, United States District Judge for the Northern District of Alabama, sitting by designation.

decision to prescribe Beyaz to Karen Hubbard to be sound and appropriate. Under our binding precedent interpreting Georgia law, the Hubbards, therefore, cannot recover. Though the Hubbards have suffered greatly, the law plainly entitles Bayer to summary judgment. We affirm the judgment of the district court.

I.

A.

On October 30, 2012, Michael Hubbard found his 41-year-old wife, Karen Hubbard, unresponsive. She had suffered a catastrophic stroke caused by a blood clot to her brain--a venous sinus thrombosis, a type of venous thromboembolism ("VTE"). The VTE caused grievous, permanent injury: brain damage, paralysis, and profound loss of cognitive functioning. At the time of her stroke, Karen Hubbard had been taking Beyaz, a birth control pill manufactured by defendant Bayer. While she first received a prescription for Beyaz on December 27, 2011, Karen Hubbard had been taking similar Bayer birth control products since 2001.

A birth control pill, also known as a combination oral contraceptive, or "COC," typically consists of two synthetic hormone components: estrogen and one of several progestins (also referred to as progesterones or progestogens). When first developed, COC pills delivered a high dose of estrogen and one of two progestins: norethindrone or ethynodiol. After studies in the 1980s determined that higher doses of estrogen posed an increased risk of VTE, or blood clots,

pharmaceutical companies generally developed second-generation COCs that featured lower levels of estrogen. To further "decrease the cardiovascular side effect profile," pharmaceutical companies produced a third generation of COCs which paired a low dose of estrogen with one of three progestins: desogestrel, gestodene, or norgestimate. In the 1990s, when further studies revealed that these progestins carried an elevated risk of VTE, manufacturers revised their product labels for these COCs and focused on developing pills with a new, "fourth generation" progestin: drospirenone, or DRSP.

Bayer first sought the FDA's approval to use DRSP in a birth control pill on November 17, 1993. Today, Bayer markets Yasmin, YAZ, and Beyaz. All are fourth-generation COCs that combine an estrogen, ethinyl estradiol ("EE"), with DRSP. Each pill of Yasmin, which became available in the United States in 2001, contains 30 micrograms of EE and three milligrams of DRSP. In 2006, the FDA approved YAZ, which combines a lower dose of estrogen (20 micrograms) with the same three milligrams of DRSP. Bayer introduced Beyaz in 2010. A Beyaz pill and a YAZ pill share the same hormonal profile--20 micrograms of EE and 3 milligrams of DRSP. The sole difference between the two pills is that Beyaz includes a supplement, folate, which "has been shown to be beneficial in [fetal] neuro development."

The medical community has been aware since the 1960s that COCs are associated with an increased risk of blood clots. But the magnitude of that risk varies depending on the make-up of particular types of pills. A higher dose of estrogen is "a clear risk factor"; indeed, "when subsequent COC's had their estrogen doses reduced, a corresponding decrease in the incidence of VTE disease occurred." Similarly, different progestins carry different VTE risks. Thus, for example, the third-generation progestins desogestrel and gestodene nearly doubled the risk of VTE from COCs in the second generation. This elevated risk found its way onto third-generation warning labels; these labels "have wording specifying an increased risk associated with their products."

Like third-generation COCs, fourth-generation pills--those containing DRSP--"carry a significantly greater risk of VTE relative to" second-generation COCs. Bayer thus includes information about the nature and extent of the VTE risk on labels for its DRSP-containing products. The 2010 Beyaz warning label, the label in place at the time of Karen Hubbard's first and final Beyaz prescription

on December 27, 2011, warned that COCs generally pose a risk of VTEs[1] and summarized studies on the VTE risks associated with DRSP-containing COCs in particular. The label noted that some studies concluded the risks of DRSP pills are comparable to those of other pills, while other studies showed Yasmin increased the risk of VTE relative to certain non-DRSP COCs.[2] The label provided reasons

---

[1] In relevant part, the label read:

5 WARNINGS AND PRECAUTIONS

5.1 Thromboembolic Disorders and Other Vascular Problems

Stop Beyaz if an arterial or deep venous thrombotic (VTE) event occurs. Although the use of COCs increases the risk of venous thromboembolism, pregnancy increases the risk of venous thromboembolism as much or more than the use of COCs. The risk of venous thromboembolism in women using COCs is 3 to 9 per 10,000 woman-years. The risk is highest during the first year of use of a COC. Use of COCs also increases the risk of arterial thromboses such as strokes and myocardial infarctions, especially in women with other risk factors for these events. The risk of thromboembolic disease due to oral contraceptives gradually disappears after COC use is discontinued.

If feasible, stop Beyaz at least 4 weeks before and through 2 weeks after major surgery or other surgeries known to have an elevated risk of thromboembolism.

Start Beyaz no earlier than 4 weeks after delivery, in women who are not breastfeeding. The risk of postpartum thromboembolism decreases after the third postpartum week, whereas the risk of ovulation increases after the third postpartum week.

COCs have been shown to increase both the relative and attributable risks of cerebrovascular events (thrombotic and hemorrhagic strokes), although, in general, the risk is greatest among older (>35 years of age), hypertensive women who also smoke. COCs also increase the risk for stroke in women with other underlying risk factors.

Oral contraceptives must be used with caution in women with cardiovascular disease risk factors.

Stop Beyaz if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions. Evaluate for retinal vein thrombosis immediately. *[See Adverse Reactions (6).]*

[2] In relevant part, the label read:

Epidemiologic studies including a DRSP-containing COC

Several studies have investigated the relative risks of thromboembolism in women using a different DRSP-containing COC (Yasmin, which contains 0.03 mg of EE and 3 mg of DRSP) compared to those in women using COCs containing other progestins. Two prospective cohort studies, both evaluating the risk of venous and arterial thromboembolism and death, were initiated at the time of Yasmin approval.[2,3] The first (EURAS) showed the risk of thromboembolism (particularly venous thromboembolism) and death in Yasmin users to be comparable to that of other oral contraceptive preparations, including those containing levonorgestrel (a so-called second generation COC). The second prospective cohort study (Ingenix) also showed a comparable risk of thromboembolism in Yasmin users compared to users of other COCs, including those containing levonorgestrel. In the second study, COC comparator groups were selected based on their having similar characteristics to those being prescribed Yasmin.

Two additional epidemiological studies, one case-control study (van Hylckama Vlieg et al.[4]) and one retrospective cohort study (Lidegaard et al.[5]) suggested that the risk of venous thromboembolism occurring in Yasmin users was higher than that for users of levonorgestrel-containing COCs and lower than that for users of desogestrel/gestodene-containing COCs (so-called third generation COCs). In the case-control study, however, the number of Yasmin cases was very small (1.2% of all cases) making the risk estimates unreliable. The relative risk for Yasmin users in the retrospective cohort study was greater than that for users of other COC products when considering women who used the products for less than one year. However, these one-year estimates may not be reliable because the analysis may include women of varying risk levels. Among women who used the product for 1 to 4 years, the relative risk was similar for users of Yasmin to that for users of other COC products.

to doubt the latter studies: one of them included only a small number of Yasmin users and the other included women of various risk levels.

In May 2011, the FDA released a drug safety communication announcing an "ongoing safety review of birth control pills that contain drospirenone." The FDA explained that its European counterpart, the European Medicines Agency, was "updating the product information on oral contraceptives containing drospirenone and ethinyl estradiol regarding the risk of venous thromboembolism after [its] review of all available data, including the same newly published data [the] FDA is reviewing." In September 2011, the FDA put out a second announcement, "informing the public that" while it had "not yet reached a conclusion," it "remain[ed] concerned . . . about the potential increased risk of blood clots with the use of drospirenone-containing birth control pills." The preliminary results of an FDA-funded study suggested "an approximately 1.5-fold increase in the risk of blood clots for women who use drospirenone-containing birth control pills compared to users of other hormonal contraceptives." On October 27, 2011--two months before Karen Hubbard received her final Beyaz prescription--the FDA announced that it was "continuing its review of the potential increased risk of blood clots with the use of birth control pills containing drospirenone."

Then, on April 10, 2012, the FDA announced that it had "completed its review of recent observational (epidemiologic) studies regarding the risk of blood

clots in women taking drospirenone-containing birth control pills." The FDA "concluded that drospirenone-containing birth control pills may be associated with a higher risk for blood clots than other progestin-containing pills." As a result of this finding, the FDA added "information about the studies to the labels of drospirenone-containing birth control pills," including Beyaz, YAZ, and Yasmin. These "revised drug labels" relayed "that some epidemiologic studies reported as high as a three-fold increase in the risk of blood clots for drospirenone-containing products when compared to products containing levonorgestrel or some other progestins, whereas other epidemiological studies found no additional risk of blood clots with drospirenone-containing products." Thus, in April 2012, Bayer revised its Beyaz warning label to include, among other information, the possibility of up to a three-fold relative increase in blood clot risk ("the risk ranged from no increase to a three-fold increase").[3] The label included graphics demonstrating that

[3] In relevant part, the label read:

> **5 WARNINGS AND PRECAUTIONS**
>
> **5.1 Thromboembolic Disorders and Other Vascular Problems**
>
> Stop Beyaz if an arterial or venous thrombotic (VTE) event occurs.
>
> Based on presently available information on DRSP-containing COCs with 0.03 mg ethinyl estradiol (that is, Yasmin), DRSP-containing COCs may be associated with a higher risk of venous thromboembolism (VTE) than COCs containing the progestin levonorgestrel or some other progestins. Epidemiologic studies that compared the risk of VTE reported that the risk ranged from no increase to a three-fold increase. Before initiating use of Beyaz in a new COC user or a woman who is switching from a contraceptive that does not contain DRSP, consider the risks and benefits of a DRSP-containing COC in light of her risk of a VTE. Known risk factors for VTE include smoking, obesity, and family history of VTE, in addition to other factors that contraindicate use of COCs *[see Contraindications (4)]*.
>
> A number of studies have compared the risk of VTE for users of Yasmin (which contains 0.03 mg of EE and 3 mg of DRSP) to the risk for users of other COCs, including COCs containing levonorgestrel. Those that were required or sponsored by regulatory agencies are summarized in Table 1.

studies had reached varying estimates regarding the comparative VTE risk of DRSP-containing COCs.[4] The warning noted that VTE risk is highest during

---

[4] In relevant part, the label read:

Table 1: Estimates (Hazard Ratios) of Venous Thromboembolism Risk in Current Users of Yasmin Compared to Users of Oral Contraceptives that Contain Other Progestins

Epidemiologic Study (Author, Year of Publication) Population Studied	Comparator Product (all are low-dose COCs; with ≤ 0.04 mg of EE)	Hazard Ratio (HR) (95% CI)
i3 Ingenix (Seeger 2007) Initiators, including new users[a]	All COCs available in the US during the conduct of the study[b]	HR: 0.9 (0.5-1.6)
EURAS (Dinger 2007) Initiators, including new users[a]	All COCs available in Europe during the conduct of the study[c]	HR: 0.9 (0.6-1.4)
	Levonorgestrel/EE	HR: 1.0 (0.6-1.8)
"FDA-funded study" (2011)		
New users[a]	Other COCs available during the course of the study[d]	HR: 1.8 (1.3-2.4)
	Levonorgestrel/0.03 mg EE	HR: 1.6 (1.1-2.2)
All users (i.e., initiation and continuing use of study combination hormonal contraception)	Other COCs available during the course of the study[d]	HR: 1.7 (1.4-2.1)
	Levonorgestrel/0.03 mg EE	HR: 1.5 (1.2-1.8)

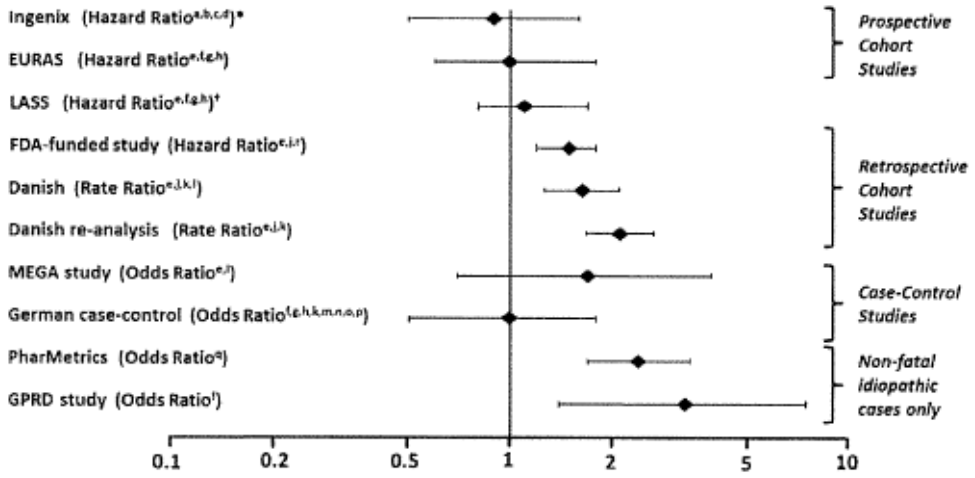
a) "New users" - no use of combination hormonal contraception for at least the prior 6 months
b) Includes low-dose COCs containing the following progestins: norgestimate, norethindrone, levonorgestrel, desogestrel, norgestrel, medroxyprogesterone, or ethynodiol diacetate
c) Includes low-dose COCs containing the following progestins: levonorgestrel, desogestrel, dienogest, chlormadinone acetate, gestodene, cyproterone acetate, norgestimate, or norethindrone
d) Includes low-dose COCs containing the following progestins: norgestimate, norethindrone, or levonorgestrel

. . .

the first year of COC use and that the risk of VTE from pregnancy is greater than the risk from using oral contraceptives.[5]

Karen Hubbard began taking Bayer's COCs in approximately 2001. She took Yasmin from 2001 until May 2006, when she began taking YAZ. Though her prescribing physician, Dr. Lawrence Rowley, didn't know for sure why she changed her prescription, he thought the change would have been made because YAZ contains a lower dose of estrogen, and his office "always prefer[s] to use the lower-dose pills." Karen Hubbard remained on YAZ until December 2011, when

Figure 1: VTE Risk with Yasmin Relative to LNG-Containing COCs (adjusted risk[#])



Risk ratios displayed on logarithmic scale; risk ratio < 1 indicates a lower risk of VTE for DRSP, > 1 indicates an increased risk of VTE for DRSP.

[5] In relevant part, the label read:

> Although the absolute VTE rates are increased for users of hormonal contraceptives compared to non-users, the rates during pregnancy are even greater, especially during the post-partum period (see Figure 2). The risk of VTE in women using COCs has been estimated to be 3 to 9 per 10,000 woman-years. The risk of VTE is highest during the first year of use. Data from a large, prospective cohort safety study of various COCs suggest that this increased risk, as compared to that in non-COC users, is greatest during the first 6 months of COC use. Data from this safety study indicate that the greatest risk of VTE is present after initially starting a COC or restarting (following a 4 week or greater pill-free interval) the same or a different COC.
>
> The risk of thromboembolic disease due to oral contraceptives gradually disappears after COC use is discontinued.

she began taking Beyaz. Though Dr. Rowley again did not know for sure what explained the change, he thought it was likely due to the folate that Bayer added to Beyaz. Karen Hubbard had been taking Beyaz for a little less than a year when she suffered a stroke in October 2012.

B.

On January 17, 2014, Karen and Michael Hubbard sued Bayer in the United States District Court for the Southern District of Illinois as part of a multidistrict litigation proceeding relating to the manufacture, marketing, and sale of certain oral contraceptives. They alleged that, as a direct result of her use of Bayer's birth control pills, including Yasmin, YAZ, Beyaz, and their generic equivalents, Karen suffered a VTE which caused "an intracerebral hemorrhage" and "life-threatening," "catastrophic injuries." The Hubbards sought compensatory and punitive damages for negligence; strict liability based on a design defect; strict liability based on a defective warning; negligence based on a failure to issue a timely post-sale warning; fraud; breach of warranty; and loss of consortium. [6]

On August 15, 2018, with the matter still pending in the Southern District of Illinois, Bayer moved for summary judgment. According to Bayer, the undisputed

[6] The Hubbards' complaint also named as a defendant generic manufacturer Teva Pharmaceuticals USA, Inc. After Teva answered, the Hubbards stipulated to the dismissal of their claims against Teva with prejudice.

facts showed that Karen Hubbard's prescribing physician, Dr. Rowley, "had actual knowledge of the risk that" the Hubbards contend Bayer failed to disclose. Dr. Rowley, Bayer claimed, "provided explicit, uncontroverted testimony that he was aware of the potentially higher risk of VTE [associated with DRSP-containing COCs] long before he wrote" Karen Hubbard's "final prescription." Thus, "no failure to disclose any information in the warning label caused Dr. Rowley to prescribe Beyaz to" Karen Hubbard, since "he was already well aware of the alleged risks." Bayer argued that the failure-to-warn claims therefore failed, and so did the others: the Hubbards had not raised a triable issue of fact on causation.

The Hubbards opposed the motion. They said that the warnings available to Dr. Rowley in December 2011 were inadequate, including because they lacked the information made available in the 2012 update to the Beyaz label. The Hubbards further claimed that Dr. Rowley's testimony on his December 2011 knowledge of the increased VTE risks associated with Beyaz was "equivocal." And Bayer's new warning "changed the way he counseled patients." Without unequivocal testimony from Dr. Rowley that he would have prescribed Beyaz to Karen Hubbard after reading an appropriate warning, the Hubbards offered, summary judgment was not warranted.

With Bayer's summary judgment motion still pending, the case was transferred to the Northern District of Georgia because the parties had completed generic discovery, obviating the need for multidistrict coordination.

After further briefing, the district court in the Northern District of Georgia granted Bayer's motion for summary judgment, reasoning that the Hubbards could not prove Bayer's inadequate warning caused Karen Hubbard's injury. "Without evidence that a different warning would have changed the prescribing decision," the district court wrote, the Hubbards could not show that Karen Hubbard's injury "would have been avoided but for Bayer's alleged failure to warn." The district court agreed with Bayer that Dr. Rowley's testimony established "that no different warning would have changed the prescribing decision and avoided the injury."

The Hubbards timely appealed the district court's order.

II.

We review a district court's grant of summary judgment de novo, viewing the evidence and drawing all reasonable inferences in the light most favorable to the nonmoving party. Tesoriero v. Carnival Corp., 965 F.3d 1170, 1177 (11th Cir. 2020). Summary judgment is appropriate only when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed R. Civ. P. 56(a). "Where the record taken as a whole could not lead a rational

trier of fact to find for the non-moving party, there is no genuine issue for trial." Tesoriero, 965 F.3d at 1177 (quotation marks and citation omitted).

The parties agree that all relevant events took place in Georgia and that, in this diversity action, Georgia law applies to the Hubbards' failure to warn claim.[7] In the typical failure-to-warn product liability case, "Georgia law insists that a plaintiff show that the defendant had a duty to warn [the plaintiff], that the defendant breached that duty, and that the breach proximately caused the plaintiff's injury." Dietz v. Smithkline Beecham Corp., 598 F.3d 812, 815 (11th Cir. 2010). But this general standard applies somewhat differently when the product at issue is a prescription drug. Under Georgia's learned intermediary doctrine, the drug manufacturer "does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor." Id. (quoting McCombs v. Synthes (U.S.A.), 587 S.E.2d 594, 594 (Ga. 2003)). "The rationale for [this] doctrine is that the treating physician is in a better position to warn the patient than the manufacturer, in that the decision to employ prescription medication involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular need and susceptibilities." Id. (quoting McCombs, 587 S.E.2d at 594) (alteration accepted).

[7] At oral argument in district court, the Hubbards agreed that because each of their claims requires a triable issue of fact on causation, all claims rise or fall with their failure-to-warn claims. They do not argue otherwise on appeal.

For purposes of summary judgment, Bayer assumes that its warning was inadequate. But that does not end our analysis. "If the warning is inadequate, or merely presumed to be, the plaintiff must demonstrate that the deficient warning proximately caused the alleged injury." Id. at 816. To establish proximate cause, the plaintiff must prove a causal link between the inadequate warning and the prescription decision. Thus, "in cases where a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided, courts typically conclude that the causal link is broken and the plaintiff cannot recover." Id. (internal quotation marks and citation omitted; alteration accepted).

While proximate cause is an issue of fact normally reserved for the jury, Georgia law provides that the court may decide questions of proximate cause as a matter of law when the evidence is "plain and undisputed." Sanders v. Lull Int'l, Inc., 411 F.3d 1266, 1271 (11th Cir. 2005) (quoting Ont. Sewing Mach. v. Smith, 572 S.E.2d 533, 536 (Ga. 2002)).

On this record, we hold that even when viewed in the light most favorable to the Hubbards, the evidence does not raise a genuine issue of material fact and that Bayer is entitled to final summary judgment as a matter of law. Dr. Rowley "provided explicit, uncontroverted testimony that, even when provided with the

most current research and FDA mandated warnings," as well as the information found in Bayer's updated 2012 Beyaz label, he would still have prescribed Beyaz to Karen Hubbard. See Dietz, 598 F.3d at 816. Moreover, Dr. Rowley's testimony indicates that he already knew in December 2011 what he considered to be substantially the same risk information later included in the 2012 Beyaz label. The causal chain is therefore broken, and the Hubbards cannot establish proximate cause.

A.

Most importantly, Dr. Rowley unambiguously testified that he views his December 2011 decision to prescribe Beyaz to Karen Hubbard as an appropriate one, even now that he knows exactly what was included in the 2012 label. At his deposition, after having discussed the risks listed in the 2012 Beyaz label as well as risks discussed in previous studies and FDA warnings, Dr. Rowley was asked "Do you believe today that your decision to prescribe Beyaz for Mrs. Hubbard was appropriate?" He responded, "Yes."

Were this not enough, Dr. Rowley's response to the 2012 Beyaz label update further indicates that knowledge of that information in December 2011 would not have changed his decision to prescribe Beyaz to Karen Hubbard. Dr. Rowley testified that he did not consider the information contained in the 2012 Beyaz label

to be significant enough to change his prescribing practices for patients already on Beyaz or similar pills:

> Q: Okay. I believe you said you recall that there may have been a new label issued sometime in 2012.
>
> A: The FDA alert.
>
> Q: When that happened, did you alert your patients?
>
> A: No.
>
> Q: Why not?
>
> A: Once again, the relative risk that was discussed was actually very small versus the fact that people have been on it for--have taken it, they're happy with it, that they have not had any complications with it. So the relative risk of trying to pull everybody back as soon as you hear a--an alert was so small that it really just didn't justify it, in my mind.
>
> Q: Is it fair to conclude that the benefits of Beyaz outweigh the risk in patients who have already been taking it for some time with no problems?
>
> . . .
>
> A: Yes.

Indeed, Dr. Rowley testified that he did not change "the way [he] prescribed birth control to patients . . . after April of 2012," and he still prescribes Beyaz, YAZ, and Yasmin (though he more frequently prescribes birth control pills containing progestins other than DRSP).

Dr. Rowley's testimony about his general prescribing practices bolsters still further the ultimate conclusion that he would have prescribed Beyaz to Karen Hubbard in December 2011 even if he had the 2012 Beyaz label in hand. Dr. Rowley explained that his standard practice is to continue a patient who has been

taking a particular birth control pill for an extended period without problems on the same pill or a similar pill, unless the patient has developed a contraindication for the pill. A patient who has tolerated a pill for a long time is "[l]ess likely to suddenly develop problems." So the "first thing" Dr. Rowley does when deciding which birth control pill to prescribe a patient is to "find out which birth control pills" the patient has taken "in the past and how" she's "done on them." If a patient "is doing well on a pill, it makes sense to keep [her] on that pill." Karen Hubbard had been doing well on Bayer's line of DRSP-containing birth control pills for many years. Her medical records indicated that she was satisfied with Yasmin in 2005 and requested a refill; that she was satisfied with Yasmin in 2006 and requested a refill (though she ended up receiving a prescription for YAZ); and that she was satisfied with YAZ and requested refills in each of 2007, 2008, 2009, and 2010.

In short, Karen Hubbard tolerated YAZ "quite well" for several years, and she had tolerated Yasmin well "for several years prior to that." Thus, in December 2011, Dr. Rowley prescribed Karen Hubbard Beyaz, which he regards as "the same medication" as YAZ: the only difference is that Beyaz contains a folate supplement, which provides benefits to women of childbearing age. As we've noted, Dr. Rowley agreed that even after the 2012 label change, "the benefits of Beyaz outweigh the risk in patients who have already been taking it for some time

with no problems." That Karen Hubbard was just such a patient--she had been taking YAZ, a materially identical drug, for several years without any problem--underscores Dr. Rowley's testimony that he would have prescribed her Beyaz even if he had the benefit of the 2012 label change at the time.

Moreover, Dr. Rowley's unequivocal testimony that knowledge of the information contained in the 2012 Beyaz label would not have altered his 2011 decision to prescribe Beyaz to Karen Hubbard puts this case on all fours with Dietz, 598 F.3d at 814–15. In Dietz, a doctor diagnosed Garrison David Dietz with major depression and prescribed Paxil, an antidepressant the defendant manufactured. Id. at 814. Eight days after beginning his Paxil prescription, Dietz committed suicide. Id. We affirmed the district court's grant of the manufacturer's motion for summary judgment on Dietz's wife's failure-to-warn claims. Id. at 814, 816. When asked at his deposition whether he "still agree[d] with [his] decision to prescribe Paxil for Mr. Dietz," the prescribing physician replied, "Yes." Id. at 814. After having read the new, updated prescribing information for Paxil, the physician testified:

> Q. [I]s there anything in that [new warning] that makes you believe that if you had read that same information in April of 2002 you would have decided not to prescribe Paxil for Gary Dietz?
>
> A. No.
>
> Q. So sitting here today, knowing Gary Dietz ultimately took his own life, do you still consider your decision to prescribe Paxil for him on

> April 3rd, 2002, to be an appropriate decision?
>
> A. I felt the risk of not treating him was worse. So I would have to make a decision, and I felt like I needed to prescribe him Paxil.

Id. at 815 (alteration accepted). Just as here, the doctor's assertion that he still considered his prescription decision "appropriate" after reviewing the updated research and warnings "sever[ed] any potential chain of causation through which [the plaintiff] could seek relief." Id. at 816.

The facts in this case are even stronger than those presented in Dietz. While Dietz did not rely on any evidence suggesting that the prescribing doctor already knew of the additional risks when he wrote the prescription, here, the record contains just such evidence. And this further supports the conclusion that an update to the Beyaz label would not have affected Dr. Rowley's December 2011 decision to prescribe Beyaz to Karen Hubbard. See id. at 816 (noting that the causal link is typically broken when "a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action"). The record demonstrates that Dr. Rowley already knew DRSP-containing COCs like Beyaz pose an increased risk of VTE when he prescribed Beyaz to Karen Hubbard in 2011, and that he did not consider the additional information contained in the 2012 Beyaz label to significantly add to his corpus of knowledge. Bayer's failure to include this information in the previous Beyaz label

could not have caused Dr. Rowley's decision to prescribe Beyaz to Karen Hubbard.

The 2012 warning label added studies suggesting that DRSP-containing COCs may pose up to a three-fold increase in VTE risk compared to COCs that use other progestins. But when Dr. Rowley prescribed Beyaz to Karen Hubbard in December 2011, he already knew DRSP-containing pills possibly posed a greater risk of VTE than other COCs. Dr. Rowley testified he was "aware of the possibility of an increased risk of blood clots from pills like Beyaz in May of 2011." Indeed, Dr. Rowley has known since 1979 that all birth control pills carry a risk of blood clots, and has since then continued to "keep up with the literature on risks associated with birth control pills that contain [DRSP] in particular." This included, for example, knowledge in 2009 of two studies suggesting that there might be a higher risk from Yasmin than from other types of birth control pills. Dr. Rowley reviewed the 2010 Beyaz label, which referenced two studies finding a small increased risk of DRSP-containing pills compared to pills containing levonorgestrel, an alternative progestin. And the three 2011 FDA updates that pre-dated Karen Hubbard's prescription suggested a slightly higher blood clot risk from DRSP-containing pills than from other pills.

Dr. Rowley testified that when measured against his general knowledge of the relatively greater risk from DRSP pills, these updates were not "like an

absolute game changer at the time." In his words, the information in the FDA updates "was no different to what had come out from previous studies [that said] there may be a slight increased risk . . . . It was something which the FDA had come out with, but there had been studies before which had also suggested that increased risk . . . ." Dr. Rowley knew in December 2011 the essence of the information that would later be added to the Beyaz label--that DRSP pills like Beyaz may pose an increased risk of VTE relative to non-DRSP pills--and did not regard it as a significant change to what he already knew about the DRSP-pill risk profile.

To be sure, the April 2012 label listed the possibility of a DRSP-related increase in blood clot risk up to three-fold, while the September and October 2011 FDA updates referred to a study suggesting only a 1.5-fold risk. But Dr. Rowley's testimony expressly offered that he did not view this change as significant. Dr. Rowley did not alert his patients about the 2012 label change, because the change was "so small that it really just didn't justify" changing prescriptions for those who were already on DRSP-containing pills and were happy with them. And the April 2012 update did not cause Dr. Rowley's practice group to "reach any new conclusion about whether" Beyaz carried "a higher risk of causing a blood clot than other birth control pills." Most significantly, Dr. Rowley did not change the way he "prescribed birth control to patients . . . after April of 2012."

All told, Dr. Rowley testified clearly that the information found in the 2012 label update would not have changed his decision to prescribe Beyaz to Karen Hubbard; and, indeed, that he already knew of the relevant risks at the time of the prescription. Under controlling case law, this precludes the Hubbards from establishing proximate cause.

B.

As the Hubbards correctly observe, the evidence does indicate that the 2012 label change had some general impact on Dr. Rowley. But for the Hubbards to show a genuine issue of material fact regarding proximate cause, this evidence must speak to whether the information in the 2012 label change would have affected in some way Dr. Rowley's decision to prescribe Beyaz to Karen Hubbard. See Dietz, 598 F.3d at 816. The evidence the Hubbards rely on, however, does not bear on Dr. Hubbard's decisionmaking regarding prescriptions, at least for patients similar to Karen Hubbard.[8]

[8] The Hubbards also argue that summary judgment was inappropriate because Dr. Rowley's testimony that he still believes his decision to prescribe Beyaz to Karen Hubbard was appropriate "could be impeached by evidence that the relative risks and benefits to Mrs. Hubbard of other COCs were such that an informed intermediary would not have prescribed Beyaz to her." This argument misses the mark. Under Dietz, the question relevant to proximate cause is not how a fully informed physician would have reasonably behaved, but rather how Dr. Rowley himself would have behaved were he fully informed. See 598 F.3d at 816. And as we have outlined, Dr. Rowley testified plainly that the information in the 2012 Beyaz label update would not have changed his risk/benefit calculation with respect to Karen Hubbard or similar patients. See supra Section II.A.

First, the Hubbards say that Dr. Rowley changed his method of counseling patients after the 2012 update. Dr. Rowley testified that, beginning at the time of the 2012 FDA statement, he began to provide his patients additional information about Beyaz: "that there is some concern that there may be a slightly higher risk of a DVT, of a clot in the leg associating with using [Beyaz] versus some other types of birth control pills." Also in 2012, Dr. Rowley began telling patients "there may be a slightly higher risk by being on the pill which has drospirenone." So the 2012 FDA update caused Dr. Rowley to more clearly communicate to his patients the possibility that DRSP-containing pills pose a slightly increased risk of blood clots relative to other pills.

But a change in communication practices says nothing about the 2012 label's impact on Dr. Rowley's decisionmaking regarding whether to prescribe Beyaz; indeed, Dr. Rowley continued to prescribe Beyaz, YAZ, and Yasmin after 2012. It says even less about the central question in this case: whether the 2012 label would have impacted Dr. Rowley's decision to prescribe Beyaz to Karen Hubbard in December 2011. Dr. Rowley already knew in December 2011 of the possibility that DRSP-containing pills posed some increased risk of blood clots yet prescribed one to Karen Hubbard anyway. And Dr. Rowley testified that he did not view the 2012 update as significant enough to justify the risk of transferring

women who did well on and were happy with their DRSP pills to another pill--women like Karen Hubbard.

Thus, whatever the impact of the 2012 label change on Dr. Rowley's patient communications practices, the risks discussed in these communications did not affect his prescribing decisions for women situated similarly to Karen Hubbard. The Hubbards' evidence on this score therefore does not create a material issue of fact in dispute about whether the 2012 label would have changed Dr. Rowley's prescription decision in 2011.

Moreover, even if a change in what Dr. Rowley communicated to his patients could be instructive, it is far from clear that the change in patient counseling after the 2012 update was a significant one. Dr. Rowley testified that even at the time of Karen Hubbard's December 2011 visit, before the 2012 update, his office would have communicated to Hubbard "safety information about the possibility of an increased risk of blood clots" from DRSP-containing pills such as Yasmin and Beyaz.

Second, the Hubbards point out that Dr. Rowley prescribes fewer DRSP-containing COCs now than he did prior to the 2012 update. By the end of 2012, Dr. Rowley prescribed 50 percent less YAZ, Yasmin, and Beyaz than he had at the beginning of 2012. Dr. Rowley further indicated that now, he typically prescribes Microgestin and Loestrin more than other birth control pills, in part because "the

progesterone is norethindrone." Again, however, this evidence does not raise a triable issue of fact regarding whether the information contained in the 2012 label would have affected Dr. Rowley's decision to prescribe Beyaz to Karen Hubbard. To the extent Dr. Rowley's post-2012-update prescribing practices express an all-things-equal preference for prescribing pills that do not contain DRSP, all things were not equal for Karen Hubbard: she had been tolerating Bayer's DRSP pills well for many years. And a patient who has tolerated a pill for a long time, in the mind of Dr. Rowley, is less likely to develop problems with that pill; thus his standard practice is to continue the patient on the same or a similar pill.

What's more, Dr. Rowley testified that the 2012 decrease in YAZ, Yasmin, and Beyaz prescriptions was not the result of any change in his own prescription decisionmaking calculus, but rather was "[b]ecause the patients themselves decided not to be on those prescriptions." Dr. Rowley explained this was "part of the discussion that we're having that there may be this increased risk from other pills," and that "the patients therefore themselves made their determination that in spite of all the benefits that they may be getting from that particular medication, they elected not to continue it because they didn't want to take that increased risk." Changes in Dr. Rowley's prescription frequencies after the 2012 label addition might tell us something about changes in patient preferences that may have resulted from discussions about the 2012 label. But they do not shed light on

whether the 2012 label would have altered Dr. Rowley's decisional calculus regarding the appropriate prescription for a woman with a long, positive history of DRSP use like Karen Hubbard. Indeed, Dr. Rowley flatly testified that he did not change "the way [he] prescribed birth control to patients . . . after April of 2012"; that even after the 2012 update "the benefits of Beyaz outweigh the risk in patients who have already been taking it for some time with no problems"; and that even today he considers his decision to prescribe Beyaz to Karen Hubbard to be "appropriate."

Nothing the Hubbards have presented alters the plain testimony that Dr. Rowley would have prescribed precisely the same drug to Karen Hubbard in 2011 if he had the additional information contained in the 2012 warning.

C.

The Hubbards also claim that when a warning is inadequate, Georgia law presumes that the inadequate warning was the proximate cause of a failure-to-warn plaintiff's injury (i.e., that an adequate warning would have resulted in a different prescription decision). While the Hubbards acknowledge that any such presumption might be rebuttable--that is, it would shift the burden of going forward to Bayer to show that its (presumptively) inadequate warning was not the proximate cause of Karen Hubbard's injury--they go even further and ask us to

hold that the presumption is irrebuttable and conclusively establishes proximate cause. We remain unpersuaded.

For one thing, Dietz squarely held that Georgia law assigns the burden of proving proximate causation to the plaintiff where a prescription drug warning is presumptively inadequate: "If the warning is inadequate, or merely presumed to be, the plaintiff must demonstrate that the deficient warning proximately caused the alleged injury to prevail." 598 F.3d at 816 (emphasis added). Based on the prescribing physician's testimony that he would have prescribed the same drug even with knowledge of the most current research and warnings, Dietz held that the plaintiff could not meet her burden of proving proximate cause and affirmed the district court's grant of summary judgment in favor of the defendant. Id. Dietz did not mention shifting burdens or in any other way suggest that Georgia law creates or applies a presumption of proximate cause, rebuttable or irrebuttable. In the absence of any clear statement of Georgia law to the contrary from the appellate courts of Georgia, Dietz forecloses a holding that Georgia law provides for a rebuttable presumption that shifts the burden to the defendant to establish the absence of proximate cause or an irrebuttable presumption that conclusively establishes proximate cause when the warning is inadequate. See Ackermann v. Wyeth Pharm., 526 F.3d 203, 212 (5th Cir. 2008) (explaining that in jurisdictions that employ a rebuttable presumption of cause in failure-to-warn cases, the effect

of the presumption is to "shift the burden of producing evidence to the party against whom it operates") (internal quotation marks and citation omitted).

We are bound by the Dietz panel's interpretation of Georgia law unless and until Georgia's courts tell us Dietz interpreted Georgia law incorrectly. See EmbroidMe.com, Inc. v. Travelers Prop. Cas. Co. of Am., 845 F.3d 1099, 1105 (11th Cir. 2017). They have not done so. And we have not found anything in Georgia law after Dietz that clearly indicates there is a rebuttable or an irrebuttable presumption.

The Hubbards rely on Porter v. Eli Lilly & Co., No. CIVA 1:06-CV-1297-JOF, 2008 WL 544739 (N.D. Ga. Feb. 25, 2008). There, based on a survey of other jurisdictions, a district court "assume[d]" that Georgia would apply a rebuttable presumption of proximate cause. 2008 WL 544739 at *11 (emphasis added). The district court held that the defendant had rebutted any such presumption by offering the prescribing physician's testimony that updated risk information in more recent warnings would not have changed his prescription decision. Id. A panel of this Court affirmed in an unpublished per curiam opinion that has no precedential effect. But, in any event, the opinion did not so much as make any mention of a presumption regarding proximate cause. It did hold that "[u]nder Georgia law, [the plaintiff] was required to prove that, but for the alleged inadequate warning, [the] decedent's physician . . . would not have prescribed

Prozac to decedent." Porter v. Eli Lilly & Co., 291 F. App'x 963, 964 (11th Cir. 2008). Neither the district court's assumption nor our unpublished, pre-Dietz opinion in Porter held that there is a presumption of proximate cause under Georgia law, nor could either opinion allow us to depart from our holding in Dietz.

Finally, even if Georgia law applies a rebuttable presumption of proximate cause, this still would not help the Hubbards because Bayer has presented more than enough evidence to rebut any such presumption. As we have already explained, the overwhelming body of record evidence indicates both that Dr. Rowley would have prescribed Beyaz to Karen Hubbard even if he had been aware of the 2012 label update and that the 2012 label update did not materially augment Dr. Rowley's December 2011 understanding of the Beyaz risk profile. In a jurisdiction that applies a rebuttable presumption in failure-to-warn cases, this rebuttal would shift the burden back to the Hubbards to demonstrate a genuine issue of material fact on proximate cause. See Eck v. Parke, Davis & Co., 256 F.3d 1013, 1019 (10th Cir. 2001) (applying Oklahoma law). The Hubbards identify no evidence from which a reasonable jury could conclude that the information contained in the 2012 warning would have altered Dr. Rowley's prescription decision. Therefore, "the causal link is broken and the [Hubbards] cannot recover." Dietz, 598 F.3d at 816 (quotation marks and citation omitted).

Accordingly, we **AFFIRM** the district court's order granting final summary judgment to Bayer.