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S.D. Illinois.

In re YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION.
This Document Relates to: Laforet–Neer v. Bayer Healthcare Pharmaceuticals Inc., et al., 10–10223–DRH–PMF.

No. 3:09–md–02100–DRH–PMF.
|
MDL No. 2100.
|
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MEMORANDUM AND ORDER

DAVID R. HERNDON, Chief Judge.

I. *Introduction and Background*

***1** Now before the Court is defendants' motion for summary judgment and to exclude testimony of plaintiff's expert Dr. Mitchell Botney (Doc. 14). Plaintiff opposes the motion (Doc. 15). Familiarity with the underlying proceedings is presumed. Although the motion is fully briefed, the Court holds in abeyance the portion of the motion regarding summary judgment until after the resolution of the trial in *Sims v. Bayer Healthcare Pharmaceuticals Inc., et al.,* 09–10012–DRH–PMF. Based on the pleadings, the applicable law and the following, the Court denies the motion to exclude plaintiff's expert Dr. Botney.

This multidistrict litigation "(MDL") relates to the manufacture, marketing, and sale of the prescription pharmaceuticals known as YAZ and Yasmin. [1] YAZ and Yasmin, which are manufactured, marketed, and sold by Bayer, are members of a class of prescription medicines known as combined hormonal oral contraceptives ("COCs"), which contain an estrogen and a progestin component. The vast majority of COC's, including YAZ and Yasmin, contain the same type of estrogen—ethinyl estradiol ("EE"). *Id.* [2] In contrast to estrogen, the progestins in COCs are of many types. The progestin in YAZ and Yasmin is a newer type of progestin known as drospirenone ("DRSP"). *Id.*

1 This MDL relates to other oral contraceptives that, like YAZ and Yasmin, contain drospirenone. However, YAZ and Yasmin are the subject drugs involved in the pending bellwether trials.

2 YAZ and Yasmin differ in their dosing schedule and the amount of estrogen they contain. The Food and Drug Administration ("FDA") approved YAZ and Yasmin as oral contraceptives in 2006. The FDA subsequently approved YAZ and Yasmin as a treatment for moderate acne vulgaris in women who choose to use an oral contraceptive and as a treatment for premenstrual dysphoric disorder ("PMDD") in women who choose to use an oral contraceptive.

DRSP-containing COCs are known as "fourth-generation" COCs (classified by the type of progestin used). *Id.* at pp. 6–5. COCs containing earlier developed progestins are categorized as "first-generation," "second-generation," and "third-generation." *Id.* at p. 6. First-generation COCs contain the progestin norethynodrel. *Id.* Second-generation COCs contain the progestin Levonorgestrel ("LNG") and third-generation COCs contain several progestins, including desogestrel, gestodene, and norgestimate. *Id.*

It is generally accepted that there is an increased risk of venous thromboembolic ("VTE") disease (disease relating to blood clotting in the veins) in COC users. It is also generally accepted that second-generation

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COCs (LNG-containing COCs) are considered to have a low risk for VTE disease. Because the VTE risk associated with second-generation COCs is relatively low, LNG-containing COCs are often selected as a reference treatment in comparative studies evaluating whether there is an association between third-generation COCs and an increased risk of VTE disease and in comparative studies evaluating whether there is an association between DRSP-containing COCs and an increased risk of VTE disease. In the mid–1990s, various reports indicated that users of third-generation COCs were at higher risk of VTE disease than users of second-generation COCs.

At issue in this litigation, is the safety of DRSP-containing COCs and whether DRSP use is associated with a higher risk of VTE disease. Specifically, Plaintiffs contend that Bayer misrepresented or omitted facts pertaining to the safety and efficacy of YAZ and Yasmin. With regard to the safety of YAZ and Yasmin, plaintiffs contend that the DRSP component of the drugs is associated with an increased risk of VTE disease and of potentially life threatening thrombosis complications, including deep vein thrombosis ("DVT") (a blood clot formation in one of the body's deep veins) and pulmonary embolism ("PE") (a clot formation that travels to the lungs).

***2** In the case at bar, plaintiff was prescribed Yasmin in December 2006, and, four months later she suffered DVT and PE. Bayer contends that plaintiff's expert witness Dr. Botney's opinions fail to meet the requirements for admissible expert testimony under Federal Rule of Evidence 702 and *Daubert v. Merrill Dow Pharms.,* 509–UC 579 1993 (*Daubert*). Specifically, Bayer seeks to preclude testimony by Dr. Botney regarding plaintiff's damages and prognosis as speculative, irrelevant and unfairly prejudicial.

II. *Legal Standard*

Federal Rule of Evidence 702, and *Daubert v. Merrell Dow Pharms ., Inc.,* 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), govern the admissibility of expert testimony. The *Daubert* standard applies to all expert testimony, whether based on scientific competence or other specialized or technical expertise. *Smith v. Ford Motor Co.,* 215 F.3d 713, 719 (7th Cir.2000) (citing *Kumho Tire Co., Ltd. v. Carmichael,* 526 U.S. 137, 141, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999)). Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed.R.Evid. 702. *Daubert* clarified Rule 702 charges the district court with the task of ensuring expert testimony is both relevant and reliable. *Daubert,* 509 U.S. at 589.

Courts in the Seventh Circuit conduct a three-step analysis under *Daubert. Ervin v. Johnson & Johnson, Inc.,* 492 F.3d 901, 904 (7th Cir.2007).[3] First, the district court must determine whether the person whose testimony is offered is in fact an expert, as codified in Rule 702 through "knowledge, skill, experience, training, or education." *Id.* (citing Fed.R.Evid. 702). Notably, although "extensive academic and practical expertise" sufficiently qualify a potential witness as an expert, *Bryant v. City of Chicago,* 200 F.3d 1092, 1098 (7th Cir.2000), "Rule 702 specifically contemplates the admission of testimony by experts whose knowledge is based on experience," *Walker v. Soo Line R.R. Co.,* 208 F.3d 581, 591 (7th Cir.2000). *Smith,* 215 F.3d at 718 (citing *Kumho,* 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.")).

3 The Court notes the Seventh Circuit has also described the *Daubert* analysis as a two-step process. *See Chapman v. Maytag Corp.,* 297 F.3d 682, 686 (7th Cir.2002). However, as *Chapman* simply combines the first two steps described in *Ervin* as a single test

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> of reliability, whether the analysis is described as a three-step or two-step process does not substantively change the Court's analysis.

Secondly, the district court must determine the expert's reasoning or methodology is reliable. *Ervin,* 492 F.3d at 904; *see Mihailovich v. Laatsch,* 359 F.3d 892, 918 (7th Cir.2004) (citing *Kumho,* 526 U.S. at 147). Specifically, the testimony must have a reliable basis in the knowledge and experience of the relevant discipline, *Kumho,* 526 U.S. at 149 (internal quotations removed), consisting in more than subjective belief or unsupported speculation. *Chapman v. Maytag Corp.,* 297 F.3d 682, 687 (7th Cir.2002); *Daubert,* 509 U.S. at 590.

***3** Further, as to reliability, *Daubert* provided the following non-exhaustive list of relevant factors: "(1) whether the scientific theory can be or has been tested; (2) whether the theory has been subjected to peer review and publication; (3) whether the theory has been generally accepted in the scientific community." *Ervin,* 492 F.3d 901, 904 (7th Cir.2007) (citing *Daubert,* 509 U.S. at 593–94). However, there is no requirement that courts rely on each factor, as the gatekeeping inquiry is flexible and must be "tied to the facts" of the particular case. *Kumho,* 526 U.S. at 150 (quoting *Daubert,* 509 U.S. at 591); *see also Chapman,* 297 F.3d at 687. Thus, "the role of the court is to determine whether the expert is qualified in the relevant field and to examine the methodology the expert has used in reaching his [or her] conclusions." *Smith,* 215 F.3d at 718 (citing *Kumho,* 526 U.S. at 153).

The district court possesses "great latitude in determining not only *how* to measure the reliability of the proposed expert testimony but also whether the testimony is, in fact, reliable." *United States v. Pansier,* 576 F.3d 726, 737 (7th Cir.2009) (citing *Jenkins v. Bartlett,* 487 F.3d 482, 489 (7th Cir.2007)). Accordingly, the court's gatekeeping function requires focus on the expert's methodology; "[s]oundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact." *Smith,* 215 F.3d at 718 (citing *Daubert,* 509 U.S. at 595; *Walker,* 208 F.3d at 587).

Resolution of an expert's credibility or the correctness of his or her theories is left to the jury's determination after opposing counsel has cross-examined the expert at issue. *Id.* (citing *Walker,* 208 F.3d at 589–90). Thus, "[i]t is not the trial court's role to decide whether an expert's opinion is correct. The trial court is limited to determining whether expert testimony is pertinent to an issue in the case and whether the methodology underlying that testimony is sound." *Id.* (citing *Kumho,* 526 U.S. at 159 (Scalia, J., concurring) (stating that the trial court's function under *Daubert* is to exercise its discretion "to choose among reasonable means of excluding expertise that is fausse and science that is junky")). However, as an expert must explain the methodologies and principles that support his or her opinion, he or she cannot simply assert a "bottom line" or *ipse dixit* conclusion. *Metavante Corp. v. Emigrant Sav. Bank,* 619 F.3d 748, 761 (7th Cir.2010) (quoting *Minix v. Canarecci,* 597 F.3d 824, 835 (7th Cir.2010)).

Lastly, the district court must consider whether the proposed testimony will assist the trier of fact in its analysis of any issue relevant to the dispute. *See Smith,* 215 F.3d at 718; *Chapman,* 297 F.3d at 687; *Daubert,* 509 U.S. at 592. It is crucial that the expert "testify to something more than what is 'obvious to the layperson' in order to be of any particular assistance to the jury.' " *Dhillon v. Crown Controls Corp.,* 269 F.3d 865, 871 (7th Cir.2001) (quoting *Ancho v. Pentek Corp.,* 157 F.3d 512, 519 (7th Cir.1998)). However, the expert need not have an opinion as to the ultimate issue requiring resolution to satisfy this condition. *Smith,* 215 F.3d at 718 (citing *Walker,* 208 F.3d at 587).

***4** Indisputably, a medical degree does not qualify a doctor to opine on all medical subjects. *Gayton v. McCoy,* 593 F.3d 610, 617 (7th Cir.2010) (citing *Carroll v. Otis Elevator Co.,* 896 F.2d 210, 212 (7th Cir.1990)). However, the Seventh Circuit recognizes that often a "physician in general practice is competent to testify about problems that a medical specialist typically treats." *Id.* (citing 29 Wright & Gold, Federal Practice and Procedure, § 6265 (1997); *Doe v. Cutter Biological, Inc.,* 971 F.2d 375, 385 (9th Cir.1992) ("The fact that the experts were not licensed hematologists does not mean that they were testifying beyond their area of expertise. Ordinarily, courts impose no requirement that an expert be a specialist in a given field, although there may be a requirement that he or she be of a certain profession, such as a doctor."); *Dickenson v. Cardiac & Thoracic Surgery of E. Tenn.,* 388 F.3d 976, 978–79 (6th Cir.2004); *United*

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States v. Viglia, 549 F.2d 335, 336 (5th Cir.1977) (holding that a pediatrician who had degrees in medicine and pharmacology but no experience in treating patients in obesity had sufficient knowledge, training, and education to testify regarding drug's effect on obese persons)). Thus, courts must individually evaluate each conclusion drawn to determine whether the purported expert "has the adequate education, skill, and training to reach them."

III. *Analysis*

Defendants moved to exlude Dr. Botney's opinions under the "Future risk of DVT" and "Side effects of anticoagulation" sections of his expert report regarding events and injuries that Mrs. Laforet–Neer may or may not experience in the future. Botney Report (Ex. J) at 9–10. Bayer cites to specific statements opining as to plaintiff's possible risks of developing a future recurrent DVT or PE, future events as she ages, hormone replacement theory, and side effects associated with anticoagulants. As these opinions do not state a "definitive diagnosis of a medical condition," Bayer argues they require exclusion. Defendants argue that these opinions are inadmissible for two reasons: (1) they address speculative, future events, and are thus irrelevant, and (2) even assuming *arguendo* that the opinions are relevant, their probative value is substantially outweighed by the "danger of unfair prejudice, confusion of the issues, or misleading [of] the jury." Fed.R.Evid. 403. Thus, according to Bayer, these opinions should be excluded under the Federal Rules of Evidence 402, 403, and 702. Plaintiff contends that Botney's statements are not speculative and are made within a reasonable degree of medical certainty due to the his medical experience

Plaintiff offers Dr. Botney to opine, from a pulmonary perspective, as to plaintiff's future damages and prognosis resulting from her PE and the side effects of anticoagulation. Specifically, Botney opines:

> "Future risk of DVT
>
> As described above, the risk for recurrent pulmonary embolism never falls to zero even if the risk diminishes with time. Noting that the risks of deep vein thrombosis are additive, a history of pulmonary embolism will increase the risk of developing a future recurrent DVT or PE should Ms. Laforet–Neer acquire other risk factors for deep vein thrombosis or pulmonary emboli in the future. As described above, additional precautions will be required during events or periods associated with increased risk of DVT or PE that would not have been needed if prior VTE had not occurred.
>
> ***5** The presence of a prior DVT or PE increases the risk of additional DVT or PE in the future during events or periods associated with increased risk DVT or PE. These include, but are not necessarily limited to, surgery, pregnancy, hormonal replacement therapy and travel (endnotes omitted).
>
> There are several examples in the medical record that demonstrated that Ms. Laforet–Neer's physicians recognized there were event periods during which she was at increased risk for additional DVT or PE—having had a prior PE—and that she required additional prophylactic precautions. These include the precautions taken at the time of her pregnancy, her surgeries in August, 2007, and September, 2009, and even the warnings about longer distance air travel.
>
> One can anticipate additional future events or periods associated with increased risk for DVT or PE as Ms. Laforet–Neer ages that will again require special precautions.
>
> One special circumstance that has arisen already in the medical records is the use of hormonal replacement therapy (HRT) if Ms. Laforet–Neer should undergo bilateral ovariectomy for symptoms associated with her underlying polycystic ovary syndrome. As noted in the medical record, Dr. Ensley wrote 'patient would like TAHBSO will contact hematologist about ability to use hormonal therapy afterward due to BSO and what I told patient would be likely severe menopausal symptoms because of her (?).' As noted above, post-menopausal hormonal replacement therapy is associated with an increased risk of DVT and pulmonary embolism—particularly if a prior DVT or PE is present—placing Ms. Laforet–Neer at an increased risk compared to taking hormonal replacement therapy without prior deep vein thrombosis or pulmonary embolism.

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> Side-effects of anticoagulation
>
> As with all medications, there are side effects with anticoagulants whether coumadin or heparin-based. These disadvantages include the additional cost of drug, the necessity for intravenous administration in the case of unfractionated heparin or subcutaneous administration for low molecular weight heparins, a risk of major bleeding, a risk of reduced bone density, a risk of vertebral fracture, and a risk of heparin-induced thrombocytopenia. These additional precautions would not have been necessary in the absence of prior pulmonary embolism.
>
> Finally, despite the refutable evidence that DVT or PE thromboprophylaxis reduces the incidence of both, it is also recognized that VTE prophylaxis is not completely successful. Despite DVT or PE prophylaxis during future periods or events associated with DVT formation or pulmonary embolism, she will be at increased risk of recurrence during that risk period."

Dr. Botney received his Bachelor of Science from the University of Michigan in 1974. In 1984, he received his Medical Doctor from the Ohio State University College of Medicine. He completed a fellowship in Respiratory and Critical Care at the Washington University School of Medicine in 1988. Thus, he has over twenty years of clinical experience as a pulmonologist. Further, he has authored numerous articles pertaining to thrombotic events. In forming his opinions, Dr. Botney consulted numerous publications concerning acute pulmonary embolism, the relation of recurrent VTE and pregnancy, the risk of VTE in relation to DRSP COC users, anticoagulation and related subjects. Finally, he consulted all of plaintiff's relevant medical records.

***6** Dr. Botney, is qualified to testify as to plaintiff's future harm and as to the risks associated with anticoagulation. Specifically, the increase of future recurrent DVT or PE that she presently faces will increase during periods of increased risk, including travel, pregnancy, surgery or hormonal replacement therapy. As stated previously, Botney is a medical doctor with twenty years of clinical experience. Thus, the Court finds he is qualified to opine, within a reasonable degree of medical certainty, concerning the future damages associated with plaintiff's PE and the risks of anitcoagulation.

As also stated previously, Dr. Botney bases his opinions concerning plaintiff's future damages on relevant medical literature, plaintiff's medical records, clinical study reports, and his years of experience. Contrary to Bayer's assertion, these opinions are not speculative as Botney bases his opinions his experiences with patients who have suffered PEs. The Court finds that Botney has opined within a reasonable degree of medical certainty that plaintiff is at an increased risk of the particular injuries at issue. As such, his opinion is not speculative. Thus, as Dr. Botney, bases his opinion on a reliable methodology; specifically, his experience and relevant medical knowledge, the Court finds his opinions as to plaintiff's possible future harm admissible. Finally, the probative value of these statements is not outweighed by their prejudicial effect.

IV. *Conclusion*

Accordingly, the Court **DENIES** defendants' motion to exclude testimony of plaintiff's expert Dr. Mitchell Botney (Doc. 14). As noted previously, defendants' motion for summary judgment remains pending and is held in abeyance until the resolution of the trial in *Sims v. Bayer Healthcare Pharmaceuticals, Inc., et al.,* 09–10012–DRH–PMF.

SO ORDERED.

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