

**IN THE UNITED STATES COURT OF APPEALS  
FOR THE FIFTH CIRCUIT**

United States Court of Appeals  
Fifth Circuit

**FILED**

March 22, 2010

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No. 09-50244  
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Charles R. Fulbruge III  
Clerk

MAX WELLS,

Plaintiff - Appellant

versus

SMITHKLINE BEECHAM CORPORATION, doing business as  
GlaxoSmithKline,

Defendant - Appellee

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Appeal from the United States District Court  
for the Western District of Texas  
\_\_\_\_\_

Before HIGGINBOTHAM, GARZA, and PRADO, Circuit Judges.

PATRICK E. HIGGINBOTHAM, Circuit Judge:

Max Wells invoked diversity jurisdiction and complained that GlaxoSmithKline had failed to warn him that one of its drugs – Requip – could make him gamble away millions. In support, Wells proffered testimony from three experts who would opine that Requip can cause pathological gambling in the general population. The company moved for summary judgment, arguing that the experts' testimony did not pass scientific muster. The district court agreed – holding that even if the court admitted the expert testimony, the opinions would not suffice to create a fact question about general causation,

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because the experts' conclusions were not scientifically reliable. Wells appealed, and we affirm on the alternative *Daubert*<sup>1</sup> ground presented to us: because the experts' opinions are not scientifically reliable, the testimony is inadmissible – leaving the liability cupboard bare.

I.

A.

Doctor Max Wells ran a successful pathology clinic but in 2000 fell ill with Parkinson's disease. Wells began taking Mirapex, a drug made by an unrelated third-party manufacturer. Mirapex is a type of "dopamine agonist," a class of drugs that stimulates the dopamine receptors in the brain to alleviate symptoms of Parkinson's. Due to the neurological disease's progression, Wells had to sell part of his clinic in 2001, and in 2002 he retired. In 2005, Wells sold his remaining interest in the clinic for a sizeable sum.

Since the 1970s, Wells had traveled regularly to Las Vegas. He enjoyed gambling, and he claims to have kept his losses under control. After his diagnosis, though, Wells began to lose more and more money. In 2004, he talked to his doctor about an article he saw warning that Mirapex might cause problem gambling. At that point Wells had already lost as much as \$2 million. In response, his doctor in October 2004 prescribed Wells a different dopamine agonist – this time Requip (generically called ropinirole), the drug at issue in this case. Requip's label did not warn about gambling.

Wells's gambling urges temporarily subsided but then came back with a vengeance. From September 2005 (when he received final payment on the sale

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<sup>1</sup> *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

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of his clinic) until January 2006, Wells surrendered \$10 million to the Nevada gaming tables – including \$4 million in January alone.<sup>2</sup> He told his doctor about the gambling problem, stopped taking Requip, and has not been back to Vegas.

B.

Wells sued GlaxoSmithKline, the manufacturer of Requip, alleging that GSK<sup>3</sup> had failed to warn patients about the side effect of pathological gambling.<sup>4</sup> For Wells to win under Texas law,<sup>5</sup> he must show that the failure to warn caused his injury.<sup>6</sup> Causation has two levels, general and specific, and a plaintiff must prove both. “General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual’s injury.”<sup>7</sup> Sequence matters: a plaintiff must establish general causation before moving to specific causation. Without the predicate proof of general causation, the tort claim fails.<sup>8</sup>

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<sup>2</sup> Some of these losses came from online gambling.

<sup>3</sup> GlaxoSmithKline refers to itself as GSK, a convention we adopt.

<sup>4</sup> The parties interchangeably call the gambling problem “compulsive” and “pathological,” but the medically proper term is “pathological.”

<sup>5</sup> Both parties agree that Texas substantive law applies in this diversity case.

<sup>6</sup> See *Ackermann v. Wyeth Pharms.*, 526 F.3d 203, 208 (5th Cir. 2008) (invoking Texas law); see also *Wright v. Ford Motor Co.*, 508 F.3d 263, 275 (5th Cir. 2007) (same). “The Supreme Court of Texas, like many courts, has equated the ‘more-likely-than-not’ causation requirement to a more than 50% probability that a defendant’s wrongful conduct caused the harm or injury.” *Young v. Mem’l Hermann Hosp. Sys.*, 573 F.3d 233, 235 (5th Cir. 2009) (per curiam) (citing *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 715–17 (Tex. 1997)).

<sup>7</sup> *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 351 (5th Cir. 2007) (citing *Havner*, 953 S.W.2d at 714) (quotation marks omitted).

<sup>8</sup> See *id.*

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Wells engaged three expert witnesses to address causation, that Requip can cause pathological gambling. In reaching their conclusions, the experts relied upon: (1) published articles documenting case-specific correlations between Requip and gambling; (2) a single unpublished study showing a nexus between Parkinson's medicines generally and gambling; (3) GSK's internal data revealing case-specific associations between Requip and gambling; and (4) the fact that GSK has since changed the Requip label to warn about possible gambling side-effects. Each of the three experts, though, conceded that there exists no scientifically reliable evidence of a cause-and-effect relationship between Requip and gambling.

The company moved for summary judgment, arguing: (1) that the expert opinions did not meet *Daubert's* admissibility requirements; or, alternatively, (2) that the lack of scientifically reliable data supporting general causation precluded recovery under Texas law. The district court assumed the expert testimony's admissibility, but found that the experts did not support Wells's claim with scientifically reliable evidence of causation as required by Texas law.

Wells appealed the summary judgment. Our review is de novo, applying the same standards as the district court.<sup>9</sup> We may affirm on any grounds supported by the record.<sup>10</sup>

## II.

### A.

*Daubert* requires admissible expert testimony to be both reliable and

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<sup>9</sup> *Riverwood Int'l Corp. v. Employers Ins. of Wausau*, 420 F.3d 378, 382 (5th Cir. 2005).

<sup>10</sup> *Berquist v. Wash. Mut. Bank*, 500 F.3d 344, 349 (5th Cir. 2007).

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relevant.<sup>11</sup> “This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.”<sup>12</sup> Although there are “no certainties in science,” the expert must present conclusions “ground[ed] in the methods and procedures of science.”<sup>13</sup> In short, the expert must “employ[ ] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.”<sup>14</sup>

“[T]he Supreme Court [has] delineated certain factors to assist courts in evaluating the foundation of a given expert’s testimony, though the Court carefully emphasized the nonexhaustive nature of the listing.”<sup>15</sup> Suggested considerations include: “whether the theory or technique the expert employs is generally accepted; whether the theory has been subjected to peer review and publication; whether the theory can and has been tested; whether the known or potential rate of error is acceptable; and whether there are standards controlling the technique’s operation.”<sup>16</sup> There is no formula, and the court must judge admissibility based on the particular facts of the case.<sup>17</sup>

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<sup>11</sup> *Knight*, 482 F.3d at 352 (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993)).

<sup>12</sup> *Daubert*, 509 U.S. at 592–93.

<sup>13</sup> *Id.* at 590.

<sup>14</sup> *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

<sup>15</sup> *Knight*, 482 F.3d at 351 (citing *Daubert*, 509 U.S. at 593).

<sup>16</sup> *Id.* (citing *Daubert*, 509 U.S. at 593).

<sup>17</sup> *See Kumho Tire Co.*, 526 U.S. at 150.

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B.

Wells proffered the testimony of three experts: Doctors Fong, Saklad, and Kalechstein. None did more than baldly state that Requip can cause problem gambling. At their depositions, the three admitted that no scientific basis existed to confirm their conclusions.

Fong explained: “I think fundamentally there is something very compelling and interesting going on here, but we don’t have enough data to suggest causality . . . . I have not come to a conclusion that there is a causal relationship between Requip and pathological gambling.” He further testified that – based on the “scientific standard that [he] appl[ies] in [his] practice as a psychiatrist and a research scientist” – the scientific literature did not establish a “cause-and-effect relationship between Requip and pathological gambling.”

Saklad’s deposition went the same way. He was asked: “Applying the scientific standard for cause and effect, has – has a cause-and-effect relationship been established between taking Requip and having one or more impulse-control disorders considered as a collective group?” He answered: “No.”

A bit more hesitant at first, Kalechstein ultimately fell in line with Fong and Saklad: “I cannot say [Requip] directly causes [pathological gambling]. What I can say is that there is an association between the two variables. . . . [T]hat’s different than talking about the issue of causation.”

Under the law of this circuit, these admissions drain the expert opinions of probative force. In *Black v. Food Lion, Inc.*, the plaintiff claimed that she slipped in the defendant’s store and that the fall caused fibromyalgia syndrome.<sup>18</sup> The district court admitted the plaintiff’s proffered expert, and we

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<sup>18</sup> 171 F.3d 308, 309 (5th Cir. 1999).

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reversed on *Daubert* grounds for abuse of discretion. We explained that the expert's testimony did "not bear the necessary indicia of intellectual rigor."<sup>19</sup> While "association" was well established, "experts have recognized that the evidence that trauma actually causes fibromyalgia is insufficient to establish causal relationships."<sup>20</sup> Given the experts' concessions in this case, *Black* controls – and we need not go any further. However, sensitive to the case-specific nature of the *Daubert* inquiry, we will closely examine the experts' methodology.

## C.

The experts based their general causation conclusion primarily on the scientific literature, which they claim shows an association between Requip and problem gambling. The literature, though, does not provide the necessary "scientific knowledge" upon which to base an opinion under *Daubert*.<sup>21</sup> Doctor Fong characterized all but one of the studies as "anecdotal evidence," and each expert conceded that the studies were not statistically significant epidemiology. They were, in fact, case studies. Although, "[c]ase-control studies are not per se inadmissible evidence on general causation,"<sup>22</sup> this court has frowned on causative conclusions bereft of statistically significant epidemiological support.<sup>23</sup>

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<sup>19</sup> *Id.* at 312.

<sup>20</sup> *Id.* (quotation marks omitted); *see also id.* at 313 n.2.

<sup>21</sup> *See Daubert*, 509 U.S. at 589–90.

<sup>22</sup> *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 352 (5th Cir. 2007).

<sup>23</sup> *See, e.g., Burleson v. Tex. Dep't of Criminal Justice*, 393 F.3d 577, 586 (5th Cir. 2004) ("Here, as in *Allen*, there are no epidemiological studies supporting a correlation between the suggested causative agent and the type of cancer experienced by the plaintiff."); *Allen v. Pa. Eng'g Corp.*, 102 F.3d 194, 197 (5th Cir. 1996) ("While appellants' experts acknowledge the

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Only one study – the Weintraub Poster<sup>24</sup> – reached statistical significance. The Poster suggests that Parkinson’s patients medicated with dopamine agonists exhibit increased impulsive behavior, including pathological gambling. But the study has other scientific problems making it insufficient as a basis for expert opinion. First, “submission to the scrutiny of the scientific community is a component of ‘good science,’” but the Weintraub Poster was never peer-reviewed or published.<sup>25</sup> Second, the study explains that its results “represented a class association, as opposed to a specific medication, finding.” In other words, the Weintraub Poster does not report a “controlled” test for Requip, a drug that functions differently than other dopamine agonists.<sup>26</sup> Finally, its authors conceded that the very “nature of the study precluded determination of causality.”

While “[w]e . . . understand that in epidemiology hardly any study is ever conclusive, and we do not suggest that an expert must back his or her opinion

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lack of statistically significant epidemiological evidence, they rely on certain studies as ‘suggestive’ of a link between EtO exposure and brain cancer. ‘Suggestiveness’ is not by the experts’ own admission statistical significance . . . ; this basis for their scientific opinion must be rejected.”).

<sup>24</sup>D ANIEL WEINTRAUB ET AL., DOPAMINERGIC THERAPY AND IMPULSE CONTROL DISORDERS IN PARKINSON’S DISEASE: A CROSS-SECTIONAL STUDY OF OVER 3,000 PATIENTS (2008) (summarizing an epidemiological study presented at a conference).

<sup>25</sup> *Daubert*, 509 U.S. at 593.

<sup>26</sup> See *Knight*, 482 F.3d at 353 (affirming rejection of a “study focused on organic solvents as a class, including a wide-range of chemicals to which [the plaintiffs] were never exposed”); see also *Burleson*, 393 F.3d at 585–86 (affirming rejection of a study showing that exposure to a substance causes cancer but not showing that the specific type of exposure suffered by the plaintiff could lead to his particular type of cancer); *Allen*, 102 F.3d at 197 (affirming rejection of a study showing that exposure to carcinogen caused a different type of cancer than the one suffered by plaintiff).



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with published studies that unequivocally support his or her conclusions,”<sup>27</sup> here “there is simply too great an analytical gap between the data and the opinion proffered.”<sup>28</sup> And the bases for the experts’ conclusions pass none of the applicable *Daubert* tests: that Requip causes problem gambling is not generally accepted, has not been subjected to peer review and publication,<sup>29</sup> and is not backed by studies meeting requisite scientific standards.<sup>30</sup> Without the expert testimony, Wells cannot prove general causation – and judgment must be entered for GSK.

### III.

Our conclusion that the trial court did not abuse its discretion is an unremarkable sustaining of the district court’s gatekeeping role under *Daubert*.<sup>31</sup>

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<sup>27</sup> *Knight*, 482 F.3d at 354.

<sup>28</sup> *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

<sup>29</sup> One of Wells’s experts, Dr. Saklad, explained in his deposition that “causation requires scientific literature that proves a statistically valid reproducible result which could be used to establish causation. Such studies have not been done.”

<sup>30</sup> It bears mentioning that, in addition to the literature, Wells’s experts purport to rely on GSK’s internal documentation in reaching the conclusion that Requip causes problem gambling. Specifically, GSK has, over the years and per the FDA’s requirements, collected data on patients suffering increased gambling when taking Requip. This data shows a relatively high number of self-reported spikes, but mining this data is not the scientific method; rather, it is rife with bias and variability. Wells also points out that GSK has now changed its Requip label to warn about possible gambling problems. This precaution, though, did not grow out of scientific knowledge of causation; rather, GSK changed the label because there *might* be an *association*. See 21 C.F.R. § 201.80(e) (“The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.”).

<sup>31</sup> See *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999) (describing *Daubert* as “setting forth the trial judge’s general ‘gatekeeping’ obligation”).

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In finding the evidence scientifically unreliable – and thus insufficient to prove causation under Texas law – it follows that the experts’ testimony was also deficient under *Daubert* given its overlap with Texas questions of scientific sufficiency.<sup>32</sup>

Perhaps Requip is a cause of problem gambling, but the scientific knowledge is not yet there. Wells urges the law to lead science – a sequence not countenanced by *Daubert*.<sup>33</sup> And while the possibilities of their relationship properly spark concerns sufficient to warrant caution, the courts must await its result. AFFIRMED.

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<sup>32</sup> The Supreme Court of Texas has explained that “the same factors may be applied” to “no evidence review of scientific evidence” as to review of admissibility of scientific testimony. *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 714 (Tex. 1997) (referencing *E.I. du Pont de Nemours & Co. v. Robinson*, 923 S.W.2d 549, 556–57 (Tex. 1995) (adopting the federal *Daubert* standard in the Texas-law inquiry into the admissibility of expert testimony)); *id.* at 712 (explaining that scientific sufficiency in Texas “is determined by looking at numerous factors including those set forth in . . . *Daubert*”).

<sup>33</sup> See *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996) (“Law lags science; it does not lead it.”).