

**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:

ALL CASES

CASE MANAGEMENT ORDER NUMBER 50

**Regarding Motions to Exclude Testimony of Plaintiffs'
Expert Witnesses
(MDL 2100 Docs. 2018, 2019, 2021, and 2024)**

I. INTRODUCTION and BACKGROUND

Defendants Bayer HealthCare Pharmaceuticals Inc. and Bayer Pharma AG (“Bayer”) move pursuant to Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993) (“*Daubert*”) to exclude the expert testimony of Curt. D. Furburg, B. Burt Gertsman, Stephen B. Hulley, and David Madigan. Plaintiffs obviously opposes these motions. Familiarity with the underlying proceedings is presumed. Based on the pleadings, the applicable law and the following, the Court denies these motions.

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.*

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.*

¹This 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.

²YAZ 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.

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 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).

Bayer contends that the putative experts' opinions fail to meet the requirements for admissible expert testimony under Federal Rule of Evidence 702 and *Daubert*. Specifically, Bayer seeks to preclude testimony by these individuals contending that the proffered opinions are beyond the scope of these witnesses' expertise, unreliable, irrelevant, prejudicial, and/or exceed the scope of permissible expert testimony.

II. LEGAL STANDARD

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).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.”)).

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

³The Court notes that 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 substantially change the Court’s analysis.

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).

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.”

III. ANALYSIS

A. Motion to Exclude Certain Testimony of Curt D. Furberg (Doc. 2018)

As to Dr. Curt D. Furberg, defendants move to preclude him from testifying about the following: (1) the risks and benefits of DRSP-containing COCs; (2) Bayer's marketing and promotion; (3) foreign regulatory actions and (4) Bayer's state of mind. The Court notes that in their response, plaintiffs withdrew Section VII of Furberg's report dealing with Off-Label and Over Promotion of Additional Indications, as well as footnotes 4 and 5 of his report. Thus, the Court need not address these arguments and denies as moot Bayer's motion to exclude Furberg's testimony as it relates to marketing and state of mind. The Court turns to address the remaining portions of the motion.

Currently, Dr. Curt D. Furberg is a Professor of Public Health Sciences at Wake Forest University School of Medicine.⁴ He has a broad range of experience in the field of public health. He has served as an investigator on over 50 clinical trials. He is also the Chair of the Steering Committee of the Cardiovascular Health Study sponsored by the National Heart, Lung, and Blood Institute, a large epidemiological study initiated over twenty years ago. He also chairs an institutional Data Safety Monitoring Committee. These independent committees monitor the efficacy and safety of treatment and prevention trials in progress and are charged with

⁴He is a medical doctor admitted to practice medicine in Sweden. He received his medical training and PHD-equivalent at the University of Umea, Umea, Sweden.

recommending early trial termination, if efficacy is clearly documented or if harmful effects outweigh the benefits. He is also the past Steering Committee Chair of the Gingko Evaluation of Memory Study sponsored by the National Center for Complementary and Alternative Medicine of the National Institutes of Health.

He has more than thirty years of expertise and experience in the areas of clinical trial design, conduct, monitoring, interpretation and epidemiology and is considered by his peers to be a national leader in this field. Dr. Furberg has authored numerous publications on clinical trials. He co-authored a textbook entitled *Fundamentals of Clinical Trials*, 4th Edition, Springer 2010, which is considered a leading text and is used widely for teaching. He also is the author of a text entitled *Data Monitoring in Clinical Trials - A Case Studies Approach*, Springer 2006; all 29 cases reviewed in this text address issues of benefit, harm and benefit-to-harm balance. He has also written or co-authored more than 400 peer-reviewed articles and 60 book chapters on various topics, including epidemiology, clinical trials, non-steroidal anti-inflammatory drugs (“NSAIDs”), hormone replacement therapy; lipid disorders, and hypertension and has served on 16 editorial boards.

Further, he is a past charter member of the FDA Drug Safety and Risk Management (“DRSM”) Advisory Committee.⁵ He has served as an expert on FDA hearings in 2008, 2009, and 2010. He was the Principal Investigator of a grant from

⁵This committee was formed by the FDA to provide expert advice on drug safety issues.

the Attorney General Consumers and Prescriber Program to develop educational modules for healthcare professionals.

Plaintiffs asked him to provide his opinions relative to the following:

“a. The clinical studies conducted by Bayer in support of its application to obtain approval from Food and Drug Administration (FDA) of the additional indication for treatment of *acne vulgaris* as well as the degree of efficacy, if any, demonstrated by the clinical studies conducted by Bayer/Schering in support of said application.

b. The clinical studies conducted by Bayer in support of its application to obtain approval from FDA of the additional indication for treatment of Pre-menstrual Dysphoric Disorder (PMDD), as well as the degree of efficacy, if any, demonstrated by the clinical studies conducted by Bayer/Schering in support of said application.

c. The off-label promotion and over promotion engaged by Bayer with respect to the additional indications above.”

In his report, Dr. Furberg rendered the following opinions:

“46. It is my opinion that there is no evidence that documents efficacy for the treatment of PMS. A number of investigators have reported an increased risk of VTE in users of DRSP-containing oral contraceptives compared to other oral contraceptives. Therefore, if there is an

increased risk of VTE in users of DRSP-containing oral contraceptives compared to other oral contraceptives, the lack of documented benefit for patients seeking treatment of PMS, and who are also in need of birth control is clearly outweighed by the increased risk of VTE found in DRSP-containing oral contraceptives.

47. It is my opinion that the clinical studies conducted by Bayer demonstrated weak efficacy for PMDD. A number of investigators have reported an increased risk of VTE in users of DRSP-containing oral contraceptives compared to other oral contraceptives. Therefore, if there is an increased risk of VTE in users of DRSP-containing oral contraceptives compared to other oral contraceptives, any benefits for patients seeking treatment for PMDD, and who are also in need of birth control, would be outweighed by the increased risk of VTE.

48. It is my opinion that the clinical studies conducted by Bayer demonstrated weak efficacy for acne. A number of investigators have reported an increased risk of VTE in users of DRSP-containing oral contraceptives compare to other oral contraceptives. Therefore, if there is an increased risk of VTE in users of DRSP-containing oral contraceptives compared to other oral contraceptives, the benefits for seeking treatment of acne, and who are also in need of birth control, would be outweighed by the increased risk of VTE.

49. To the extent that Berlex/Bayer communicated or otherwise marketed their DRSP-containing oral contraceptives as efficacious for the restricted indications (acne and PMDD) or an unapproved indication (PMS), it is my opinion that such communications and marketing activities constitute a violation of federal regulations and established marketing standards.”

First, defendants argue that Furberg’s risk-benefit testimony must be excluded because he neither is an epidemiologist nor does he deal with epidemiological data in making risk/benefit decisions on patient care. Specifically, defendants maintain that Furberg is not qualified to testify that YAZ’s allegedly greater VTE risks outweigh the medicine’s benefits for treatment of patients taking the drug for dual indications of birth control-acne or birth control- PMMD. Defendants further maintain that any opinion on this subject must be made by an epidemiologist. Defendants also assert Furberg’s methodology is unreliable because he acknowledges that he has not assessed the risks of any COC and that his opinions are premised on the claim that “[a] number of investigators have reported an increased risk of VTE in users of DRSP-containing oral contraceptives compared to other contraceptives.” Plaintiffs counter that they do not offer Dr. Furberg to opine about the risks of YAZ/Yasmin. Plaintiffs contend that they engaged Furberg to review the clinical studies evaluating the efficacy with respect to PMS, PMDD and acne. Plaintiff contends that he is qualified to offer these core opinions: (1) that there is no evidence that documents

efficacy for the treatment of PMS; (2) that the clinical studies conducted by Bayer demonstrated a weak efficacy for PMDD and (3) that the clinical studies conducted by Bayer demonstrated a weak efficacy for acne.

Obviously, the breadth of knowledge, experience and expertise Furberg has is considerable. He has vast training and practice in both clinical and research settings. His opinions in this case are based upon the clinical trials that Bayer submitted to the FDA in support of its application for added indications for acne and PMDD – the individual study data available to and used by Bayer. Further, his methodology is reliable. To arrive at his opinions, he employed the methods and analysis he has applied in his lengthy and distinguished career as an expert in the fields of drug safety and clinical trial design. Furberg’s background in epidemiology, drug safety and clinical trials suits him to assist the jury in its determination. In addition, his review of the published data from the clinical trials and his experience in the field qualify him to interpret the data as it relates to the efficacy for acne, PMS and PMDD.

Specifically, in the acne trials, he noted, *inter alia*, a primary outcome with questionable clinical significance was the problem with accuracy of the data as well as large amounts of missing data because of a large drop-out rate; possible problems of “unblinding;” use of multiple outcomes without appropriate statistical adjustments; and problems in the non-inferiority comparisons. In the PMDD trials, he found insufficient clarity in the definition of the primary outcome; a large number of statistical adjustments; failure to make appropriate adjustments for multiple

comparisons; a discontinuation rate of 85% raising a serious question about who the trial results applied to; as well as shortcomings in the design because PMDD can last for years, but the trial period was too short to determine whether there was any long-term benefit.

Moreover, a reading of the report indicates that Dr. Furberg does not seek to offer an opinion about the risk/benefit decisions that prescribers make. Rather, the report reveals that Furberg intends to offer an opinion about the evidence supporting (or not) supporting the information prescribers were given about the benefit side. He opines that the benefit information was not supported by the evidence and that if the risk/benefit calculation was based on a representation about efficacy, it was based on faulty information. Further, the Court rejects Bayers' argument that Furberg may not ground any of his opinions on the opinions of others. Rule 702 states that an expert's testimony must be "based on sufficient facts or data." Dr. Furberg based his testimony on information he obtained from other experts on the issue of increased risk of VTEs posed by YAZ and Yasmin. That is permissible. 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." 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.” Further, Furberg’s opinions are more than just his subjective belief or unsupported speculation. While the methodology and principles he examined are certainly subject to scrutiny, the record does not indicate that the methodology and principles Furberg relies upon are unreliable. To the extent that defendants disagree with Furberg’s conclusions or that certain portions of his testimony may be less credible, the appropriate method of challenging such testimony is through cross-examination rather than exclusion. Thus, the Court finds that this testimony is admissible and that it will assist the jury.

Defendants also move to exclude Furberg from testifying about how drug risks and benefits could be assessed under a non-existent, hypothetical regulatory regime. In particular, defendants seek to preclude his deposition testimony in which he stated that he “wishes the regulatory system was different [a]nd better.” and including testimony regarding YAZ’s allegedly small benefits and weak efficacy would mean under that system. Defendants maintain that Furberg is not qualified to offer such testimony and that this testimony would not be helpful to the jury. Plaintiffs maintain that Furberg has never sought to offer such an opinion about “how drug risks and benefits could be assessed under a non-existent, hypothetical regulatory regime” and nothing in Furberg’s report refers to any regulatory regime, whether actual or hypothetical. Plaintiffs further maintain that defendants are seeking to

exclude Furberg's personal opinions about what would make a better regulatory system as irrelevant after defendants elicited that testimony from him during the deposition and that this portion of the motion should be denied as moot. The record indicates that plaintiffs are correct. Thus, the Court denies as moot this portion of the motion.

As to Furberg's opinions on foreign regulatory actions, defendants argue that these opinions should be excluded as Furberg admits he is not an expert in this field; that the opinions are just another spin on historical facts and that he previously has been excluded from testifying about foreign regulatory actions. Bayer also moves to exclude these opinions under Rule 403. Specifically, defendants move to exclude Furberg's testimony that "indications for Yasmin were clearly rejected by the European authorities and the Australian regulatory" and "West European countries did not approve the PMDD indication for Yaz." Plaintiffs counter Furberg properly considered the views of scientists working for foreign regulatory agencies. Specifically, plaintiffs maintain that Furberg is considering facts - what other scientists said on the topic - relevant to his opinions and that he may consider what other scientists in the field considered in rendering his opinions. The Court agrees with plaintiffs.

The Court finds that Furberg can give opinions within his area of expertise about what he has reviewed in this case, including facts -what other scientists have said on the topic - that are relevant to his opinions. First, Furberg determined that

the efficacy of acne and PMDD was weak after reviewing the Bayer studies; then he considered the views of other scientists in the community on this subject to see whether his conclusions were similar to their conclusions. His opinions are not based on the regulatory outcome of the other countries, but based rather on the scientific opinions expressed by experts in the foreign regulatory agencies. See *Daubert*, 509 U.S. at 592 (“[A]n expert is permitted wide latitude to offer opinions, including those that are not based on first hand knowledge or observation.”). Further, these are appropriate summaries of the underlying documents that he reviewed. See Fed. R. Evid. 1006 (permitting summary evidence); *United States v. Pree*, 408 F.3d 855, 869-70 (7th Cir. 2005)(approving use of an “expert summary witness” who is permitted both to summarize evidence for the jury and to offer an expert analysis of the facts). Furberg may testify about these matters. “[A]ny questions or problems concerning the expert’s testimony may be thoroughly explored during cross-examination of the witness.” *United States v Gonzalez*, 933 F.2d 417, 429 (7th Cir. 1991). Further, the Court finds that these opinions will not confuse the jury as the testimony at issue is more probative of the issues at bar and helpful, than it is prejudicial.

B. Motion to Preclude B. Burt “Bud” Gerstman from Testifying as to Certain Opinions (Doc. 2019)

Bayer also moves to exclude plaintiffs’ generic expert B. Burt Gertsman from rendering the following opinions: (1) that physicians should not prescribe DRSP -

containing COCs for their patients because other COCs are a safer choice; (2) the FDA's regulation of DRSP-containing COCs, including Bayer's submissions to the FDA; and (3) that studies refuting his epidemiology opinions are biased simply because of their industry funding source.⁶ Defendants maintain that Dr. Gertsman lacks qualifications that permit him to render these opinions and that his methods are uniformly unreliable. Plaintiffs argue that these challenges demonstrate Bayer's mis-characterization and misunderstanding of Dr. Gertsman's reports and testimony in that Gertsman is not making suggestions about individual prescriber's decisions; that his testimony does not involve a narrative of regulatory history and that he does not dismiss or disregard epidemiological studies solely on the basis of their funding source. Plaintiffs further argue that each of these points lie squarely within the field of epidemiology and Gertsman's field of expertise.

Gertsman's report addressed the following:

"[T]he potential of Yasmin and Yaz to cause adverse thromboembolic events, especially relative to low-dose levonorgestrel (LNG-) containing COC formulations."

Gertsman opined the following:

"Thus, it is my opinion, to a reasonable degree of scientific certainty, based on the available evidence discussed in this Report, that the risk

⁶In this motion, Bayer does not seek to exclude Gertsman's opinion about epidemiology studies of various COCs, including those containing DRSP in advance of trial.

of VTE associated with DRSP-containing COCs, such as Yasmin and Yaz, is higher than the risk associated with low-dose LNG-containing formulations. In practical terms, low dose LNG-containing formulations offer a safer choice with regard to VTE than preparations containing DRSP, while providing the same contraceptive benefit.

Based on the current studies, it is my conclusion that women using DRSP-containing COCs are at about twice the risk of VTE compared to women using LNG-containing formulations. The risk of VTE associated with DRSP can also be expressed on an absolute scale, in terms of the number of women potentially affected. Baseline rates of VTE in populations will vary depending on the age distribution of the population, the prevalence of other risk factors in the population, and the pattern and duration of COC use. As an example, the average rate of the VTE in healthy young women with no known risk factors taking low-dose LNG-containing COCs has been reported as 2.5 per 10,000 WYs. Had this same population of women used DRSP-containing COCs, this rate would increase approximately to 5 per 10,000 WYs, resulting in an additional 2.5 cases per 10,000 WYs.” (Footnotes omitted.).

Dr. Gertsman earned a PhD in Epidemiology and Comparative Pathology from the University of California, Davis, in 1989. Prior to that, he earned his Masters in Public Health in Epidemiology from the University of California, Berkeley in 1984.

He graduated from Harpur College with a bachelor's degree in Biology in 1976 and obtained his Doctorate of Veterinary Medicine in 1980. He has published articles in the field of hormonal contraception, including articles establishing that the reduction in dose of estrogen below 50mcgs. reduced the risk of VTE. He developed a method of validating the diagnosis of VTE by requiring proof of anticoagulation therapy after the diagnosis.

He also has served as an epidemiologist for the FDA and instructed epidemiology fellows at the National Institutes of Health and Centers for Disease Control. At the FDA, Gertsman specialized in post-marketing research and drug safety. He helped develop the database currently in use at the FDA for post-marketing surveillance of drugs. He has taught undergraduate, graduate and post-graduate courses in epidemiology and biostatistics for about 30 years. Currently, Gertsman serves as a Professor of Epidemiology and Biostatistics at San Jose State University.

First, defendants argue that Gertsman is unqualified to offer any opinion about what COC, if any, prescribers should choose for their patients because he is a veterinarian and has never treated patients seeking birth control and has never prescribed a COC, much less any other drug, to humans. Defendants also assert that his opinion lacks foundation because it does not address individual patients; that this opinion will not assist the trier of fact because there is no requirement that a later drug be more safe than an earlier approved drug for the same indication and

that it lacks foundation and is unreliable because pregnancy carries health risks, including risk of VTE, yet Gertsman simply assumes that YAZ and Yasmin provide the same contraceptive benefits as other COCs. Plaintiffs respond that Gertsman is not offering an opinion “about what COC if any, prescribers should choose for their patients.” Further, plaintiffs assert that the language Bayer seeks to exclude nowhere contains the word prescribe and does not purport to speak to what prescribing physicians do or ought to do in a particular case. Plaintiffs argue that Gertsman’s opinion, based upon his review of the epidemiologic literature and the other data described in his report, speaks to the overall safety of LNG-containing formulations for the population at large. Plaintiffs maintain that this opinion is within his expertise as an epidemiologist.

Gertsman’s extensive career and credentials in epidemiology and biostatistics make him qualified to provide the opinion that as a general matter, LNG-containing formulations are safer than COCs that contain DRSP. He bases his opinions on his years of experience in these fields. Further, he cites to numerous reports, studies and data in his report, in addition to his own publications, as forming the basis for these opinions. Although Gertsman has never prescribed medicine to humans and has not personally conducted an analysis of YAZ or Yasmin’s effectiveness as birth control, he is qualified to opine in this manner on these opinions. His deposition further supports his opinion on this topic, “As an epidemiologist, a patient is not the individual person, it is an aggregate of people. So my interventions are on an

aggregate scale, not on an individual scale.” This approach is consistent in the study of epidemiology and supports the general causation question grounded in epidemiology. Further, the Court finds that this will assist the jury to know that from an epidemiological standpoint LNG-COCs are a safer choice. To the extent that defendants disagree with Gertsman’s conclusions or that certain portions of his testimony may be less credible, the appropriate method of challenging such testimony is through cross-examination rather than exclusion. Thus, the Court finds that this testimony is admissible and that it will assist the jury.

Next, Bayer moves to exclude Gertsman’s narrative re-telling of the regulatory history of YAZ and Yasmin and his subjective inexperienced take on how the drugs’ labels should read. Defendants posit that Gertsman has no personal knowledge of the FDA reviewer’s inquiry and admittedly speculates about what prompted the FDA to issue the labeling that it did. Further, Gertsman is not qualified to issue such opinions as he lacks experience in drug labeling that permits him to pass on the agency’s warnings as he attempts to do here. Further, Bayer asserts that Gertsman’s response that Bayer possessed data constituting a legitimate warning sign regarding VTE risk in 2001 or 2004 and latter presented FDA with an “unbalanced presentation of data” are inadmissible because he imputes bad intent to Bayer. Plaintiffs respond that Bayer has misrepresented Gertsman’s opinion and that there is no impermissible narrative in his testimony. Plaintiffs argue that Gertsman may tell the jury the facts concerning FDA’s conclusion about VTE rates in clinical trials,

in order to explain how these facts confirmed and supported his opinion on the rate of VTE observed with Yasmin was a cause for concern. The Court agrees with plaintiffs.

The Court does not find that plaintiffs are offering Gertsman for the purpose that Bayer suggests. The Court finds that Gertsman is qualified to opine on the medical facts and science regarding YAZ/Yasmin and to compare that knowledge with what was provided in the text and labeling and warnings on YAZ/Yasmin. In his report, Gertsman noted, based on his research, analysis and experience, that Bayer praised the negative studies and condemned the positive studies associating YAZ and Yasmin with VTEs and that Bayer failed to acknowledge the limitations in the negative studies or the strengths of the positive studies. Gertsman has the education, training and experience to opine that the summary of the epidemiology studies approved by the FDA for inclusion in the April 2010 label was inappropriate.

Lastly, defendants assert that the Court should exclude Gertsman's opinion and that certain epidemiology evidence should be ignored because the industry funded the studies in question. Specifically, Bayer contends that these "funding bias" opinions are not based on a reliable methodology and this would unfairly prejudice Bayer if admitted. Bayer also argues that Gertsman's deposition testimony makes it clear that he applies a subjective double-standard, finding work that undermines his opinions "biased," while asserting that which facially supports his conclusions is unaffected. Plaintiffs counter that Bayer completely misrepresents

Gertsman's opinion about funding source. Plaintiffs state that Gertsman never dismissed or disregarded a study solely because of its funding source, instead Gerstman considers the funding source among a number of factors in assessing epidemiological studies. The Court agrees with plaintiffs.

As Gertsman explained in his report:

“The mere fact that a researcher or study was funded by a particular source does not make that study or researcher ‘right’ or ‘wrong.’ However, the observation of systematic differences in study results and in published opinion pieces based on sponsorship is worrying.”
(Endnotes omitted).

Further, as to analyzing the results Gertsman stated:

“Many factors must be taken into account when addressing results from individual epidemiologic studies. Observed associations must be weighed in terms of their precision (lack of random error) and validity (lack of systematic error). Standard statistical techniques, such as confidence intervals, play a role in quantifying the precision of estimates. However, even these quantifications require that we must assume certain conditions have been met. Even though these numbers may seem “black-and-white,” their proper interpretation requires a certain amount of “gray.”

Gertsman examined the design of each DRSP study and explained in detail the strengths and weaknesses of each study design. In examining the study design, Gertsman discussed issues concerning: selection of an appropriate source population; the potential effect due to “nonconstant hazzard”; confounding; misclassification of exposure and disease; selection bias; precision and power; and funding source. As to the funding source issue, Gertsman relied and referred to two publications: (1) Stelfox HT, Chau G, O’Rourke K, Detsky AS. Conflict of Interest in the debate over calcium-channel antagonists. *The New England journal of medicine*. Jan 8 1998;338(2):101-106 and (2) Rochon PA, Gurwitz JH, Simm RW, et al. A study of manufacturer-supported trials of nonsteriodal anti-inflammatory drugs in the treatment of arthritis. *Archives of internal medicine*. Jan 24 1994;154(2):157-163. The funding source provides the whole picture of the analysis that Gertsman performed. The Court finds that this information will aid the jury on this issue. Further, Gertman’s experience supports his qualifications to critique flaws in the studies. The Court notes that it must keep in mind that the question of whether the expert is credible or whether the theories being applied by the expert are correct, is a “factual one that is left for the jury to determine after opposing counsel has been provided the opportunity to cross-examine the expert regarding his conclusions and the facts on which they are based.” *Smith*, 215 F.3d at 719, Furthermore, “[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.* While the methodology and principles are certainly subject to scrutiny, it has been subjected to peer review and publication. Gertsman’s opinions about the funding source are admissible. At trial, defendants will be able to cross examine Gertsman on the funding source regarding its validity, how he applied it to the studies and how it influenced his ultimate opinion in this case. Further, the Court finds that the probative value of this evidence outweighs its prejudice to Bayer and that it will assist the jury evaluating the evidence.

C. Motion to Exclude the Testimony of Dr. Stephen B. Hulley (Doc. 2021)

As to plaintiffs’ expert Stephen B. Hulley, defendants move to exclude (1) his methodology for evaluating quality of studies; (2) his opinions regarding biological plausibility of the association between DRSP-containing COCs and VTEs; and (3) his opinions as to regulatory actions.⁷ In particular as to quality of studies, defendants argue that Hulley’s opinions that the quality of studies can be evaluated on the “impact factor” of their publication sources should be excluded because these opinions are not based on a reliable foundation, are unduly prejudicial and are outside the scope of his expertise. Likewise, defendants maintain that his opinion regarding biologic plausibility is untested, speculative and he is not qualified to offer it. Lastly, his opinions as to regulatory agency and labeling are outside his expertise. Plaintiffs respond that Hulley offers the “impact factor” as additional corroborative

⁷Bayer’s motion states that it intends to leave for trial most of its challenges to Hulley’s epidemiology opinions.

evidence that supplements his own extensive analysis of the differences among the various studies that he has reviewed; that the biologic plausibility is a standard criterion that epidemiologist consider in their work and that Hulley has expertise on this subject; and that Hulley does not plan to offer any regulatory opinions concerning European and FDA regulatory matters.

Plaintiffs retained Hulley to provide opinions on the the following;

“Do oral contraceptives that contain drospirenone (DRSP-OCs) increase the risk of venous thrombo-embolic events (VTE) when compare with oral contraceptives that contain levonorgestrel (LNG-OCs)?”

As to this question, Hulley concluded the following:

“Taking all of the above into account, it is my opinion that the available evidence strongly supports the conclusion that DRSP-containing oral contraceptives more than double the risk of VTE when compare to the risk observed with oral contraceptives that contain LNG.”

Dr. Stephen Hulley is a physician and an epidemiologist. He received his M.D. from Harvard Medical School and a Masters in Public Health from the School of Public Health at UC Berkeley. He has held faculty positions at Stanford University and the University of California, San Francisco, (“UCSF”). From 1994-2006, Hulley chaired the Department of Epidemiology and Biostatistics at UCSF, where he lead the Training In Clinical Research (“TICR”) program. He designed, created and led

numerous large studies of cardiovascular health, including the \$50 million 20-Center Heart and Estrogen-progestin Replacement Study (“HERS”). He is the lead author of a 1998 report from the HERS study published by the Journal of the American Medical Association (“JAMA”) that showed an increase in myocardial infarction and coronary heart disease (“CHD”) death.⁸

Hulley began teaching the “Designing Clinical Research” course at UCSF 25 years ago, and he is the lead author of the textbook of the same name. For 23 years, Hulley chaired the Steering Committee for the NIH-Funded \$100 million multicenter Coronary Artery Risk Development In young Adults (“CARDIA”) cohort study. He has published at least 200 articles in the peer-reviewed medical literature, including two dozen concerning the effects of hormone therapy. He led the Epidemiology Subcommittee of the National Cholesterol Education Panels I and II (the US Cholesterol Policy). Also, he was selected by the American Heart Association to present at two pre-eminent lectureships in cardiovascular epidemiology in 2002 and 2003.

Obviously, Hulley possesses the necessary credentials to issue his opinion in this case. In rendering his opinion, Hulley examined seven epidemiological studies that sought to compare the thromboembolic risks of DRSP-COCS with those of LNG-COCs. In examining these studies to formulate his opinion, Hulley summarized and

⁸This study was the first to demonstrate that treating postmenopausal women with estrogen and progestin leads to a significant increase in VTE.

individually critiqued the studies, combined the evidence in a meta-analysis; commented on the value of studying idiopathic VTE; and addressed publication and sponsorship issues. Further, he cited to published works in rendering his opinion.

Defendants contend that Hulley's methodology using the impact factor regarding the quality of the journals is unsound and should be disregarded. Plaintiffs maintain that Hulley evaluated each study on its merits and the reference to the quality of the journal was a factor but not the sole factor in reaching his opinions as to the studies. Further, plaintiffs maintain that the impact factor is a generally accepted measure of the quality of the journal and its regard in the scientific community. The Court agrees with plaintiffs.

A review of Hulley's report indicates that the quality of the journals was one out of many factors that he considered when examining the studies. The reference to the quality of the journals and to the other factors demonstrates that Hulley thoroughly examined the studies to decipher how these various aspects may have effected the different outcomes of the studies. The Court finds that this information will aid the jury on this issue of the case. Further, Hulley's experience as an author of the leading text on study designs supports his qualifications to critique flaws in studies. The Court notes that it must keep in mind that the question of whether the expert is credible or whether the theories being applied by the expert are correct, is a "factual one that is left for the jury to determine after opposing counsel has been provided the opportunity to cross-examine the expert regarding his conclusions and the facts on

which they are based.” *Smith*, 215 F.3d at 719, Furthermore, “[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.* While the methodology and principles are certainly subject to scrutiny, it has been subjected to peer review and publication. Hulley’s opinions about the quality of the journals are admissible. At trial, defendants will be able to cross examine Huley on the “impact factor” regarding its validity, how he applied it to these studies and how it influenced his ultimate opinion in this case.

Next, defendants move to exclude this portion of Hulley’s report:

“Thrombin generation-based activated protein C (APC) sensitivity is a global test for the net prothrombotic effect, and predicts the risk of VTE. Van Vliet et al have shown that women who are receiving DRSP-OC have a significantly higher level of APC than those taking LNG-OC, and that women who switch from LNG-OC to DRSP-OC have an increase in APC (Van Vliet 2004). Woman taking the third generation OC’s desogestrel and gestodene have levels of APC that are similar to levels of women taking DSRP-OC. Similar patterns are observed for two determinants of APC resistance, free protein S and free tissue factor pathway inhibitor (TFPI) (Van Vliet 2008).

These studies provide a pathophysiological mechanism [sic] that creates biologic plausibility for the observed patterns of the relationship between type of OC progestin, with DRSP-OCs resembling the third generation OC progestins gestodene and desogestrel in causing higher levels of prothrombotic factors in blood than LNG-OCs.”

Defendants argue that Hulley is not qualified to offer opinions regarding the biological plausibility of a mechanism and that the basis for that opinion is untested and speculative. Plaintiffs counter that biologic plausibility, also known as consistency with other knowledge, is one of the nine so-called Hill factors that epidemiologists use in assessing whether an association can be judge to be causal. Plaintiffs admit that factor alone is not determinative; but that it is a basic tool of epidemiology to consider. Further, Plaintiffs maintain that Hulley’s published, peer-reviewed work includes review of the plausible mechanisms of increased VTE risk and that Hulley cites to and relies on others who have studied possible explanations of the association between DRSP and VTEs in opining about this factor in his analysis. Further, plaintiffs note that Hulley is not opining that APC-resistance (“APC^{res}”) in fact provides the explanation for the epidemiological findings, but only that the findings are biologically plausible in light of what is known about APC^{res} and VTEs. Further, plaintiffs maintain that Hulley is more than qualified to opine about this subject as he has written about APC^{res} and VTEs in “Factor V Lieden, Hormone Replacement Therapy, and Risk of Venus Thomboembic Events on Woman with

Coronary Disease.” In its reply, Bayer argues that Hulley did not mention the Hill criteria in his report or in his deposition and that he is not qualified to make such a finding.

As stated above, the Court finds that Hulley, as an epidemiologist, is qualified to make his ultimate opinion, including his finding about biologic plausibility. Further, the methodology that he utilized in his report is reliable as well as the portion on biologic plausibility. Biologic plausibility is a standard criterion that epidemiologists consider in their work. Moreover, Hulley is published and peer reviewed in this area and the publications that he cites to in his report have been subject to peer review and the APC^{res} theory has been the subject of research in the scientific community.⁹ Of course, if a method has not gained general acceptance, it “may properly be viewed with skepticism.” *Daubert*, 509 U.S. at 594. But viewing a method with skepticism is a far cry from the bright-line rule of exclusion that defendants advocate. “There are no certainties in science,” *Daubert, Id.* at 590, and establishing reliability does not mean that plaintiffs must prove that the assessments of their experts are correct. Perceived weaknesses in the conclusions, go to weight rather than to admissibility. Thus, Bayer’s arguments might undercut the credibility of Hulley’s statements as to biological plausibility, however, they do not effect the

⁹Bayer contends that the APC^{res} theory that Hulley cited in his reports (which coauthored by Dr. Jan Rosing another one of plaintiffs’ experts) is unsupported speculation in that it is not in clinical use, has not been validated and cannot be reliably reproduced by other scientists. As set forth more thoroughly in the Court’s Order addressing defendants’ motion to exclude the expert testimony of Rosing, the Court disagrees with defendants’ arguments as to the admissibility and characterization of Rosing’s articles and APC^{res} theory.

admissibility of his testimony. Obviously, Bayer may address these issues on cross examination. Therefore, the Court finds that Hulley's statements regarding biological plausibility will aid the jury in understanding this issue.

Defendants also move to exclude Hulley's opinions on governmental actions by the FDA or his opinions about regulatory activity in Europe. Plaintiffs maintain that Bayer seeks to exclude opinions that Hulley does not plan to offer concerning European and FDA regulatory matters. Thus, the Court denies as moot this portion of the motion based on plaintiffs' representations. Further, the Court finds that Hulley is qualified to opine on the medical facts and science regarding YAZ/Yasmin and to compare that knowledge with what was provided in the text and labeling and warnings on YAZ/Yasmin.

D. Motion to Exclude the Testimony of Dr. David Madigan (Doc. 2024)

As to Dr. David Madigan, defendants move to exclude Madigan's opinion that YAZ and Yasmin are at a higher risk of causing VTEs than other oral contraceptives and that the labels on these contraceptives should have reflected that. Defendants argue that adverse reporting data cannot be used to reliably compare relative risks of different drugs because of its inherent shortcomings and limitations. Further, defendants contend that Madigan's opinion that the "loud and clear" signal for the greater risk associated with DRSP required label change as early as 2002 is beyond his expertise. Plaintiffs counter that Bayer's motion to exclude Madigan's testimony

is based on a fundamental mis-characterization of his opinions. Specifically, plaintiffs maintain that they offer Madigan's testimony to show that "safety signals" should have put Bayer on notice of the dangers of YAZ and Yasmin at an early point, and also that, in the context of the overwhelming epidemiological evidence that DRSP-containing COCs present greater risks than other COCs, these "safety signals" provide supplemental confirmation of those greater risks. Plaintiffs contend that Madigan's testimony is not about quantifying the actual dangers of YAZ and Yasmin.

Plaintiffs asked Madigan to research the following:

"5. I was asked to examine whether a signal of venous thrombotic risk existed for Yasmin and Yaz, using industry standard pharmacovigilance techniques and data sources, from the inception of marketing through 2010. I was also asked to assess the strength of that signal in comparison to the signal, if any, for such events in oral contraceptives containing other progestins."

Based on his research, Madigan concluded as follows:

"46. Based on my review of FDA spontaneous report data for Yasmin and Yaz, it is apparent that industry standard pharmacovigilance techniques and data resources reveal the presence of a clear signal for venous thrombotic events for drospirinone Ocs shortly after these drugs were approved for marketing in the United States. By standard

metrics of “signal” detection, the signal is loud, consistent, and not ambiguous. Of perhaps greater concern, the signal was striking in comparison to that for OCs in other progestin classes - whether compared against progestin classes as a whole or market leaders within those classes. In short, the spontaneous report data for Yasmin and Yaz are quite concerning, and are in no way reassuring concerning the safety of these drugs generally, or in relation to other OCs.”

Dr. Madigan holds a doctorate in statistics, and is currently Professor in and Chair of the Department of Statistics at Columbia University. Madigan has taught and published extensively in the field of statistics. Currently, he sits on the FDA’s Advisory Committee on Drug Safety and Risk Management. He has served as Director of the Rutgers University Institute of Biostatistics and currently serves as an editor of a peer-reviewed academics statistics journal, *Statistical Science*. Dr. Madigan has consulted for various pharmaceutical companies and has otherwise applied his scientific training to questions of drug safety and public health.¹⁰

Madigan’s credentials as a statistician amply qualify him to testify as an expert with respect to the interpretation of the data he analyzed. Further, his written submissions and testimony described clearly and justified cogently his statistical methods, selection of three different endpoints, sources of data, as well as

¹⁰He has consulted for Boehringer-Ingelheim, Jarvik Heart, Novartis, Pfizer, Sanofi-Aventis, Takeda, and Wyeth on a variety of issues, many related to drug safety.

conclusions he drew from his analysis. In particular, he examined the FDA's AERS database and applied various data-mining techniques. Specifically, he applied two industry standard signal-detection algorithms (MGPS and PRR) to SRS databases in order to detect safety signals (as a comparator, he looked at other classes of oral contraceptives, as defined by progestin type, in the same manner). Thereafter, he compared YAZ/Yasmin with individual products using the PRR. Finally, to conduct his analysis, he used a commercial-marketed pharmacovigilance software platform. The methodology that he employed, as well as his published articles and other articles that rely on this methodology, have been tested, subjected to peer review and publication and are accepted in the general scientific community. Contrary to defendants' assertions, Madigan's opinions concern the detection and assessment of a pharmacovigilance safety signal raising concerns about an increased rate of VTE with YAZ/Yasmin. In addition, his report acknowledges that there are limitations of adverse event data and takes them into account in rendering his opinion. Thus, the Court finds that Madigan's opinions survive Rule 702 review. Further, the Court concludes that Madigan's testimony is sufficiently reliable and will assist the trier of fact in understanding the use of adverse event reports in the proper context, as required by Rule 702. Thus, the question is whether the jury will believe his conclusions. Moreover, his proposed testimony relates to issues in this case. The Court finds that his methodology is acceptable under the gatekeeping requirements and that his opinions are admissible. Clearly, these issues that Bayer raise are

questions of fact for the jury to determine. Any attack by defendants as to the weight of Madigan's testimony is a subject appropriate for cross examination.¹¹

IV. CONCLUSION

Accordingly, the Court **DENIES** defendant's motions to exclude experts (Docs. 2018, 2019, 2021, and 2024). The Court is persuaded that plaintiffs have carried their burden of demonstrating that each of their challenged expert witnesses has the requisite qualifications to testify as to his respective opinion regarding the interpretation of clinical trials and/or the analysis and interpretation of data. The record is sufficient to demonstrate the relevance of evidence of the associations identified in plaintiffs' evidentiary proffers and defendants' arguments go to the weight, rather than to the admissibility, of plaintiffs' evidence.

SO ORDERED

  David R. Herndon
2011.12.16
17:25:14 -06'00'

Chief Judge

United States District Court

Date: December 16, 2011

¹¹As to Bayer's argument that Madigan should not be allowed to testify as to labeling opinions as he admittedly is not an expert in this area, the Court denies this portion of the motion as moot. In their response, plaintiffs contend that Madigan is not intending to offer a labeling opinion and that what Madigan testified to is when a signal became apparent.