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

Plaintiff Kerry Sims has filed a motion in limine to exclude expert epidemiology testimony offered by alleged unqualified Bayer employees (Doc. 156). Plaintiff contends that this evidence should be excluded because the witnesses are not qualified to offer expert opinions on epidemiology. Plaintiff further argues that if the Court finds that the witnesses are qualified, their tendered opinions should be excluded because their opinions are duplicative and will not aid the jury. In the alternative, plaintiff requests the opportunity to voir dire these witnesses about their qualifications before their testimony is received by the jury and for permission to renew this application at that time. Defendants Bayer HealthCare Pharmaceuticals Inc. and Bayer Pharma AG (Bayer) respond by

contending that plaintiff misconstrues the law on expert qualification, improperly downplays the relevant qualifications and experience of Bayer's employee-experts, and mischaracterizes their deposition testimony. For the following reasons, plaintiff's motion is **DENIED** in part and **GRANTED** in part. Plaintiff's motion in limine to exclude expert epidemiology testimony offered by unqualified Bayer employees (Doc. 156) is **DENIED**, however, plaintiff's request to voir dire these witnesses about their qualifications before their testimony is received by the jury and for permission to renew this application at that time is **GRANTED.**

II. BACKGROUND

a. MDL Generally[1]

This multidistrict litigation (MDL) relates to the manufacture, marketing, and sale of the prescription pharmaceuticals known as YAZ and Yasmin.[2] 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). *Id*.[3] In contrast to estrogen,

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

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*.

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 (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 threating 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 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. This motion pertains to the epidemiological studies that were conducted regarding the risk of VTE disease among women using Yasmin and YAZ.

III. PLAINTIFF'S MOTION IN LIMINE

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).[4] First, the district court must determine whether the person whose testimony is offered is in

[4] 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.

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 Chi.,* 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 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience." (quoting *Kumho*, 526 U.S. at 156)).

Secondly, the district court must determine whether 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 of more than subjective belief or unsupported speculation. *Chapman*, 297 F.3d at 687; *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 at 904 (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. *Smith*, 215 F.3d at 719 (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." *Smith*, 215 F.3d at 719 (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." *Gayton*, 593 F.3d at 617 (citing 29 Wright & Gold, Federal Practice and Procedure, § 6265

(1997)); see also *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." *Gayton*, 593 F.3d at 617.

Moreover, "it is common in technical fields for an expert to base an opinion in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert." *Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 613 (7th Cir. 2002). In fact, "[m]edical professionals have long been expected to rely on the opinions of other medical professionals in forming their opinions." *Walker*, 208 F.3d at 588. "Indeed, courts frequently have pointed to an expert's reliance on the reports of others as an indication that their testimony is reliable." *Id.* Such testimony need only be excluded when an expert is "just parroting the opinion" of another expert. *CTS Corp.*, 285 F.3d at 613. Otherwise,

an expert may rely on information provided by non-testifying experts, so long as he does not merely serve as a spokesman for the absent expert, vouching for the truth of his statements. *In re James Wilson Assocs.*, 965 F.2d 160, 172-73 (7th Cir.1992).

Indeed, Rule 702 states that an expert's testimony must be "based on sufficient facts or data." FED. R. EVID. 702. The Advisory Notes to the 2000 Amendments to Rule 702 make clear that "[t]he term 'data' is intended to encompass the reliable opinions of other experts." FED. R. EVID. 702 advisory committee's note. Relying on the published works of other professionals is permissible in medicine, as it is in other fields. 33A FED. PROC., L.ED. § 80:251(2008). The Supreme Court has written that "a judge assessing a proffer of expert scientific testimony under Rule 702 should also be mindful of other applicable rules." *Daubert,* 509 U.S. at 595. The Court explicitly suggested that lower courts consider Federal Rule of Evidence 703, which permits experts to use facts or data "of a type reasonably relied upon by experts in the particular field." *Id.*

b. Arguments and Analysis

1. *Daubert* Analysis

Plaintiff contends that six of Bayer's employee-experts are not qualified to comment on the design, methodology, or reliability of the epidemiological studies at issue. The crux of plaintiff's argument is that these employees are not qualified to testify about these epidemiological studies because they are not

epidemiologists, do not work in Bayer's epidemiology department, and rely on other experts for their opinions. Specifically, plaintiff is seeking to exclude testimony from these Bayer employees that the independent studies finding an increased risk of VTE disease among women using Yasmin and YAZ were flawed and unreliable while the Bayer studies finding no reported increased risk of VTE disease among Yasmin and YAZ users were "well designed" and reliable.

Plaintiff does not really contest that these employees are not qualified to give relevant and reliable testimony in general, but rather are seeking merely to exclude epidemiology testimony as a whole because none of defendant's employees are epidemiologist or because they rely on other experts in epidemiology for the basis of some their opinions. Plaintiff does not contest that the methodology applied by these experts is unreliable (with the exception of one expert which will be addressed) or that this testimony will not assist the jury. Accordingly, the Court need not discuss those aspects of the *Daubert* analysis, although the Court would find both of those requirements have been met because the methodology these experts have applied is reliable and because their testimony will assist the jury. The Court begins by setting forth plaintiff's position, what defendant proffers each expert to testify about and defendants' response to plaintiff's position, followed by each employee's qualifications, and then whether the witness qualifies as an expert under a *Daubert* analysis.

a. Michael Devoy

Plaintiff contends that Dr. Devoy is not qualified to comment on the design,

methodology, or reliability of the epidemiological studies at issue because during his deposition Dr. Devoy admitted that he was not qualified in epidemiology; does not hold a degree in epidemiology or pharmacoepidemiology; does not hold a degree in public health; has not published any articles on the subject of epidemiology in a peer review journal; his knowledge of the EURAS protocol is only based on reading of the paper and some of the reports; he relied on experts to forms his opinions of the Bayer-funded studies; he sent a proposed epidemiological study to Bayer's epidemiologists and scientists for their evaluation of the study's strengths and limitations; he received input from other internal and external reports raising significant limitations with the epidemiological studies that show an increased risk of VTE; he relied on internal discussion with internal experts in epidemiology and external persons to identify the weaknesses of the Lidegaard's reanalysis; and he tries to understand the data and seeks if necessary, epidemiological expertise.

Defendants contend that Dr. Devoy's opinions concern Bayer's pharmacovigilance related to drospirenone-containing oral contraceptives, and includes the assessment of available sources of data, including adverse event report data and epidemiological studies. Plaintiff argues that Dr. Devoy is qualified by his education and work experience to render these opinions.

Micheal Devoy is a medical doctor who has been employed by pharmaetical companies since 1991. He joined Bayer in 2005, and is now the head of global medical affairs and pharmacovigilgance. As part of his work, he has overseen

many aspects of pharmacovigilance, including the identification, analysis, and assessment of potential safety signals from adverse event reports, clinical trials, published literature, and other sources. He reviews epidemiological studies in the course of his normal work.

Dr. Devoy earned his medical degree with distinction at the University College in London. After practicing internal medicine for several years, Dr. Devoy joined Glaxo Group Research ("Glaxo") in the United Kingdom as a clinical research physician in December 1991. While at Glaxo, he held several other positions including director of medical and regulatory affairs in Australia and vice president in Asia Pacific and the United Kingdom. Dr. Devoy joined Bayer as senior vice president, global medical development from March 1, 2005, to December 31, 2006, and has held the position of senior vice president, global medical affairs and pharmacovigilance since January 1, 2007.

Dr. Devoy's extensive experiences qualifies him to give expert opines about the epidemiological studies that he has reviewed in this case. First, simply because Dr. Devoy is not an epidemiologist does not mean he cannot testify to the epidemiological studies that he has reviewed. See, e.g., *Gayton*, 593 F.3d at 617; *Cutter Biological, Inc.*, 971 F.2d at 385. Dr. Devoy regularly reviews epidemiological studies in the course of his employment and this experience allows him to testify about the studies he has reviewed in this case. Second, Dr. Devoy is permitted to base his opinion in part on what other experts believe and is allowed rely on the reports and studies of other experts. See *CTS Corp.*, 285

F.3d at 613 ("[I]t is common in technical fields for an expert to base an opinion in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert."); *Walker*, 208 F.3d at 588; *Daubert*, 509 U.S. at 595. Dr. Devoy is not simply parroting or acting as a spokesperson for other experts. Rather, he is being proffered to testify as an expert regarding Bayer's pharmacovigligance, which happens to include the assessment of epidemiological studies. Based upon his experience, Dr. Devoy is certainly qualified to testify about these matters. Any concern about his testimony goes to Dr. Devoy's credibility and can be appropriately handled through cross-examination. Thus, the motion is denied as to Dr. Devoy.

b. Cristoph Hofmann

Plaintiff contends that Dr. Hofmann is not qualified to render an expert opinion on the design, methodology, or reliability of the epidemiological studies at issue because he is not an expert in biostatistics or statistics nor can he explain how to calculate a hazard ratio, is not an epidemiologist, has never participated in the design of an epidemiological study, and because he relies on epidemiological experts from within the company for everything but "medical background."

Defendants proffer that Dr. Hoffman's opinions concern pharmacovigilgance, including Bayer's pharmacovigilance related to drospirenone-containing oral contraceptives. Defendants contend that Dr. Hoffman is qualified to render these opinions based on his education and work experience.

Defendants suggests that Dr. Hoffman does not propose to testify to matters beyond his expertise, such as "statistical analyses" and writing a study protocol.

Dr. Hofmann is a medical doctor who has been a member of Bayer's global pharmacovigilgance department since May 2000, and is now head of global pharmacoviglance. As part of his practice, he regularly reviews epidemiological studies. Dr. Hofmann obtained both his medical degree in 1993 and a doctorate in medicine in 1996 from the Free University of Berlin. Since 2000, he has been board-certified in internal medicine. Prior to joining Bayer in 2000 as a drug safety scientist, Dr. Hofmann practiced in the fields of cardiology, intensive care, and gastroenterology.

The Court finds that Dr. Hofmann's experience qualifies him to testify about the epidemiological studies he has reviewed in this case. As Dr. Hofmann stated in his deposition, "[i]n his practice of pharmacovigilance, [he] regularly review[s] studies, epidemiological studies." He reviews epidemiological studies relating to COCs in the course of his employment and as the Court explained above and Dr. Hofmann explained in his deposition, one does not "need a degree in epidemiology" to interpret epidemiological studies. See, e.g., *Gayton*, 593 F.3d at 617; *Cutter Biological, Inc.*, 971 F.2d at 385. As to plaintiff's argument that Dr. Hofmann is not an expert in biostatics or statistics or that he cannot explain how calculate a hazard ratio, Dr. Hofmann does not propose to testify about these matters. Thus, this argument is moot. Moreover, as the Court mentioned above, Dr. Hofmann is allowed to rely on other epidemiological experts so long as he is

not simply parroting their opinions. See *CTS Corp.*, 285 F.3d at 613 ("[I]t is common in technical fields for an expert to base an opinion in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert."); *Walker*, 208 F.3d at 588; *Daubert*, 509 U.S. at 595. This is something that can be addressed on cross-examination, but Dr. Hofmann's experience in reviewing epidemiological studies qualify him to testify about these studies at trial. Accordingly, the motion is denied as to Dr. Hofmann.

c. Leo Plouffe, Jr.

Defendants contend that Dr. Plouffe is not qualified to testify about the scientific value and reliability of the epidemiological studies of thrombolic events in users of Yasmin and YAZ because Dr. Plouffe admits he is not a pharmacoepidemiologist, it not an expert on methodology, has no formal education in epidemiology, is not a member of any epidemiological society or professional organization, has never designed or conducted an epidemiological study, nor participated in one.

Defendants contend that Dr. Plouffe's opinions concern the testing and pre-approval clinical development of Yasmin and YAZ, and the scientific value and reliability of the available observational and epidemiological studies of thromboembolic events in users of Yasmin and YAZ, among other things. Defendants argue that Dr. Plouffe is qualified to testify as an expert to testify about the design, methodology, and reliability of epidemiological studies.

Dr. Plouffe is board-certified in obstetrics and gynecology and in reproductive endocrinology and infertility. Dr. Plouffe's education regarding contraception began during his medical training. As a practicing physician working in obstetrics and gynecology, Dr. Plouffe has treated patients desiring birth control. Dr. Plouffe has advised patients on oral contraception and other forms of contraception, and has prescribed various contraceptives, including COCs. In addition to his clinical practice, Dr. Plouffe actively engaged in both clinical and bench research during his medical training and as a faculty member at the Medical College of Georgia. He regularly reviews medical literature concerning the safety and efficacy of hormonal contraception.

Since joining Bayer in 2009, Dr. Plouffe has been involved with Yasmin and hormonal contraception (including DRSP-based contraception). As part of his experience and work as a scientist and clinician, Dr. Plouffe has participated in the monitoring and conduct of clinical studies. He has experience in designing and reviewing protocols, interim reports, final study reports, and publications of clinical and epidemiological studies, including those evaluating Yasmin. As vice president of United States medical affairs for women's healthcare, Dr. Plouffe provides medical and scientific support for products currently approved and for those under investigation; reviews and examines scientific literature regarding the safety and efficacy of hormonal contraception, including oral contraceptives; participates in planning future pharmaceutical development; and identifies areas for further research. He also participates in the evaluation of epidemiological

studies. Further, he communicates with regulatory authorities concerning the safety and efficacy of the company's oral contraceptives.

The Court finds Dr. Plouffe's extensive experience reviewing epidemiological studies qualifies him to testify about the studies he has reviewed in this case. Dr. Plouffe testified in his deposition that he has analyzed the available body of epidemiological literature in the normal course of his employment. Moreover, he has authored clinical statements for both the FDA and the Dutch Medicines Board concerning the epidemiology studies on Yasmin. This experience qualifies Dr. Plouffe to testify about the epidemiological studies he has reviewed in this case. As to plaintiff's argument that Dr. Plouffe is not an expert on methodology, this argument relies on an out-of-context quotation from Dr. Plouffe's deposition and ignores that Dr. Plouffe demonstrated his knowledge of epidemiological concepts and his ability to analyze the strengths and weaknesses of various epidemiological methodologies throughout his deposition. Plaintiff's argument that Dr. Plouffe is not an epidemiologist is rejected for the same reasons as stated above. Thus, plaintiff's motion as to Dr. Plouffe is denied.

d. Jutta Pospisil

Plaintiff argues that Dr. Pospisil is not qualified to comment on the validity or reliability of epidemiological studies since her opinions are mere restatements of the opinions of others, and are not based on her independent analysis. Defendants proffer that Dr. Prospisil's opinions concern pharmacovigilance, including Bayer's pharmacovigilance related to drospirenone-

containing oral contraceptives. Defendants aver that her education and experience render her qualified to testify about these opinions.

Dr. Pospisil obtained her medical degree from the Free University of Berlin in 1998. She obtained her doctorate in December 1999. Before her employment at Bayer in 2001, she received training and practiced obstetrics and gynecology at the Clinic of Gynecology and Obstetrics at the University Hospital Benjamin Franklin, Berlin and the Clinic of Gynecology and Obstetrics at DRK Kliniken Westend Frauenklinik-Berlin. Since 2001, Dr. Pospisil has worked extensively in areas of clinical safety and postmarketing surveillance. During that time, she performed quantitative and qualitative pharmacovigilance, including the review of single case reports, aggregate reports, preparation of periodic reports, including PSURs and annual reports, in connection with DRSP products. In the course of her employment, she reviewed and reached opinions based on epidemiological literature.

The Court finds that Dr. Pospisil's experience qualifies her to testify about the epidemiological studies she has reviewed in this case. Dr. Pospisil regularly reviews these studies in the course of her employment and despite plaintiff's argument that her opinions are mere restatements of the opinions of others, the Court disagrees. As the Court mentioned above, Dr. Pospisil is allowed to rely on other epidemiological experts so long as Dr. Pospisil is not simply parroting their opinions. See *CTS Corp.*, 285 F.3d at 613 ("[I]t is common in technical fields for an expert to base an opinion in part on what a different expert believes on the

basis of expert knowledge not possessed by the first expert."); *Walker*, 208 F.3d at 588; *Daubert*, 509 U.S. at 595. This is something that can be addressed on cross-examination, but Dr. Pospisil's experience in reviewing epidemiological studies qualify Dr. Pospisil to testify about these studies at trial. Accordingly, the motion is denied as to Dr. Pospisil.

e. Iike Schellschmidt

Plaintiff contends that Dr. Schellschmidt's testimony should also be excluded because Dr. Schellschmidt admitted during her deposition to her lack of education and training in epidemiology.

Defendants contend that Dr. Schellschmidt's opinions concern the safety of Yasmin and YAZ, as demonstrated by clinical trials, adverse event reports, and epidemiological studies. Defendants contend that Dr. Schellschmidt is qualified by her education, training, and experience to render these opinions.

Dr. Schellschmidt is a medical doctor with training in obstetrics and gynecology. She is also a board-certified clinical pharmacologist. Dr. Schellschmidt's education regarding contraception began during her medical training. As a practicing physician working in obstetrics and gynecology, Dr. Schellschmidt treated patients with a variety of obstetric and gynecological issues, including the desire for birth control. Dr. Schellschmidt counseled patients on contraceptive options, including oral contraceptives, and prescribed hormonal contraceptives, including COCs, to her patients. Dr. Schellschmidt also reviewed

and analyzed medical literature regarding the safety and efficacy of hormonal contraception, including oral contraceptives, in order to reach an opinion regarding the clinical import of the data and the results. Since joining Bayer in 1997, Dr. Schellschmidt has worked extensively on Yasmin and hormonal contraception (including DRSP-based contraception) and was involved in studies supporting the FDA approval of Yasmin and YAZ. As part of her work as a scientist and core clinician, Dr. Schellschmidt participated in the monitoring and conduct of clinical studies, many times as the medical officer. She reviewed protocols, interim reports, final study reports, and publications of clinical and epidemiological studies evaluating Yasmin. Dr. Schellschmidt also attended several Ingenix, EURAS, and INAS advisory board meetings as a guest. In addition, Dr. Schellschmidt participated in the analysis of epidemiological studies and the presentation of data, including epidemiological and spontaneous reports, to regulatory bodies, including the FDA. An example of this is the "white paper" entitled "Yasmin® and Serious Thromboembolic Events," which she coauthored and which was provided to FDA on August 17, 2004, prior to an October 2004 meeting with FDA that was attended by Dr. Schellschmidt and others.

In her current role as vice president, global medical affairs women's healthcare, among many other responsibilities, Dr. Schellschmidt reviews and examines scientific literature regarding the safety and efficacy of hormonal contraception, including oral contraceptives. She also participates in the company's evaluation of epidemiological studies, such as those published

by Jick and Lidegaard. Her work includes communicating with regulatory authorities about the safety and efficacy of the company's women's healthcare products, including oral contraceptives.

Dr. Schellschmidt extensive experience reviewing epidemiological studies qualify her to testify about the studies she has reviewed in this case. As part of her work as a scientist and core clinician, Dr. Schellschmidt reviewed epidemiological studies evaluating Yasmin. In addition, Dr. Schellschmidt participated in the analysis of epidemiological studies and the presentation of data, including epidemiological and spontaneous reports, to regulatory bodies, including the FDA. For example, she coauthored a "white paper" entitled "Yasmin® and Serious Thromboembolic Events," that was provided to the FDA on August 17, 2004, prior to an October 2004 meeting with FDA. Moreover, in current role as vice president of global medical affairs women's healthcare, Dr. Schellschmidt participates in the company's evaluation of epidemiological studies, such as those published by Jick and Lidegaard. This extensive experiences qualifies Dr. Schellschmidt to testify about the studies she has reviewed. If plaintiff wishes to addresses Dr. Schellschmidt's education and training in epidemiology that is something that can be addressed on cross-examination. The motion as it relates to Dr. Schellschmidt is denied.

f. John Talian

Defendants further aver that Dr. Talian's testimony regarding the design,

methodology, or reliability of the epidemiological studies at issue should also be excluded because Dr. Talian also admitted that he is too limited in his epidemiological education, training, and experience. Defendants contend that Dr. Talian is not being offered to provide expert opinions on the methodology or reliability of the epidemiological studies at issue. Rather, defendants posit that Dr. Talian's opinions concern the regulatory aspects of these studies. Accordingly, plaintiff's motion as to Dr. Talian is moot because he is not being proffered to testify about the design, methodology, or reliability of the epidemiological studies.

2. Rule 403 – Cumulative Expert Testimony

Plaintiff also asserts that these six employees should not be permitted to become the mouthpiece for Bayer's actual epidemiologists by simply repeating the same testimony as defendants' four retained expert witnesses prepared to assess the reliability of the epidemiological studies, or the nearly identical opinions from six employees on the same issue. Defendants counter that this argument is without merit and premature. More specifically, defendants contend that although each of Bayer's employee-experts share similar broad conclusions about the epidemiology studies, they approach this literature from different perspectives within their particular area of expertise and each has different firsthand knowledge concerning these studies. Thus, defendants argue that the testimony will not be cumulative, and if it becomes duplicative or cumulative at trial, plaintiff can make that objection at trial. The Court agrees with defendants.

Pursuant to the Federal Rules of Evidence, particularly Rule 403, "[t]he court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." FED. R. EVID. 403. "It is within a district court's sound discretion to admit or to refuse evidence challenged as cumulative." *United States v. Kizeart*, 102 F.3d 320, 325 (7th Cir. 1996). "'Evidence is "cumulative" when it adds very little to the probative force of the other evidence in the case, so that if it were admitted its contribution to the determination of truth would be outweighed by its contribution to the length of trial, with all the potential for confusion, as well as prejudice to other litigants, who must wait longer for their trial, that a long trial creates.'" *Id.* (quoting *United States v. Williams*, 81 F.3d 1434, 1443 (7th Cir. 1996).

Here, the Court agrees with defendants that this evidence is not cumulative because each of these employee-experts has expertise in different areas and their testimony will be based upon their respective areas of expertise. If, however, the evidence becomes cumulative at trial, plaintiff can certainly object to it at trial. Thus, plaintiff's motion in this regard is denied.

IV. CONCLUSION

The Court finds Drs. Devoy, Hoffman, Plouffe, Pospisil, and Schellschmidt are all qualified to opine about the epidemiological studies within their specific areas of expertise. The argument as to Dr. Talian is moot. Accordingly, plaintiff's

motion in limine to exclude expert epidemiology testimony offered by unqualified Bayer employees is **DENIED** (Doc. 156). Plaintiff can, however, voir dire these witnesses about their qualifications before their testimony is received by the jury and may renew this application at that time**.**

IT IS SO ORDERED.

Signed this 22nd day of December, 2011.

Chief Judge
United States District Court