UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE: YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	)	**3:09-md-02100-DRH-PMF**
	)	**MDL No. 2100**

This Document Relates to: *Kerry Sims v. Bayer Corp., et al.*, No. 3:09-cv-10012-DRH-PMF

MEMORANDUM AND ORDER

I. INTRODUCTION

Defendants Bayer HealthCare Pharmaceuticals Inc. and Bayer Pharma AG (Bayer) move to exclude certain opinions of plaintiff's case-specific experts Mitchell Botney, M.D., Anthony Disciullo, M.D., Henry Rinder, M.D., and Mehrdad Sehizadeh, M.D. Bayer also moves for summary judgment on plaintiff's failure to warn and defective manufacture and construction strict products liability claims (Doc. 81).[1] Further, in Bayer's reply (Doc. 171) to plaintiff's response (Doc. 87), it moves for summary judgment as to plaintiff's negligence *per se* claim brought for the first time in her third amended complaint (Doc. 165). For the following reasons, Bayer's motion to exclude certain opinions of plaintiff's case-specific experts and for summary judgment as to plaintiff's failure to warn claim is

[1] The Court notes plaintiff's response concedes insufficient evidence to submit a defective manufacturing claim. Plaintiff agrees to withdraw and dismiss the claim. However, she emphasizes that dismissal of this claim does not relate in any way to plaintiff's strict liability design defect claim (Doc. 88, p. 1 n. 3). Accordingly, Bayer's motion for summary judgment as to plaintiff's defective manufacturing claim is moot.

DENIED (Doc. 81). Bayer's motion for summary judgment as to plaintiff's negligence *per se* claim is also **DENIED** as untimely (Doc. 187).

II. BACKGROUND

a. MDL Generally[2]

This multidistrict litigation (MDL) relates to the manufacture, marketing, and sale of the prescription pharmaceuticals known as YAZ and Yasmin.[3] 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 (Doc. 2090, p. 6). The vast majority of COC's, including YAZ and Yasmin, contain the same type of estrogen – ethinyl estradiol (EE) (Doc. 2090, p. 6).[4] 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) (Doc. 2090, p. 6).

DRSP-containing COCs are known as "fourth-generation" COCs (classified by the type of progestin used) (Doc. 2090, pp. 5-6). COCs containing earlier developed progestins are categorized as "first-generation," "second-generation," and "third-generation" (Doc. 2090, p. 6). First-generation COCs contain the progestin norethynodrel (Doc. 2090, p. 6). Second-generation COCs contain the

[2] The documents cited in this section of the Court's Order are filed in 09-md-2100-DRH.
[3]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.
[4] 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.

progestin Levonorgestrel (LNG) and third-generation COCs contain several progestins, including desogestrel, gestodene, and norgestimate (Doc. 2090, p. 6)

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 (Doc. 2102-14, p. 5; Doc. 2090-2, p. 2). It is also generally accepted that second-generation COCs (LNG-containing COCs) are considered to have a low risk for VTE disease (Doc. 2102-14, p. 6). 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 (*See e.g.*, Doc. 2102-4) and in comparative studies evaluating whether there is an association between DRSP-containing COCs and an increased risk of VTE disease (*See e.g.*, Doc. 2102-14 pp. 5-6). 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 (Doc. 2090-2, p. 2).

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, including plaintiff Sims currently in issue, 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 (a clot formation that travels to the lungs).

b. Facts Pertaining to Plaintiff Sims' Claims

In June 2008, plaintiff requested that her gynecologist switch her current COC prescription to YAZ. Plaintiff cites to advertisements promoting YAZ's ability to treat moderate acne as motivating her request. Plaintiff's physician then prescribed YAZ. Plaintiff used YAZ continuously from June 2008 to July 2008. In July 2008, plaintiff was diagnosed with a pulmonary embolism (PE) while taking YAZ (Doc. 87, pp. 2-3). Relevant to the instant dispute, plaintiff contends Bayer knew or should have known by 2003 that DRSP COCs carry a higher risk for VTE than other commonly used COCs. Plaintiff cites to numerous reports, studies, and FDA actions as the basis for this contention (Doc. 87, pp. 5-6). Based on Bayer's alleged knowledge, plaintiff claims Bayer's YAZ label is misleading and does not adequately warn of YAZ's increased risk of thrombotic events, including PE (Doc. 87, pp. 7-8). The Court refers to Bayer's motion (Doc. 81) and plaintiff's statement of material facts in response (Doc. 87) for the remainder of the disputed factual allegations.

III. BAYER'S MOTION TO EXCLUDE CERTAIN STATEMENTS OF PLAINTIFF'S EXPERTS

a. Legal Standard

i. Generally

FEDERAL RULE OF EVIDENCE 702, and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (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 (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).[5] 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

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

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.")).

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.

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).

ii. Physician Testimony

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 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." *Id.*

b. Arguments and Analysis

1. *Daubert* Analysis Generally

The following qualifications and statements concerning the reliability of the experts' opinions are applicable to all statements for which Bayer seeks exclusion. As to the third prong under Fed. R. Evid. 702 and *Daubert*, whether the proposed testimony will offer assistance to the trier of fact, the Court finds all of the experts' opinions as stated in their reports are helpful to the trier of fact's analysis of issues relevant to the dispute. All of the at-issue experts opine from the perspective of medical doctors. Accordingly, they testify as to something more than what is obvious to a layperson. Thus, the Court will only independently analyze the qualifications of the relevant expert and the reliability of their opinions.

a. Dr. Mitchell Botney

i. Qualifications

Plaintiff offers Dr. Botney to opine, from a pulmonary perspective, as to plaintiff's future damages and prognosis resulting from her PE (Doc. 90, p. 2).

Dr. Botney received his Bachelor of Science from the University of Michigan in 1974. In 1984, he received a Doctorate of Medicine 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 (*See* Doc. 90-2).

ii. Reliability

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, and other related subjects. Further, he consulted the depositions of plaintiff and Dr. Mark Erwin. Finally, he consulted all of plaintiff's relevant medical records (*See* Doc. 90-4).

b. Dr. Henry Rinder

i. Qualifications

Plaintiff offers Dr. Rinder to opine, from a hematology perspective, regarding plaintiff's future damages and prognosis resulting from her PE (Doc. 90, p. 2). Dr. Rinder is a board certified Internal Medicine doctor, specializing in Hematology. Dr. Rinder received his Bachelor of Science from Yale University in 1979. In 1984, he received a Doctorate of Medicine from the University Of Vermont College Of Medicine. In 1988, he completed a fellowship in Hematology at the Yale University School of Medicine. He is currently an attending physician at the Yale University School of Medicine. Dr. Rinder has over nineteen years of

clinical experience diagnosing and treating patients with venous thrombotic events. Further, Dr. Rinder has authored numerous texts concerning thrombosis and bleeding, including a text titled, "Hematology in Clinical Practice" (*See* Doc. 90-5).

ii. Reliability

In forming his opinions, Dr. Rinder consulted plaintiff's medical and hospital records. He further consulted relevant deposition testimonies and medical summaries submitted in 09-md-2100, the general MDL proceeding (*See* Doc. 90-6). Moreover, he reviewed relevant medical literature concerning the relationship between VTE and COC users. Lastly, he relied on relevant clinical study reports, their corresponding clinical reports, and relevant internal Bayer documents (*See* Doc. 90-8).

c. Dr. Anthony Disciullo

i. Qualifications

Plaintiff offers Dr. Disciullo to opine, from the perspective of an OB/GYN, regarding plaintiff's future damages, prognosis, and his experience with Bayer's marketing techniques. He is a board certified OB/GYN who has practiced in the Boston area since 1975 (Doc. 90-9, p. 2). He received a Bachelor of Arts in Biology from Boston College in 1964, and a Doctorate of Medicine from New York Medical College in 1968. He has held numerous academic appointments, including his current position as Assistant Clinical Professor of Obstetrics, Gynecology, and Reproductive Biology at the Harvard Medical School. Dr.

Disciullo is an attending physician at four Boston area hospitals (Doc. 90-9, p. 3). His practice is limited to gynecology with a focus on laparoscopic and pelvic reconstructive procedures (*See* Doc. 90-9). According to Dr. Disciullo, a "considerable portion" of his practice requires him to prescribe hormonal contraception (HC) in addition to COCs (Doc. 90-11, p. 2). Additionally, Dr. Disciullo has received several awards, conducted numerous research studies, co-authored various medical journal articles, and authored educational texts (*See* Doc. 90-9).

ii. Reliability

Dr. Disciullo states his opinions "are based on the materials referenced throughout the body of [his] report as well as [his] clinical training, education and background knowledge of the subject matter" (Doc. 90-11, p. 2). Specific to plaintiff, Dr. Disciullo forms his opinions as to her future damages and prognosis on her medical records and relevant deposition testimony (Doc. 90-10, p. 2). Additionally, Dr. Disciullo cites to an expansive list of medical literature, clinical study reports, published studies corresponding to clinical reports, deposition transcripts and exhibits, and other Yasmin and Yaz-related materials as forming the basis of his opinions (*See* Doc. 90-12).

d. Dr. Mehrad Sehizadeh

i. Qualifications

Plaintiff offers Dr. Sehizadeh, from the perspective of a radiologist, to opine as to plaintiff's PE diagnosis (Doc. 90, p. 3). He is a board certified radiologist

with ten years' experience of interpreting radiologic studies. He received a Doctorate of Medicine from the Tehran University of Medical Sciences in 1991. He received his certification from the American Board of Radiology in 2002. He is licensed in three states and is currently a Neuroradiologist partner at Midwest Radiological Associates, PC (*See* Doc. 90-13).

ii. Reliability

In forming his opinions, Dr. Sehizadeh relied on a publication concerning the diagnosis of chronic pulmonary thromboembolism, and all of plaintiff's relevant medical records. These records include plaintiff's chest and abdomen scans relevant to the diagnosis of her PE, all dated from July 16, 2008, to July 31, 2008. Moreover, he relied on his years of experience as a radiologist (*See* Doc. 90-14).

2. *Daubert* Applied to Specific Statements

a. Dr. Sehizadeh's Opinion as to Age of Plaintiff's PE

First, Bayer seeks exclusion of certain statements of plaintiff's expert Dr. Sehizadeh, a radiologist, opining as to the age of plaintiff's PE. Bayer argues as Dr. Sehizadeh is not a thoracic radiologist, he is not qualified to opine in this manner. As Dr. Sehizadeh does not generally determine the age of a PE "by days or weeks," Bayer argues his opinion stating plaintiff's PE was three to seven days old at the time of her diagnosis requires exclusion. Bayer states as Dr. Sehizadeh cannot cite to articles in support of his contention, it is unfounded (Doc. 81, pp. 7-8).

Plaintiff responds Dr. Sehizadeh's opinions as to the age of plaintiff's PE are admissible as Dr. Sehizadeh is a board-certified radiologist who was on staff at plaintiff's hospital during her admission for treatment of her PE. Plaintiff cites Dr. Sehizadeh's ten years of experience interpreting more than 80,000 radiologic studies, including approximately 2,000 CTA chest scans and 12,000 chest radiographs, as the basis for his status as a qualified expert. Plaintiff states Dr. Sehizadeh's methodology of reviewing radiology films to diagnose plaintiff's acute PE is reliable as it it identical to the methodology any radiologist would employ when making this diagnosis. Further, plaintiff states, Dr. Sehizadeh bases his opinion that plaintiff's PE was less than three days old at the time of diagnosis on his years of medical experience and knowledge concerning the difference between an acute PE and a chronic PE. Thus, plaintiff contends it is admissible under *Daubert* (Doc. 90, pp. 17-19).

i. Dr. Sehizadeh's Opinion as to Age of Plaintiff's PE Admissible Under *Daubert*

1. Qualifications

The Court finds Dr. Sehizadeh's years of general experience as a radiologist and specifically his experience related to plaintiff, qualify him to opine in this manner. Although Dr. Sehizadeh is not a thoracic radiologist, he is indisputably a radiologist with over ten years of experience. A physician in general practice is competent to testify about problems that a medical specialist typically treats, due to his or her relevant medical training and experience. In this instance, Dr. Sehizadeh is a specialist. He is a radiologist. Although he may not regularly

opine as to the specific age of PEs, he regularly reads CTA chest scans and radiographs such as those underlying the basis of his opinion. Thus, he is qualified to opine in this manner.

2. Reliability

As plaintiff states, Dr. Sehizadeh formed his opinion as to the age of plaintiff's PE according to the methodology radiologists employ on a daily basis. He reviewed her radiology films. He further explains the bases of his opinion concerning the age of plaintiff's PE. In his report Dr. Sehizadeh states,

> Considering the pleural effusion and pulmonary consolidation on the left side after initial diagnosis while on treatment, central position of embolus in CTA, dilation of the affected left lower lobe pulmonary arterial branch in CTA and normal appearance of the chest radiographs on 7/16/2008 and 7/18/2008; I believe that pulmonary embolism [was] not more than three days old at the time of diagnosis on 7/18/2008 and [was] definitely less than one week old at that time.

(Doc. 90-14, p. 4). Thus, the Court finds Dr. Sehizadeh adequately explains the methodology underlying his opinion. Bayer disagrees with Dr. Sehizadeh's conclusions. However, Bayer's arguments are more properly addressed on cross-examination. As Dr. Sehizadeh is qualified and his opinions are reliably based, his statements are admissible pursuant to *Daubert.*

b. Opinions as to Possible Future Harm

Bayer next argues specific opinions of Drs. Botney, Disciullo, and Rinder require exclusion as speculative and unreliable. Bayer cites to specific statements opining as to plaintiff's possible risks concerning post-thrombotic syndrome, future VTEs, pregnancy complications, future surgery, flying, hormone

replacement theory, and psychological damages. As these opinions do not state a "definitive diagnosis of a medical condition," Bayer argues they require exclusion. Bayer also cites to Fed. R. Evid 401, holding evidence is relevant where it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more or less probable," as further requiring the statements' exclusion. As the experts in issue cannot opine as to whether these circumstances are reasonably likely to occur, Bayer argues they are inadmissible. Further, Bayer states the prejudicial effect of these statements outweighs their probative value under Fed. R. Evid. 403.

Plaintiff responds that pursuant to Illinois law; specifically, *Dillon v. Evanston Hosp.*, 771 N.E.2d 357, 370 (Ill. 2002), she need not prove future harm is "more likely than not" to occur. Rather, plaintiff contends, evidence of future harm is admissible, and not speculative, so long as the increased risk of future injury is likely to occur within a reasonable degree of medical certainty. Thus, plaintiff argues she need only present expert testimony within a reasonable degree of medical certainty that plaintiff is at an increased risk of a particular future injury.

i. Post-Thrombotic Syndrome Opinions

Plaintiff states Drs. Rinder and Disciusllos' opinions as to plaintiff's increased risk of developing post-thrombotic syndrome are not speculative as made within a reasonable degree of medical certainty. For example, plaintiff states, Dr. Rinder opines that plaintiff is, "at risk for post-thrombotic syndrome

which occurs in 20% of patients who have experienced VTE" (Doc. 90-6, p. 4). Further, as to Dr. Disciullo, plaintiff cites to his opinion that "[p]ost-thrombotic syndrome may occur in instances of DVT" (Doc. 90-11, p. 6). Plaintiffs argue as these and similar opinions are stated within a reasonable degree of medical certainty due to the doctors' experience and training, they are admissible (Doc. 90, pp. 6-7).

ii. Future VTEs

Plaintiff next contends the statements of Drs. Botney, Disciullo, and Rinder concerning plaintiff's increased risk of a future VTE are similarly not speculative as made within a reasonable degree of medical certainty due to the experts' medical experience (Doc. 90, pp. 7-9). For example, plaintiff cites to Dr. Botney's statement that, "the risk of recurrence [of VTE] varies with time after the incident event, being highest during the first 6 to 12 months but never falling to zero" (Doc. 90-3, p. 6). Plaintiff states Dr. Disciullo similarly opines to a reasonable degree of medical certainty that, "[p]atients who develop DVT and/or [PE] are at an increased risk for clotting events in the future" (Doc. 90-10, p. 4). Lastly, as to Dr. Rinder, plaintiff states he sufficiently opined to a reasonable degree of medical certainty that "the likelihood of recurrent VTE is higher throughout their lifetime in individuals with a previous VTE" (Doc. 90-7, p. 7).

iii. High Risk Pregnancy

As to Bayer's contention that certain statements of Drs. Botney, Disciullo, and Rinder concerning plaintiff's risk of pregnancy complications require

exclusion as speculative, plaintiff argues it is undisputed that any future pregnancy of plaintiff will be "high risk." Further, plaintiff argues, even conceding it is more likely than not that plaintiff will have a "successful" pregnancy, the increased risks any pregnancy will incur entitle her to compensation. Concerning Dr. Botney's opinion, plaintiff cites to his statement that plaintiff is at an "increased risk for thrombosis during pregnancy," noting, "'official' recommendations . . . include offering anticoagulation to pregnant women with previous . . . [PE] secondary to oral contraceptives" (Doc. 90-3, pp. 9, 12). As to Dr. Disciullo, plaintiff cites his statement that the pregnancy of someone with a prior VTE will require, "additional office visits, time off from work if she is employed, the need to visit the laboratory for periodic blood draws, and further expense and pain/stress of frequent blood draws and daily injections" (Doc. 90-11, p. 10). Lastly, plaintiff cites to Dr. Rinder's statement that, "[i]f [plaintiff] becomes pregnant, she is now at further increased risk of VTE during and after pregnancy and must be prophylactically treated with anticoagulation" (Doc. 90-2, p. 3). Thus, plaintiff states these statements are admissible as made within a reasonable degree of medical certainty (Doc. 90, pp. 9-12).

iv. Future Surgery

As similarly argued previously, plaintiff contends Drs. Botney and Rinder are not required to testify it is more likely than not that plaintiff will require future surgery. Plaintiff cites to two statements of Drs. Botney and Rinder as demonstrating the reasonable degree of medical certainty with which they opine

regarding future surgery complications. As to Dr. Botney, plaintiff cites to his opinion that, "[n]ow that [plaintiff] has had a DVT/PE, she may require DVT prophylaxis where none would be required, or require higher levels of prophylaxis than would have been necessary with future surgeries" (Doc. 90-3, p. 12). Plaintiff cites to Dr. Rinder's opinion that if plaintiff, "requires any surgery, especially orthopedic surgery given her running lifestyle, she will require significant anticoagulant prophylaxis for VTE, more so than a comparable individual without VTE history, and with its attendant increased risk of bleeding complications for such prophylaxis" (Doc. 90-6, p. 4). Plaintiff states these, and similar statements, are stated with a reasonable degree of medical certainty; thus, admissible (Doc. 90, p. 12).

v. Increased Risk Associated With Flying

Plaintiff contends Dr. Disciullo states his opinion as to the increased risk associated with flying due to plaintiff's VTE with a reasonable degree of medical certainty. For example, plaintiff cites to Dr. Disciullo's statement that, "to reduce [her] elevated risk, there are some things that [she] can do, but [she] can never get rid of the elevated risk over baseline" (Doc. 90-17, p. 5: 11-23). As Dr. Disciullo opines as to the increased risk associated with flying after diagnosis of a VTE with a reasonable degree of medical certainty, plaintiff argues his opinion is not speculative and is admissible (Doc. 90, pp. 12-13).

vi. Inability to Use Hormone Replacement Therapy

Regarding her experts' opinions as to her future inability to use hormone replacement theory, plaintiff states, it is undisputed that she is not a candidate for estrogen based hormone replacement therapy (HRT) to relieve menopausal symptoms. Plaintiff argues Drs. Botney and Disciullo are not required to testify plaintiff is "more likely than not" to require HRT, only that she cannot seek future treatment for this common medical condition. Plaintiff cites to Dr. Botney's statement that HRT, "is associated with an increased risk of deep vein thrombosis or pulmonary embolism- even more so now that [plaintiff] has had a prior DVT and PE" (Doc. 90-3, p. 12). Plaintiff similarly cites to Dr. Disciullo's statement that plaintiff will experience, "foreclose[ure] from using HRT containing any form of estrogen," so that she, "will be unable to avail herself of hormonal remedies to ease her through [menopause]" (Doc. 90-10, p. 5). Plaintiff states as these opinions are grounded in a reasonable degree of medical certainty, they are admissible (Doc. 90, pp. 13-14).

vii. Psychological Damages

Lastly, pertaining to Bayer's arguments seeking exclusion of certain statements of Dr. Disciullo concerning plaintiff's possible future psychological damages as speculative, plaintiff cites to Dr. Disciullo's report. Dr. Disciullo states, "VTE is a potentially life-threatening event and brings with it fear of possible death that can extend long after the pain and fear from the acute event is over" (Doc. 90-11, p. 10). Further, plaintiff cites Dr. Disciullo's statement that,

"[i]n the event [plaintiff] decides to become pregnant, her pregnancy shall . . . be classified as a 'high risk' pregnancy, which can be frightening to such a young person, especially one who has never experienced a 'normal' pregnancy" (Doc. 90-10, p. 4). Thus, plaintiff argues, as she need only submit evidence that she is at an increased risk of future psychological harm, not that she will experience harm of a certain degree, Dr. Disciullo's opinions stated to a reasonable degree of medical certainty are admissible.

1. Opinions as to Possible Future Harm Admissible

At the outset, the Court notes Bayer's arguments concerning the admission of expert testimony opining as to plaintiff's future harm are more akin to a motion *in limine* than a motion seeking exclusion under *Daubert*. Thus, the Court must first determine whether evidence of future harm is admissible as a general matter under Illinois law.[6] Then, it will address whether the statements are admissible under Fed. R. Evid. 702 and *Daubert*.

a. Evidence of Future Harm Admissible if Stated Within a Reasonable Degree of Medical Certainty

Concerning recovery of damages for future harm, the Illinois Supreme Court has held, "simply that a plaintiff must be permitted to recover for *all* demonstrated injuries . . . A plaintiff can obtain compensation for a future injury that is not reasonably certain to occur, but the compensation would reflect the low probability of occurrence." *Dillon*, 771 N.E.2d at 504. However, speculative

[6] Plaintiff Sims is a resident of Belleville, Illinois. Thus, Illinois state law applies to the substantive issues of this diversity action. *See Thomas v. H & R Block Eastern Enters.*, 630 F.3d 659, 663 (7th Cir. 2011).

damage of future harm is inadmissible. *See Kamp v. Preis*, 774 N.E.2d 865, 871 (Ill. App. 2002). As to the level of certainty required, Illinois courts have held the argument that, "future damages must be supported by testimony that the injury is at least 51% likely to occur—is not acceptable. So long as the increased risk of future injury is proven within a reasonable degree of [medical] certainty and is proximately caused by the defendant's negligence, evidence of that possibility is not speculative." *Id.* at 871-72 (citing *Anderson v. Golden*, 664 N.E.2d 1137, 1139 (Ill. App. 1996)). Thus, as an initial matter, the experts' purported testimony is admissible, as all of the medical experts opine within a reasonable degree of medical certainty. Moreover, as to Bayer's argument seeking exclusion of evidence of future harm pursuant to Fed. R. Evid. 401, as damages for future harm are clearly recoverable under Illinois law, the evidence instantly in dispute is relevant. Finally, the probative value of these statements is not outweighed by their prejudicial effect. Therefore, provided the statements satisfy the requirements of Fed. R. Evid. 702 and *Daubert*, they are admissible.

b. Expert Opinions Concerning Future Harm Admissible Under *Daubert*

i. Qualifications

Drs. Botney, Disciullo, and Rinder are all qualified to testify as to plaintiff's future harm; specifically, her increased risk of developing post-thrombotic syndrome, future VTEs, experiencing a high risk pregnancy, requiring future surgery, experiencing risks associated with flying, and an inability to use HRT. As stated previously, all three experts are medical doctors with twenty, nineteen, and

thirty-five years of clinical experience, respectively. Thus, the Court finds they are qualified to opine, within a reasonable degree of medical certainty, concerning the future damages associated with plaintiff's PE.

ii. Reliability

As also stated previously, Drs. Botney, Disciullo, and Rinder base their opinions concerning plaintiff's future damages on relevant medical literature, plaintiff's medical records, clinical study reports, deposition testimonies, and their years of experience as clinicians. Contrary to Bayer's assertion, these opinions are not speculative as the expert physicians' base their opinions on their experiences with patients who have suffered PEs. The Court finds the experts have opined within a reasonable degree of medical certainty that plaintiff is at an increased risk of the particular injuries at issue. As such, their opinions are not speculative. Thus, as Drs. Botney, Disciullo, and Rinder base their opinions on a reliable methodology; specifically, their experience and relevant medical knowledge, the Court finds their opinions as to plaintiff's possible future harm admissible.

c. Miscellaneous Opinions of Dr. Disciullo

i. Marketing and Advertising Opinions

Bayer argues certain statements of Dr. Disciullo concerning Bayer's advertising and warnings require exclusion. Specifically, Bayer seeks exclusion of Dr. Disciullo's statements commenting on plaintiff's interest in YAZ's ability to treat acne. Dr. Disciullo opines plaintiff's request to switch her COC prescription

to YAZ resulted from Bayer's YAZ marketing campaigns. He also opines that YAZ is an unsafe method of acne treatment. Bayer states these opinions are beyond Dr. Disciullo's expertise as an OB/GYN and are inappropriate as the subject of expert testimony (Doc. 81, p. 12).

Plaintiff responds that Dr. Disciullo bases his opinion that Bayer's, "concerted efforts to expand the [acne treatment] indications through promotional materials geared towards physicians, as well as direct-to-consumer advertising aimed at young women," misled women, "into thinking that these 'low dose' pills were as safe or safer than [older pills]," on his thirty-five years of experience as an OB/GYN (Doc. 90, p. 15) (citing Doc. 90-11, pp. 5-6). Moreover, plaintiff argues, Dr. Disciullo consulted Bayer internal documents and relied on his personal experience interacting with Bayer marketing tactics and prescribing COCs. Thus, plaintiff contends, his opinions concerning Bayer's marketing and advertising are reliable and within his expertise (Doc. 90, pp. 15-16).

As to Dr. Disciullo's statements opining that YAZ is an unsafe method of acne treatment, plaintiff argues he bases his opinion on clinical data from clinical acne trials. Further, plaintiff contends this opinion is consistent with relevant medical literature. Therefore, plaintiff contends his opinion is admissible (Doc. 90, p. 16).

1. Marketing and Advertising Opinions Permissible Under *Daubert*

a. Qualifications

Dr. Disciullo's bases his opinion as to the marketing techniques of Bayer on his experience as a prescriber of COCs. Similarly, Dr. Disciullo's bases his opinion as to the merits of prescribing COCs to treat moderate acne on his years of experience as a prescriber of COCs. Although Dr. Disciullo has never personally conducted an analysis of YAZ or Yasmins' effectiveness as to acne treatment, he is qualified to opine, based on relevant experience and literature, in this manner. Dr. Disciullo cites to numerous reports, studies, internal Bayer documents, and his own preference as a prescriber of COCs, as forming the basis of these opinions. Accordingly, Dr. Disciullo is qualified to opine in this manner.

b. Reliability

Dr. Disciullo thoroughly explains the basis of his opinions in his report. Dr. Disciullo cites to the availability of other medication that also treat moderate acne. Based on this availability, Dr. Disciullo believes the risks of YAZ and Yasmin outweigh the benefits. He bases this opinion on his reading of the relevant available literature concerning the safety of YAZ and Yasmin, in addition to his own experience. Bayer is free to attack the credibility of this opinion on cross-examination. However, as Dr. Disciullo bases his opinion on his own relevant experience, in addition to medical studies and reports, it is reliable and admissible.

ii. Opinions Regarding Knowledge of Plaintiff and her Doctors

Bayer also seeks exclusion of Dr. Disciullo's opinion that, "as a result of [the] omission [of clinical study results from the YAZ label] prescribing physicians are unaware of the substantial increase in risk for clotting events for their patients, as occurred in the case of [plaintiff]" (Doc. 90-10, p. 4). Bayer argues as Dr. Disciullo has no knowledge concerning whether plaintiff's doctor informed her of YAZ-related risks, his opinion is speculative and improper (Doc. 81, pp. 12-13).

Plaintiff responds it is irrelevant whether Dr. Disciullo can comment as to the influence of Bayer's promotional materials or alleged lack of information on any specific prescribing physician. Plaintiff argues Dr. Disciullo bases his opinion as to the information relevant to a prescriber's decisions on his thirty-five years of experience as a prescriber of medication. Thus, plaintiff argues this opinion is not speculative and is properly admissible (Doc. 90, p. 17).

1. Opinions Regarding Knowledge of Plaintiff and her Doctors Permissible Under *Daubert*

a. Qualifications

Once again, Dr. Disciullo is similarly qualified to opine in this manner as he bases his opinions on his own clinical experience, in addition to his experience as an educator at Harvard Medical School. Dr. Disciullo is qualified to opine as to the information physicians deem relevant in making a risk/benefit analysis of medication. As he bases his opinions on his own experience, they are not speculative. Notably, Dr. Disciullo clarifies he will not testify as to why a

particular physician prescribed Yasmin or Yaz to a particular plaintiff (*See* MDL 2100 Doc. 2100-3, pp. 168-69: 25, 1-5). Thus, he is qualified to opine as to his own personal experience prescribing COCs.

b. Reliability

Dr. Disciullo bases his opinion on his own personal experience concerning information physicians deem important when making prescription-related decisions. Specifically, Dr. Disciullo explains the relevant criteria physicians use when evaluating prescription drugs (*See* MDL 2100 Doc. 2100-1, p. 4). Thus, Dr. Disciullo does not state "bottom line" conclusions. He explains the reasoning of his opinions based on relevant experience and documents. Thus, as Dr. Disciullo limits his testimony to own personal experience, his opinions are the product of a reliable methodology and are admissible.

The Court finds Drs. Botney, Disciullo, Rinder, and Sehizadeh are all qualified to opine as to the statements for which Bayer seeks exclusion. Further, the methods underlying their opinions are reliable. Accordingly, Bayer's motion to exclude certain statements of plaintiff's experts pursuant to Fed. R. Evid. 702 and *Daubert* is **DENIED**.

IV. BAYER'S MOTION FOR PARTIAL SUMMARY JUDGMENT ON FAILURE TO WARN CLAIM

i. Legal Standard

Summary judgment is appropriate only when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the

moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). A genuine issue of material fact exists when the evidence is such that a reasonable jury could find for the nonmovant. *Buscaglia v. United States,* 25 F.3d 530, 534 (7th Cir. 1994). The movant in a motion for summary judgment bears the burden of demonstrating the absence of a genuine issue of material fact by specific citation to the record; if the party succeeds in doing so, the burden shifts to the nonmovant to set forth specific facts showing that there is a genuine issue of fact for trial. Fed. R. Civ. P. 56(e); *Celotex Corp. v. Catrett,* 477 U.S. 317, 325 (1986). In considering motions for summary judgment, a court construes all facts and draws all inferences from the record in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 255 (1986).

ii. Arguments and Analysis

1. Failure to Warn Claim

Bayer moves for summary judgment as to plaintiff's claim that Bayer failed to adequately warn consumers after it knew or should have known of the serious health risks associated with YAZ and Yasmin (*See* Doc. 165, p. 13). Bayer argues that under Illinois law, the learned intermediary doctrine bars plaintiff's claim, as adequately warning a physician fulfills a pharmaceutical company manufacturer's duty to warn of the potential adverse effects of drugs (Doc. 81, p. 13) (citing *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 392 (Ill. 1987)). Further, Bayer argues the Illinois Supreme Court has applied the learned intermediary doctrine to oral contraceptives (Doc. 81, p. 13) (citing *Martin ex rel. Martin v.*

Ortho. Pharm. Corp., 661 N.E.2d 352, 356-57 (Ill. 1996)). Thus, Bayer argues it is entitled to summary judgment on plaintiff's claim.

Plaintiff responds that the learned intermediary doctrine only applies if the manufacturer provides adequate warnings (Doc. 88, p. 5) (citing *Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 43 (Ill. 2002)). Most pertinent to plaintiff's claims is the disputed adequacy of Bayer's consumer warnings concerning YAZ and Yasmin. Thus, plaintiff claims the learned intermediary doctrine does not apply. Moreover, as the bulk of the instant factual disputes concern the adequacy of Bayer's warnings, plaintiff argues summary judgment is improper. The Court agrees.

As Bayer states, the learned intermediary doctrine applies to pharmaceutical companies under Illinois law. *See Kirk*, 513 N.E.2d at 393 (stating, "there is no duty on the part of manufacturers of prescription drugs to directly warn patients"). However, the learned intermediary doctrine only applies where the manufacturer has adequately warned the prescribing physician. *See Hansen*, 764 N.E.2d at 43 (stating, "[d]octors who have not been *sufficiently* warned of the harmful effects of a drug cannot be considered 'learned intermediaries' and the adequacy of warnings is a question of fact, not law, for the jury to determine") (citing *Proctor v. Davis*, 682 N.E.2d 1203, 1215 (Ill. App. 1997)); *see also McNichols v. Johnson & Johnson*, 461 F. Supp. 2d. 736, 749 (S.D. Ill. 2006) (stating, "[u]nder Illinois law, the learned intermediary doctrine is a shield against liability only where the manufacturer of a prescription drug has

given adequate warning of known dangerous propensities of the drug to physicians").

Plaintiff alleges Bayer did not provide adequate warnings of YAZ and Yasmins' known dangerous propensities. Thus, construing the alleged facts in favor of plaintiff, the learned intermediary doctrine does not apply. Moreover, one need only glance at the expert opinions, depositions, and pleadings relevant to the instant dispute to determine the adequacy of Bayer's warnings is a factual dispute underlying the bulk of plaintiff's claims. Accordingly, Bayer's motion for partial summary judgment is **DENIED.**

2. Negligence *Per Se* Claim

In Bayer's reply to plaintiff's response (Doc. 171), it moves for summary judgment as to plaintiff's negligence *per se* claim, brought for the first time in her third amended complaint (Doc. 165). As Bayer's motion is untimely, plaintiff has not has a possibility to respond to Bayer's arguments. Accordingly, Bayer's motion for summary judgment as to plaintiff's negligence *per se* claim is **DENIED without prejudice**. Accordingly, Bayer is free to renew its argument at the end of plaintiff's case-in-chief.

V. CONCLUSION

The Court finds Drs. Botney, Disciullo, Rinder, and Sehizadeh are all qualified to opine as to the statements for which Bayer seeks exclusion. Moreover, the methodology on which the experts base their opinions is reliable. Further, the Court finds summary judgment on plaintiff's claim for failure to warn

is not appropriate. Accordingly, Bayer's motion to exclude certain statements of plaintiff's case-specific expert testimony and for partial summary judgment is **DENIED** (Doc. 81). Further, its untimely motion for summary judgment presented in its reply to plaintiff's response is **DENIED without prejudice** (Doc. 171).

SO ORDERED

Chief Judge
United States District Court **Date: December 16, 2011**