[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

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