

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF ILLINOIS**

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**IN RE: YASMIN AND YAZ  
(DROSPIRENONE) MARKETING, SALES  
PRACTICES AND PRODUCTS LIABILITY  
LITIGATION**

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**3:09-md-02100-DRH-  
PMF  
  
MDL No. 2100**

**This Document Relates to:**

**ALL CASES**

**CASE MANAGEMENT ORDER NUMBER 47**

**Regarding Motions to Exclude Testimony of Plaintiffs'  
Regulatory Expert Witnesses  
(MDL 2100 Docs. 2015, 2023, 2026, and 2016)**

**I. INTRODUCTION**

Defendants Bayer HealthCare Pharmaceuticals Inc. and Bayer Pharma AG (“Bayer”) move to exclude the testimony of plaintiffs’ experts John D. Abramson, M.D., David A. Kessler, M.D., Suzanne Parisian, M.D., and Cheryl D. Blume, Ph.D., (Docs. 2015, 2023, 2026, & 2016) as Bayer believes their purported opinions fail to meet the requirements for admissibility under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993)

(*Daubert*). Familiarity with the underlying proceedings is presumed. For the reasons that follow, Bayer's motions to exclude are denied.

## II. BACKGROUND

This multidistrict litigation (MDL) relates to the manufacture, marketing, and sale of the prescription pharmaceuticals known as YAZ and Yasmin.<sup>1</sup> 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.*<sup>2</sup> 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-

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<sup>1</sup> 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.

<sup>2</sup> 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.

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 contend that Bayer misrepresented or omitted facts pertaining to the safety and efficacy of YAZ and Yasmin. With regard to the safety of YAZ and

Yasmin, plaintiffs contend that the DRSP component of the drugs is associated with an increased risk of VTE disease and of potentially life threatening thrombosis complications, including deep vein thrombosis (DVT) (a blood clot formation in one of the body's deep veins) and pulmonary embolism (a clot formation that travels to the lungs). The proffered experts that are the subject of the motions to exclude addressed in this order offer opinions regarding the regulations and marketing of YAZ and Yasmin.

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 most, if not, all testimony by Drs. Abramson, Kessler, Parisian, and Blume.

### **III. LEGAL STANDARD**

Federal Rule of Evidence 702 and *Daubert*, 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 that 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. *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007).<sup>3</sup> 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 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). See *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.”) (citing *Kumho*, 526 U.S. at 156)).

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<sup>3</sup> 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.

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 in 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 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). However, 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).

Resolution of an expert's credibility or the correctness of his or her theories under the particular circumstances of a given case is a factual inquiry, left to the

jury's determination after opposing counsel has cross-examined the expert at issue as to the conclusions and facts underlying his or her opinion. *Smith*, 215 F.3d at 718 (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 718 (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"))).

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); *Viglia*, 549 F.2d at 336 (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."

Furthermore, "[s]ocial science testimony . . . must be tested to be sure that the person possesses genuine expertise in a field and that her court testimony 'adheres to the same standards of intellectual rigor that are demanded in [her] professional work.'" *Tyus v. Urban Search Mgmt.*, 102 F.3d 256, 263 (7th Cir. 1996) (quoting *Braun v. Lorillard, Inc.*, 84 F.3d 230, 234 (7th Cir. 1996)). "[T]he measure of intellectual rigor will vary by the field of expertise and the way of demonstrating expertise will also vary." *Tyus*, 102 F.3d at 263. Indeed, "in certain fields, experiences is the predominant, if not the sole, basis for a great deal of reliable expert testimony." *United States v. Conn*, 297 F.3d 548, 556 (7th Cir. 2002) (quoting FED. R. EVID. 702, 2000 advisory committee note). For example, in cases involving narcotics dealers, experienced narcotics investigators apply the knowledge they have gained through years of experience and, essentially, describe for the jury what they know about narcotics dealers. *Conn*, 297 F.3d at 556. Genuine expertise may be based on experience and training, but

the district court must ensure that it is dealing with an expert, not just a hired gun. *Tyus*, 102 F.3d at 263.

#### **IV. ANALYSIS**

##### **A. Motion to Exclude the Testimony of Dr. John Abramson (Doc. 2015)**

###### **Defendants' Position**

Defendants contend that Dr. Abramson seeks to “testify that Bayer (1) engaged in an improper ‘off-label’ marketing campaign for Yasmin® and YAZ®, and (2) ‘encouraged prescribers and women who would not otherwise have prescribed or used an oral contraceptive to prescribe or use Yasmin [or YAZ].” Defendants argue that Dr. Abramson’s testimony should be excluded for the following reasons: 1) Dr. Abramson is not qualified to offer expert opinions about the marketing of prescription drugs; 2) Dr. Abramson’s attempt to provide a narrative description of documents should be excluded because it is unreliable; and 3) Dr. Abramson’s opinions should be excluded because they exceed the scope of permissible expert testimony.

###### **Plaintiffs' Position**

Plaintiffs argue that Dr. Abramson is being proffered to testify regarding “(i) the information physicians and health benefit providers rely upon in making decisions about the appropriate use of medications, (ii) the methods by which

pharmaceutical companies influence physicians, health benefit providers and patient/consumers to make clinical and formulary decisions about the use of medications, and (iii) the methods that are at times used by pharmaceutical companies to increase doctors' prescribing of drugs (a) for uses that are not approved by the FDA, (b) based on unsubstantiated claims of safety or efficacy, or (c) based on unsubstantiated comparative claims." More specifically, Dr. Abramson "offers relevant, well-supported, and helpful opinions about Bayer's off-label, unsubstantiated, and misleading marketing of Yasmin and YAZ to prescribing physicians and patients/consumers." In support, plaintiffs contend that Dr. Abramson has the appropriate expertise to support his testimony and argue that Bayer's attack on Dr. Abramson's methodology is meritless.

### **Dr. Abramson's Proposed Expert Testimony**

Dr. Abramson summarized his opinions in his expert report as follows:<sup>4</sup>

If there is a increased risk of VTE in users of DRSP-containing oral contraceptives compared to other oral contraceptives, I offer the following opinions:

A. The comprehensive off-label, unsubstantiated and/or otherwise misleading marketing of Yasmin [and YAZ] encouraged prescribers and women who would not otherwise have prescribed or

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<sup>4</sup> Dr. Abramson's report was actually broken down into separate opinions for Yasmin and YAZ but because the two opinions (labeled A and B) were the same for both drugs, the Court has combined them. The same holds true for his third opinion (labeled C) as it relates to the first sentence. Thereafter, the opinions are different for each drug.

used an oral contraceptive to prescribe or use Yasmin [or YAZ], thereby placing the user at increased risk of VTE.

B. The comprehensive off-label, unsubstantiated and/or otherwise misleading marketing of Yasmin [and YAZ] encouraged prescribers and women who intended to prescribe or use an oral contraceptive for the prevention of pregnancy to prescribe or use Yasmin [or YAZ] when there were other oral contraceptives with less risk of VTE available. Accordingly, those women who used Yasmin [or YAZ] as a result of these marketing efforts were unnecessarily exposed to an increased risk of VTE.

C. Brand Planning and Marketing for Yasmin [and YAZ], as informed by market research, was guided by the goal of expanding the market for users of Yasmin [and YAZ] beyond the FDA-approved indications and/or was based upon unsubstantiated claims so as to maximize sales. The indications and scientific evidence contained in the product insert for Yasmin were often ignored in marketing efforts, thereby placing users at increased risk of VTE.

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... The indications and scientific evidence contained in the product insert for Yaz, as well as specific feedback from FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC") about misleading, unsubstantiated, and violative claims contained in submitted marketing material, were often ignored in subsequent marketing efforts, thereby placing users at increased risk of VTE. The primary areas where Yaz violated the boundaries of permissible marketing were:

1. Blurring the distinction between treatment of women suffering from PMDD and those suffering from less severe premenstrual symptoms.
2. Claiming that the unique physiological properties of drospirenone and the 24/4 day regimen conferred clinical benefits related to menstrual symptoms and/or acne.
3. Exaggerating the efficacy of Yaz in the treatment of PMDD and acne.
4. Using Public Relations as a way to bypass FDA restrictions on off-label marketing.

5. Continuing to provide drug reps with marketing material that contained claims deemed misleading by DDMAC.

D. The off-label, unsubstantiated and/or otherwise misleading marketing materials that were still in use at the time of Bayer's receipt of the FDA's October 2008 Warning Letter show that Bayer's disregard for repeated communications from DDMAC persisted up until that time. As a result, prescribers and women who would not have prescribed or taken an oral contraceptive at all but for the misleading claims of the non-contraceptive benefits of Yaz, and prescribers and women who would have prescribed or taken another oral contraceptive with a lower risk of VTE but for the misleading claims of the benefits of Yaz, were exposed to unnecessary risk without substantial evidence of offsetting benefit.

#### **Whether Dr. Abramson Qualifies as an Expert?**

First, the district court must determine whether Dr. Abramson is an expert through "knowledge, skill, experience, training or education." *Ervin*, 492 F.3d at 904 (citing FED. R. EVID. 702). Defendants do not contend that Dr. Abramson is not an expert generally, but rather dispute whether Dr. Abramson may give testimony about the marketing of prescription drugs. The Court finds that Dr. Abramson may provide expert testimony about those matters.

Defendants contend that Dr. Abramson is not qualified to offer expert opinions about the marketing of prescription drugs. Specifically, defendants argue that Dr. Abramson is not qualified to testify that Bayer's marketing of Yasmin and YAZ violated the United States Food and Drug Administration ("FDA") rules, policies, or guidelines governing the marketing of prescription drugs because Dr. Abramson admits he is not an "expert in FDA regulations."

Further, defendants contend that Dr. Abramson should be prohibited from testifying about Bayer's marketing strategy for Yasmin and YAZ based upon a series of "internal documents" that he admits were never used with physicians or consumers. Lastly, defendants posit that Dr. Abramson is not an expert on the effect of marketing on individual prescribers or consumers. Plaintiffs contend that these arguments are meritless.

In Dr. Abramson's deposition, he testified that he believed that through his research he had expertise on the effect of marketing and prescription drugs on prescribers and consumers and that he was an expert on such matters. He testified that he was qualified to give his opinions based upon his experience as a family practice physician and "as a Robert Wood Johnson fellow for two years learning about research design, epidemiology and statistics." He further elaborated that his education and training, as well as having written a book and peer reviewed articles on the subject, allow him to testify as an expert. This experience includes his experience as a "teacher of primary care and as a teacher of health policy and as somebody who lectures at Harvard Medical School about pharmaceutical policy" along with the experience he has gained in his work with Wells Fargo and Prudential managed care institutions. He also testified that he taught in various contexts about the effect of marketing. He testified that he had expertise to allow him to understand the dialogue between the FDA and pharmaceutical companies, "expertise beyond the vast majority of practicing

physicians to understand what the scientific issues are . . . .” Dr. Abramson’s qualifications support his conclusion that his knowledge, skill, experience, training, and education qualify him to testify as an expert about the marketing of prescription drugs. See *In re Zyprexa Prods. Liab. Litig.*, 493 F. Supp. 2d 571, 580 (E.D. N.Y. 2007) (finding Dr. Abramson met *Daubert* standards).

Dr. Abramson graduated *cum laude* from Harvard College in 1970. He attended Dartmouth Medical School and graduated with a degree in medicine from Brown Medical School in 1976. He then served as a primary care physician in the National Health Service Corps from 1977 to 1979 and completed his residency at Case Western Reserve University from 1979 to 1981. He also completed a Robert Wood Johnson Fellowship in family medicine at Case Western University from 1980 to 1982, earning a Master of Science in family practice degree. During this fellowship, Dr. Abramson received training in the interpretation of scientific data and the study of statistics, research design, and health policy. Following his fellowship, Dr. Abramson served as a family practitioner from 1982 to 2002. From 1986 to 1993, Dr. Abramson served as association medical director of Pru-Care of Massachusetts. Dr. Abramson also served as a senior research associate on the faculty of the Institute for Health Policy, Heller School, Brandeis University from 1992 to 1993, as chair of the graduate medical education committee at Beverly Hospital from 1993 to 1995, and as chair of the department of family practice the Lahey Clinic in Burlington,

Massachusetts from 1994 to 2001. In 1997, Dr. Abramson began teaching at Harvard Medical School as a clinical instructor in ambulatory care and did that until 2009, when he became a lecturer in the department of health care policy, where he currently teaches.

In 2002, Dr. Abramson left clinical practice to devote himself full-time to researching the integrity of the information that doctors rely upon when making clinical decisions, specifically in regard to the pharmaceutical industry and its impact on public health, public safety, and the quality of American healthcare. Since the beginning of 2002, he has been researching, writing, lecturing, and teaching about how the information about drugs and other medical products available to practicing physicians impacts their medical decisions. He has had articles published in peer-reviewed journals addressing bias in the scientific evidence upon which doctors rely. Specifically, he has had four articles published in peer-reviewed journals and published a book about the growing commercial influence on the production and dissemination of medical information available to physicians, the public, and health policymakers (including marketing of prescription drugs to physicians and the public). He also is currently the executive director of health management for Well Fargo Health Solutions.

Based upon Dr. Abramson's extensive academic and practical experience, the Court finds that Dr. Abramson qualifies as an expert in this case. Dr.

Abramson has been a physician for over twenty-five years in various capacities, has published several peer-reviewed articles, and a book about the influence of the pharmaceutical industry on the practice of medicine, including the marketing of prescription drugs to physicians and the public. Accordingly, the Court finds that Dr. Abramson is qualified to testify as an expert for things he addresses in his report.

### **Whether Dr. Abramson's Reasoning or Methodology is Reliable?**

Second, the Court must determine whether Dr. Abramson's reasoning or methodology is reliable. Defendants argue that Dr. Abramson's attempt to provide a narrative description of documents should be excluded because it is unreliable. Specifically, defendants' position is that Dr. Abramson's marketing opinions lack any reliable methodology. Defendants also assert that Dr. Abramson cannot supplement his narrative with speculation about the state of mind of Bayer, the FDA, or other third parties. Defendants contend that Dr. Abramson's personal and ethical opinions should be excluded because Dr. Abramson's testimony does not satisfy the knowledge requirement. Further, defendants argue that Dr. Abramson's legal conclusions are improper and should be excluded.

Plaintiffs counter that Dr. Abramson may testify as an expert summary witness, and that Bayer's argument is founded on the faulty premise that all

narrative testimony is prohibited. Plaintiffs suggest that the decisions on which Bayer relies that preclude experts from providing “narrative” testimony are merely applying the familiar trial objection that the “document speaks for itself,” and that that rule should be enforced at trial, in the context of specific documents and expert testimony, not by the way of a *Daubert* motion. As to the reliability of Dr. Abramson’s methodology, plaintiffs contend that Dr. Abramson properly applied his expertise to the documentary record in this case. With regard to defendant’s argument regarding state of mind, plaintiff argues that Dr. Abramson does not speculate about the state of mind of Bayer, the FDA, or other third parties. Plaintiffs further dispute that Dr. Abramson offers personal or ethical opinions or legal conclusions.

In order for Dr. Abramson’s testimony to be admissible, it must have a reliable basis in the knowledge and experience of the relevant discipline and must fit the facts of the case. *Kumho*, 526 U.S. at 149-50. In making this determination, the Court may look at a number of factors, including as is relevant to this case, whether the scientific theory has been subjected to peer review and publication. *Ervin*, 492 F.3d at 904 (citing *Daubert*, 509 U.S. at 593-94). The expert must explain the methodologies and principles that support his or her opinion. *Metavante*, 619 F.3d at 761 (quoting *Minix*, 597 F.3d at 835). “An expert’s testimony is not unreliable simply because it is founded on his experience rather than on data; indeed, Rule 702 allows a witness to be ‘qualified as an

expert by knowledge, skill, experience, training, or education.” *Metavante Corp.*, 619 F.3d at 761. The Court treats the reliability of an expert’s opinion separately from his or her overall qualifications. *Bourelle v. Crown Equip. Corp.*, 220 F.3d 532, 537 (7th Cir. 2000). Even shaky expert testimony may be admissible, assailable by its opponents through cross-examination. *Metavante Corp.*, 619 F.3d at 762.

When asked at his deposition what data supported his opinions, Dr. Abramson stated that it was the totality of Bayer’s marketing effort and it starts with the marketing research that was done and is referred to in his report. He further elaborated that the empirical data for his opinion was that Bayer did market research, formed a strategy based upon market research, carried out their strategy, and had good sales as a result. He testified that he has “a clinical background in studying scientific literature and FDA and DDMAC rulings and applied that experience and expertise to the study of this issue.” Dr. Arbamson has written scientific peer reviewed articles and a book on this subject. Based upon these reasons, the Court finds that Dr. Abramson’s reasoning or methodology is reliable.

Dr. Abramson’s opinions are more than just his subjective belief or unsupported speculation. While the methodology and principles he applies are certainly subject to scrutiny, they have been subjected to peer review and

publication and the record does not indicate that the methodology and principles Dr. Abramson relies upon for coming to his conclusions are unreliable. Accordingly, Dr. Abramson's opinions are admissible. To the extent that defendants disagree with Dr. Abramson'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. *Daubert*, 509 U.S. at 596.

As to defendant's argument regarding narrative testimony, the Court has broad discretion over the mode and order of examining witnesses and presenting evidence and may allow testimony in narrative form at trial if the Court finds that it would be helpful to the jury. See FED. R. EVID. 611; *United States v. Pless*, 982 F.2d 1118, 1123 (7th Cir. 1992) ("Fed. R. Evid. 611(a) provides district judges with authority to allow testimony in narrative form rather than as answers to specific questions [citations omitted], and we ourselves have said that 'there is . . . nothing particularly unusual, or incorrect, in a procedure of letting a witness relate pertinent information in a narrative form as long as it stays within the bounds of pertinency and materiality' (*United States v. Garcia*, 625 F.2d 162, 169 (7th Cir. 1980))."); *Hutter N. Trust v. Cnty. Chamber of Commerce*, 467 F.2d 1075, 1078 (7th Cir. 1972) (finding the denial of a *pro se* plaintiff's request to testify in the narrative form well within the proper exercise of the judge's discretion). The same holds true with regard to testimony in summary format.

See *United States v. Pree*, 408 F.3d 855, 869-71 (7th Cir. 2005) (finding summary witness's testimony was properly admitted in criminal tax prosecution, because witness relied only on evidence already in record and he was available for cross-examination); *United States v. Petty*, 132 F.3d 373, 379 (7th Cir. 1997) (finding the since the court could have admitted the charts under Rule of Evidence of 1006 (although it did not), it did not abuse its discretion in allowing the witness to testify as to their contents under Rule 611(a)); *United States v. Swanquist*, 161 F.3d 1064, 1072-73 (7th Cir. 1998); FED. R. EVID. 1006 ("The proponent may use a summary, chart, or calculation to prove the content of voluminous writings, recordings, or photographs that cannot be conveniently examined in court."). Such matters will be decided at trial in context specific situations and will be ruled upon then.<sup>5</sup> The Court's rulings on these matters will likely be impacted by whether the evidence that the narrative or summary relates to is admitted. Moreover, if evidence is admitted in narrative or summary form, defendants will have an opportunity during cross-examination or presentation of its own evidence to address any concerns defendants might have. See *Pree*, 408 F.3d at 871 ("Where . . . the defense conducted a thorough cross examination of the witness concerning the disputed matters, and also had the opportunity to present its own

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<sup>5</sup> This also applies to defendants' arguments about whether Dr. Abramson is testifying about someone else's state of mind or is providing personal or ethical opinions. Plaintiffs dispute that Dr. Abramson testifies or is going to testify about these matters, and if such testimony is elicited at trial, defendants may object to it at that time.

version of those matters, the likelihood of any error in admitting summary evidence diminishes.”) (quoting *United States v. Norton*, 867 F.2d 1354, 1363 (11th Cir. 1989)).

### **Whether the Proposed Testimony Will Assist the Trier of Fact?**

Lastly, the Court must determine whether the testimony will assist the trier of fact with its analysis of any of the issues involved in the case. *Smith*, 215 F.3d at 718. In doing so, “the trial court is not compelled to exclude the expert just because the testimony may, to a greater or lesser degree, cover matters that are within the average juror’s comprehension.” *Ancho v. Pentek Corp.*, 157 F.3d 512, 519 (7th Cir. 1998) (quoting *United States v. Hall*, 93 F.3d 1337, 1342 (7th Cir. 1996)). Still, if the expert testimony is obvious to a layperson, expert testimony would be useless. *Ancho*, 157 F.3d at 519.

Here, the Court finds Dr. Abramson’s proposed testimony will assist the trier of fact to understand the evidence or determine a fact in issue. Dr. Abramson’s testimony is not something that is obvious to a layperson, and his testimony will help the jury better understand this case. As Dr. Abramson testified in his deposition, he “is trained to understand research design, statistics and epidemiology to evaluate what the issues are, why they’re important, what they would mean to lay people and whether or not DDMAC’s instructions have been adhered to in future marketing materials.” The Court believes this type of testimony will be helpful to the jury and will assist laypeople’s understanding of

the evidence or determine a fact in issue. See *Tyus*, 102 F.3d at 263 (finding it error to exclude the testimony of the expert prepared to testify about the way an advertising campaign sends a message to its target market and how an all-White campaign affects African Americans when “[t]his kind of social research, which would demonstrate the way one of the most important industries in our country actually operates, would have given the jury a view of the evidence well beyond their everyday experience.”). “Indeed, anyone who watches television knows that the major consumer product companies in the country spend billions crafting their advertising campaigns, to reach exactly the right audience, with exactly the right pitch. It is doubtful they are making these decisions by asking six or twelve random people on the street what might appeal to them.” *Id.* Having an expert in the marketing of this industry will undoubtedly assist the trier of fact.

### **Conclusion**

For the reasons stated above, the motion to exclude Dr. Abramson’s testimony is denied (Doc. 2015).

### **B. Motion to Exclude the Testimony of Dr. David A. Kessler (Doc. 2023)**

#### **Defendants’ Position**

Defendants contend that Dr. Kessler’s opinions and speculation about disclosures to the FDA are inadmissible under *Buckman Co. v. Plaintiffs’ Legal*

*Comm.*, 531 U.S. 341 (2001); that Dr. Kessler may not offer legal conclusions about federal and state law; that Dr. Kessler may not give a factual narrative or speculate about the knowledge and intent of Bayer and others; and that Dr. Kessler may not offer opinions in areas where he is not qualified as an expert.

### **Plaintiffs' Position**

Plaintiffs dispute all of these arguments, and generally defend Dr. Kessler's report. Specifically, plaintiffs contend that Dr. Kessler's opinions are not precluded by *Buckman*; that Dr. Kessler may testify that state and federal law impose complementary obligations, and that Bayer's off-label promotion of Yasmin and YAZ violated the FDCA; that Dr. Kessler does not speculate about defendants' state of mind, nor does he provide impermissible narratives; and that Dr. Kessler's testimony is within the scope of his expertise.

### **Dr. Kessler's Proposed Expert Testimony**

While it would have been helpful for plaintiffs to point out specifically what Dr. Kessler was being tendered to testify about rather than just generally defending the expert's report, Dr. Kessler's report is insightful on this issue. Dr. Kessler summarized his opinions as follows: "[t]he manufacturer, not FDA, is primarily responsible for the safety of its products"; that "FDA regulations and state law provide independent and complementary layers of consumer protection"; that "Bayer violated its duties under FDA regulations and state law by

selectively presenting data as to thromboembolic events, which did not adequately inform FDA, doctors or consumers of the thromboembolic risks, from pre-marketing to the present”; and that “Bayer engaged in extensive off-label promotion of Yasmin and YAZ for unapproved uses, in violation of FDA regulations, to increase sales” and “[t]hat off-label promotion increased the risk of thromboembolic events in patients in violation of state law duties.”

### **Dr. Kessler’s Qualifications**

Dr. Kessler holds a medical degree from Harvard University and a law degree from the University of Chicago. He also has an advanced professional certification in management that he obtained from New York University School of Business Administration. Dr. Kessler was appointed by President George H. W. Bush as the Commissioner of the FDA in 1990 and served in that role until 1997. As Commissioner, Dr. Kessler had the ultimate responsibility for implementing and enforcing the United States Food, Drug, and Cosmetic Act.

He has taught food and drug law at Columbia University Law School, and has testified many times before the United States Congress on food, drug, and consumer protection issues under federal and state law. Over the last thirty years, he has published numerous articles in legal and scientific journals on the federal regulation of food, drugs, and medical devices. He also has special training in pharmacoepidemiology at Johns Hopkins Hospital. He currently is a professor of pediatrics, epidemiology and biostatistics, Dean of the School of

Medicine, and is Vice Chancellor of Medical Affairs at the University of California, San Francisco. He also acts as a senior advisor to TPG Capital, a leading global private firm, which owns pharmaceutical and biomedical companies, and serves on the boards of Aptalis Pharma and Tokai Pharmaceuticals, advising them on the standards and duties of care within the pharmaceutical industry.

Defendants do not dispute that Dr. Kessler’s “experience may equip him to offer some appropriate testimony about FDA’s regulatory scheme works,” but rather seek to exclude Dr. Kessler’s testimony for many reasons that are inapplicable using a *Daubert* analysis. For example, defendants do not contend that Dr. Kessler is not an expert, that his reasoning or methodology is unreliable, or that his testimony would not be helpful to the jury, all relevant inquiries under a *Daubert* analysis. To the contrary, defendants seek to exclude Dr. Kessler’s for other reasons that perhaps should have been raised in motions in limine or as objections at trial. Nonetheless, the Court will address defendant’s arguments and apply a *Daubert* analysis were applicable.

### ***Buckman***

Defendants first contend that Dr. Kessler’s opinions and speculation about disclosures to the FDA are inadmissible under *Buckman*. Defendants assert that Dr. Kessler devotes much of his report and deposition to his opinions about whether Bayer satisfied a duty to provide information to the FDA and his

speculation about what the FDA might have done differently if it had different information. Defendants contend such speculation is exactly what *Buckman* precludes. Plaintiffs contest this, arguing that *Buckman* does not pre-empt state law claims, such as those alleged in this case, based upon a failure to adequately warn doctors and patients of the risks of adverse events.

In *Buckman*, patients claimed to have suffered injuries from implantation of orthopedic bone screws into their spines. The patients brought suit alleging that a regulatory consultant to the manufacturer made fraudulent representations to the FDA in the course of obtaining approval to market the screws. The Supreme Court held that state-law fraud-on-the-FDA claims were pre-empted by federal law, specifically the FDCA, as amended by the Medical Device Amendments Act of 1976 (“MDA”). 531 U.S. at 348. The Court found that the FDA was empowered to punish and deter fraud against the FDA, and that by allowing fraud-on-the-FDA claims under state tort law, the FDA’s authority might be skewed. *Id.*

Here, *Buckman* does not pre-empt evidence of when Bayer informed the FDA of information relating to Yasmin and YAZ. *Buckman* is a claim preemption case focusing on fraud-on-the-FDA claims, not an evidence preemption case. See *Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010) (“But the *Buckman* court specifically distinguished such ‘fraud-on-the-agency’ claims, i.e., claims not

related to a field of law that states had traditionally occupied, from claims based on state law tort principles . . .”). Further, a comparison between *Buckman* and the landmark case *Wyeth v. Levine*, 555 U.S. 555 (2009), demonstrates exactly why *Buckman* is completely distinguishable from this case and why there is no way to analyze *Buckman* to have any impact on this case. The Supreme Court made clear in *Wyeth* that federal law does not prevent judges and juries in failure to warn cases from considering a drug companies compliance with FDA regulations. *Wyeth*, 555 U.S. at 568-73.

### **Legal Conclusions**

Defendants next contend that Dr. Kessler may not offer legal conclusions about federal and state law. Plaintiffs argue that “[e]xperts in pharmaceutical cases are permitted to testify that a [d]efendant acted unreasonably and/or violated the standard of care by providing an inadequate warning of the risk of adverse events, and that such testimony does not invade the province of the judge or jury.”

Here, the Court finds that Dr. Kessler’s testimony is permissible because of the complex nature of the process and procedures and the jury needs assistance understanding it. As the court in *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164 (S.D. N.Y. 2009), observed based upon a similar objection:

A lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care in the pharmaceutical industry. [The expert's] assessment of the reasonableness of Merck's conduct in light of her experience and her understanding of FDA regulations will be helpful to the jury. An expert may offer testimony embracing an ultimate issue of fact that the jury will decide. Fed. R. Evid. 704(a). Cross-examination and competing expert testimony by Merck's regulatory experts will ensure that the jury carefully weighs her testimony.

*Id.* at 190-91. Similarly here, Dr. Kessler's testimony will assist the trier of fact in understanding the federal regulations, and the jury will be instructed that that the Court, not Dr. Kessler nor any other witness, will instruct the jury on the law that applies in this case.

#### **Factual Narrative/State of Mind**

Defendants next contend that Dr. Kessler may not give a factual narrative or speculate about the knowledge and intent of Bayer and others. More specifically Dr. Kessler argues that Dr. Kessler's factual narratives and summaries of Bayer documents are not the proper subject of expert testimony. Defendants further assert that Dr. Kessler's speculation and personal opinions about the knowledge and intent of Bayer, the FDA, physicians or patients should be excluded. For example, defendants posit that Dr. Kessler's repeatedly speculates about what the FDA would have done differently with respect to Yasmin and YAZ had it been provided with different information. Plaintiffs dispute this, contending that Dr. Kessler does not speculate about defendant's state of mind, nor does he provide

impermissible narratives. Furthermore, plaintiffs contend that Dr. Kessler may testify as to what a reasonable FDA official would have done with information about VTE adverse events.

With regard to defendants' position that Dr. Kessler seeks to testify about Bayer's state of mind, Dr. Kessler repeatedly assured defendants during his deposition that he did not intend to testify about the intent or motive of Bayer's personnel. If he attempts to do so at trial, an objection may be raised at that time. See *DePaepe v. General Motors Corp.*, 141 F.3d 715, 720 (7th Cir. 1998) ("He could give an opinion as an engineer that reducing the padding saved a particular amount of money; he might testify as an engineer that GM's explanation for the decision was not sound (from which the jury might infer that money was the real reason); but he could not testify *as an expert* that GM had a particular motive.").

As to defendant's argument regarding narrative testimony, the Court has broad discretion over the mode and order of examining witnesses and presenting evidence and may allow testimony in narrative form at trial if the Court finds that it would be helpful to the jury. See FED. R. EVID. 611; *Pless*, 982 F.2d at 1123 ("Fed. R. Evid. 611(a) provides district judges with authority to allow testimony in narrative form rather than as answers to specific questions [citations omitted], and we ourselves have said that 'there is . . . nothing particularly unusual, or

incorrect, in a procedure of letting a witness relate pertinent information in a narrative form as long as it stays within the bounds of pertinency and materiality’ (*United States v. Garcia*, 625 F.2d 162, 169 (7th Cir. 1980)).”); *Hutter N. Trust*, 467 F.2d at 1078 (finding the denial of a *pro se* plaintiff’s request to testify in the narrative form well within the proper exercise of the judge’s discretion). The same holds true with regard to testimony in summary format. See *Pree*, 408 F.3d at 869-71 (finding summary witness’s testimony was properly admitted in criminal tax prosecution, because witness relied only on evidence already in record and he was available for cross-examination); *Petty*, 132 F.3d at 379 (finding the since the court could have admitted the charts under Rule of Evidence of 1006 (although it did not), it did not abuse its discretion in allowing the witness to testify as to their contents under Rule 611(a)); *Swanquist*, 161 F.3d at 1072-73; FED. R. EVID. 1006 (“The proponent may use a summary, chart, or calculation to prove the content of voluminous writings, recordings, or photographs that cannot be conveniently examined in court.”). Such matters will be decided at trial in context specific situations and will be ruled upon then. The Court’s rulings on these matters will likely be impacted by whether the evidence that the narrative or summary relates to is admitted. Moreover, if evidence is admitted in narrative or summary form, defendants will have an opportunity during cross-examination or presentation of its own evidence to address any concerns defendants might have. See *Pree*, 408 F.3d at 871 (“Where . . . the defense conducted a thorough cross

examination of the witness concerning the disputed matters, and also had the opportunity to present its own version of those matters, the likelihood of any error in admitting summary evidence diminishes.”) (quoting *Norton*, 867 F.2d at 1363).

Further, despite defendant’s argument to the contrary, Dr. Kessler may testify as to what a reasonable FDA official would have done with information about VTE adverse events. As the former Commissioner of the FDA, with unquestioned knowledge of the regulatory scheme and requirements, Dr. Kessler may testify about what a reasonable FDA official would have done with information about VTE adverse events because his experience uniquely qualifies for him to do so. His testimony with regard to these matters is relevant and reliable and can be subjected to cross-examination.

### **Unqualified Opinions**

Lastly, defendants argue that Dr. Kessler may not offer opinions in areas where he is not qualified as an expert. Particularly, defendants argue that Dr. Kessler is not qualified to opine about the effect of corporate strategy on profits or on how many women were prescribed the products and for what purpose, the requirements of state law, or foreign regulatory issues. Plaintiffs contend that Dr. Kessler’s testimony is within the scope of his experience, and that Dr. Kessler never offered an opinion on foreign regulatory matters.

Dr. Kessler's experience in enforcing the FDCA, working with the DDMAC, and advising drug companies provides sufficient experience and expertise to understand defendant's marketing scheme and to opine as to its economic purpose. Dr. Kessler's report provides extensive support for his opinions surrounding this matter. Moreover, as the Commissioner of the FDA, Dr. Kessler enforced the FDCA that applied to drug companies' conduct throughout the country. He received a law degree from the University of Chicago and has taught food and drug law at Columbia University Law School, as well as written "amicus briefs on the "interaction between State and federal law." Furthermore, he advises drug companies on how to meet their legal obligations. While Dr. Kessler has never sat for the bar exam and is not licensed to practice law in any particular state, his past experience qualifies him to testify about a drug company's duty of care under state law.

Because plaintiffs contend that Dr. Kessler has not given any testimony on foreign regulatory law, this argument would appear to be moot. Nevertheless, Dr. Kessler can give opinions within his area of expertise about what he has reviewed in this case, including facts, i.e., what other scientists have said on the topic, that are relevant to his opinions. *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."). "[A]ny questions or problems concerning the expert's testimony may be thoroughly explored during cross-examination of

the witness.” *Gonzalez*, 933 F.2d at 429. 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.

### **Conclusion**

For the reasons stated above, the motion to exclude Dr. Kessler’s testimony (Doc. 2023) is denied.

### **C. Motion to Exclude the Testimony of Suzanne Parisian (Doc. 2026)**

#### **Defendants’ Position**

Defendants also seek to exclude the testimony of plaintiffs’ expert Dr. Suzanne Parisian. Defendants contend that Dr. Parisian should be excluded for three reasons: 1) Dr. Parisian would not be a helpful or controllable witness at trial; 2) Dr. Parisian’s factual narrative and legal conclusions are improper advocacy that should be excluded; and 3) Dr. Parisian may not testify about inadmissible issues or matters for which she lacks expertise.

#### **Plaintiffs’ Position**

Plaintiffs dispute defendants’ contentions. Specifically, plaintiffs argue that Dr. Parisian has appropriate expertise to support her testimony; that Bayer’s attack on Dr. Parisian’s methodology is meritless; and that Dr. Parisian’s

testimony is not preempted by *Buckman*. Moreover, plaintiffs contend that defendants' attacks on Dr. Parisian are more properly classified as attacks on Dr. Parisian's character and credibility as opposed to *Daubert* motions.

### **Dr. Parisian's Proposed Expert Testimony**

Plaintiffs proffer Dr. Parisian to offer testimony concerning FDA regulatory and labeling issues. Specifically, plaintiffs contend that Dr. Parisian is qualified to testify about: (1) "the complex FDA regulatory framework governing the approval, labeling, advertising, and marketing of pharmaceutical and medical products," (2) "the FDA's process for determining efficacy and safety of pharmaceutical drugs and devices, including safety testing, monitoring, and reporting," (3) "the FDA's requirements for the development of product labeling and marketing[]," (4) "manufacturer responsibility and compliance with FDA regulations and guidelines," and (5) "the manufacturer's responsibilities post approval."

In her report, Dr. Parisian offers five opinions: 1) the FDA does not have the primary role, resources or responsibility to monitor Bayer's drug products post approval to ensure they continue to comply with the fact and implementing regulations; 2) Bayer failed to ensure adequate and timely updating of its United States DRSP COC labels to provide relevant safety information to health care providers and women; 3) Despite the FDA's history of continuing safety concerns

for DRSP products and Bayer's need to commit to risk management, Bayer has delayed providing the FDA with post market safety information; 4) Bayer's pharmacovigilance procedures for DRSP COCS were flawed and unable to effectively identify and investigate safety signals associated with DRSP COCS; and 5) Bayer engaged in health care provider and direct-to-consumer promotions for YAZ/Yasmin that promoted unapproved use, lacked fair balance, did not comply with the Act, minimized and downplayed risks and failed to reveal material facts.

Because many of defendants arguments do not involve a *Daubert* analysis at all, but rather go to objections that may be raised at trial or to issues that would have been more properly brought in motions limine, the Court begins by conducting a *Daubert* analysis generally, and then will address each of defendants' arguments specifically.

#### **Whether Dr. Parisian Qualifies as an Expert?**

First, the district court must determine whether Dr. Parisian is an expert through "knowledge, skill, experience, training or education." *Ervin*, 492 F.3d at 904 (citing FED. R. EVID. 702). Dr. Parisian received a masters degree in biology from the University of Central Florida, her medical degree from the University of South Florida in 1978, and a board certification in anatomic and clinical pathology in 1989. From 1991 to 1995, Dr. Parisian served as a commissioned officer in the United States Public Health Service, during which time she was

primarily assigned as one of ten medical officers to the Center for Devices and Radiological Health at the FDA. During that time, she was also assigned clinical responsibilities at the Armed Forces Institute of Pathology, Office of the Medical Examiner for the Armed Forces.

As an FDA medical officer, Dr. Parisian helped broadly cover both pre-market evaluation and post-market compliance issues. She was responsible for reviewing mandatory adverse event reports, product recalls, labeling, and communications from manufacturers to physicians and the public regarding performance of FDA-regulated products. In 1993, Dr. Parisian became involved primarily with premarketing evaluation of devices for the Office of Device Evaluation. She also participated with the FDA's Office of Compliance and General Counsel in review of products, including physician and prescription product labeling, manufacturing and device records, user, physician, and corporate communications, complaint files, and failure investigations obtained by the FDA. She was also one of the first clinical instructors in FDA's Center for Devices and Radiological Health Staff College, where she taught FDA reviewers about pre-market application design, informed consent, and methods available to protect human subjects, and review of clinical data submitted to the agency by sponsors of pre-marketing applications. Dr. Parisian also participated in numerous other activities with the FDA that are chronicled in her report, including working on 162 health hazard evaluations/health risk assessments,

helping to draft agency documents for the industry outlining the requirements for obtaining FDA's marketing approval and the FDA Safety Alerts directed to the healthcare providers and their patients, and acting as a liaison for the FDA with other entities.

In August 1995, after leaving the FDA, Dr. Parisian founded MD Assist, Inc., a regulatory and medical consulting firm specializing in matters involving the regulation of United States products by the FDA. In 2001, her book, *FDA Inside and Out*, was published. Currently, Dr. Parisian is licensed to practice medicine in the States of Virginia and Arizona. Since 1997, she has been involved in providing support for litigation.

The Court finds that Dr. Parisian's knowledge, skill, experience, training, and education qualify Dr. Parisian to offer testimony concerning FDA regulatory and labeling issues. Dr. Parisian's experience with the FDA and thereafter provide her specialized knowledge that uniquely qualify to testify about the matters in her report. See *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d at 190 ("The Court finds that Dr. Parisian is qualified based upon her experience as a Medical Officer at the FDA to offer testimony about regulatory requirements relating to the development, testing, marketing, and surveillance of prescription drugs.").

### **Whether Dr. Parisian's Reasoning or Methodology is Reliable?**

Second, the Court must determine whether Dr. Parisian's reasoning or methodology is reliable. In her report, Dr. Parisian stated the following:

Based on the work I have done, using the methodology I was first trained to use at FDA for clinical review and health risk assessment, as well as my scientific and medical education, professional training, and experience, I have reached the following opinions regarding the actions of the defendants. The documents reviewed are the same general types of documents I would have reviewed at the FDA, including the medical literature, adverse events reports, complaints, marketing application documents, manufacturing documents, clinical trials, preclinical data, and communications with the FDA. I have also reviewed corporate documents that have been obtained through discovery and deposition.

Based upon this explanation as well Dr. Parisian's knowledge and experience, the Court finds that Dr. Parisian's reasoning or methodology is reliable. Dr. Parisian's opinions are based on more than a subjective belief or unsupported speculation; they are based on the same methodology she utilized while at the FDA. This type of experience makes Dr. Parisian's methodology reliable. See *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d at 190 ("The Court further finds that Dr. Parisian has followed an appropriate methodology.").

### **Whether the Proposed Testimony Will Assist the Trier of Fact?**

Lastly, the Court must determine whether the testimony will assist the trier of fact with its analysis of any of the issues involved in the case. *Smith*, 215 F.3d at 718. In doing so, "the trial court is not compelled to exclude the expert just

because the testimony may, to a greater or lesser degree, cover matters that are within the average juror's comprehension." *Ancho*, 157 F.3d at 519 (quoting *Hall*, 93 F.3d at 1342). Still, if the expert testimony is obvious to a layperson, expert testimony would be useless. *Ancho*, 157 F.3d at 519.

Here, the Court finds that Dr. Parisian's testimony would not be useless to the jury, and will assist the trier of fact. Her expertise and experience will certainly be helpful to the jury's understanding of this complicated industry. See *Tyus*, 102 F.3d at 26 (finding it error to exclude the testimony of the expert prepared to testify about the way an advertising campaign sends a message to its target market and how an all-White campaign affects African Americans when "[t]his kind of social research, which would demonstrate the way one of the most important industries in our country actually operates, would have given the jury a view of the evidence well beyond their everyday experience.").

#### **Uncontrollable or Unhelpful Witness**

Defendants' first contention is that Dr. Parisian's testimony should be excluded because she is an uncontrollable and unhelpful witness who refuses to answer questions asked of her and would therefore confuse the jury, delay the trial, and unfairly prejudice Bayer. To support this argument, defendants rely heavily on two district court cases – *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323 (S.D. Fla. 2010) and *In re Prempro Prods. Liab. Litig.*, 554 F.

Supp. 2d 871 (E.D. Ark. 2008) – where Dr. Parisian’s testimony was excluded. Defendants posit that Dr. Parisian’s behavior at her deposition in this case should render the same result. Specifically, defendants assert that Dr. Parisian repeatedly sought to evade questions regarding her core opinions, offered opinions that were not disclosed in her expert report, and demonstrated an eagerness to advocate for plaintiffs, regardless of whether the facts support her opinions. Plaintiffs argue that defendants attack on Dr. Parisian is not so much a *Daubert* challenge as it is an attack on her character and courtroom demeanor. The Court agrees.

Defendants’ arguments miss the mark. “[J]udges merely need to follow *Daubert* in making a Rule 702 determination,” *Naeem v. McKesson Drug Co.*, 444 F.3d 593, 608 (7th Cir. 2006), but defendants argument fails to articulate why Dr. Parisian’s testimony is neither relevant nor reliable and the Court has found that it is. *Daubert*, 509 U.S. at 589. First, defendants do not dispute that Dr. Parisian is an expert. Second, defendants fail to explain why Dr. Parisian’s reasoning or methodology is reliable. And lastly, while defendants contend that Dr. Parisian’s testimony will confuse the jury, defendants fail to explain how, and this Court finds that Dr. Parisian’s testimony will not confuse the jury but rather will assist the jury in its analysis by testifying to matters beyond what is obvious to a layperson. What defendants seem to be complaining about is Dr. Parisian’s credibility, but that matter is a factual inquiry left to the jury’s determination. See

*Smith*, 215 F.3d at 718 (citing *Walker*, 208 F.3d at 589-90). Numerous courts have found Dr. Parisian to be reliable expert witness. If Dr. Parisian behaves as defendants contend she will, defendants can certainly make objections at that time.

### **Factual Narratives and Summaries**

Defendants next argue that Dr. Parisian fails to offer reliable testimony and instead seeks to advocate for plaintiffs as a regulatory historian who draws factual and legal conclusions based on her review of a select set of regulatory and Bayer documents chosen by plaintiffs' counsel. Defendants propose that “[n]early all of Dr. Parisian’s proposed testimony at trial would consist of a factual history of Yasmin and YAZ and Dr. Parisian reading or summarizing internal Bayer documents for the jury.” Defendants contend that this testimony does not require the “specialized knowledge” contemplated by Rule 702, but rather is mere advocacy on plaintiff’s behalf.

As the Court has previously noted, the Court has broad discretion over the mode and order of examining witnesses and presenting evidence and may allow testimony in narrative form at trial if the Court finds that it would helpful to the jury. See FED. R. EVID. 611; *Pless*, 982 F.2d at 1123 (“Fed. R. Evid. 611(a) provides district judges with authority to allow testimony in narrative form rather than as answers to specific questions [citations omitted], and we ourselves have

said that ‘there is . . . nothing particularly unusual, or incorrect, in a procedure of letting a witness relate pertinent information in a narrative form as long as it stays within the bounds of pertinency and materiality’ (*United States v. Garcia*, 625 F.2d 162, 169 (7th Cir. 1980).”); *Hutter N. Trust*, 467 F.2d at 1078 (finding the denial of a *pro se* plaintiff’s request to testify in the narrative form well within the proper exercise of the judge’s discretion). The same holds true with regard to testimony in summary format. See *Pree*, 408 F.3d at 869-71 (finding summary witness’s testimony was properly admitted in criminal tax prosecution, because witness relied only on evidence already in record and he was available for cross-examination); *Petty*, 132 F.3d at 379 (finding the since the court could have admitted the charts under Rule of Evidence of 1006 (although it did not), it did not abuse its discretion in allowing the witness to testify as to their contents under Rule 611(a)); *Swanquist*, 161 F.3d at 1072-73; FED. R. EVID. 1006 (“The proponent may use a summary, chart, or calculation to prove the content of voluminous writings, recordings, or photographs that cannot be conveniently examined in court.”). Such matters will be decided at trial in context specific situations and will be ruled upon then. The Court’s rulings on these matters will likely be impacted by whether the evidence that the narrative or summary relates to is admitted. Moreover, if evidence is admitted in narrative or summary form, defendants will have an opportunity during cross-examination or presentation of its own evidence to address any concerns defendants might have. See *Pree*, 408

F.3d at 871 (“Where . . . the defense conducted a thorough cross examination of the witness concerning the disputed matters, and also had the opportunity to present its own version of those matters, the likelihood of any error in admitting summary evidence diminishes.”) (quoting *Norton*, 867 F.2d at 1363).

### **Intent, Motive, or State of Mind**

Defendants also assert that Dr. Parisian cannot testify about Bayer’s “intent, motives or states of mind” because she has no basis in any relevant body of knowledge or expertise. Plaintiff counter that Dr. Parisian is not being proffered to provide any unsupported opinions on the intent of Bayer, but rather she will explain the FDA’s regulatory system to the jury and explain the ways in which Bayer failed to comply with those regulations. Plaintiff explains that to the extent Dr. Parisian refers to Bayer’s knowledge or intent, she cites to the evidence on which her statements are based.

Dr. Parisian specifically states in her report that “[t]here are no unsupported opinions intended to be offered regarding the ‘state of mind’ or ‘intent’ of Bayer regarding its actions for marketing of Yasmin and Yaz” and plaintiffs assert that Dr. Parisian is not being proffered to provide any unsupported opinions on the intent of Bayer. Accordingly, defendants’ motion in this regard is moot. If Dr. Parisian attempts to testify to such matters at trial, defendants can make an appropriate objection at that time. See *DePaepe*, 141

F.3d at 720 (“He could give an opinion as an engineer that reducing the padding saved a particular amount of money; he might testify as an engineer that GM’s explanation for the decision was not sound (from which the jury might infer that money was the real reason); but he could not testify *as an expert* that GM had a particular motive.”).

### **Methodology**

Defendants next propose that Dr. Parisian’s narrative testimony is inadmissible because she does not use reliable methodology to reach her opinions in that Dr. Parisian’s review was constrained by the documents plaintiffs’ counsel selected for her. Plaintiffs counters that Dr. Parisian did not have to review all potentially relevant documents. Plaintiffs suggest that if Dr. Parisian failed to consider some material document or other information, that would be a matter for cross-examination, not a basis to exclude her testimony. Furthermore, plaintiffs contend that Dr. Parisian’s analysis of the documents and testimony is consistent with the material she employed at the FDA to determine and assess regulatory compliance.

As the Court indicated earlier, the Court finds Dr. Parisian’s methodology to be reliable. Her experience at the FDA uniquely qualifies her to apply the methodology she applied at the FDA to the facts at issue in this case. Moreover, the Court agrees with plaintiff’s assessment that if Dr. Parisian did not review a

relevant document, that would something defendants could raise on cross-examination and is not a reason to exclude her testimony.

### **Legal Conclusions**

Further, defendants aver that Dr. Parisian may not opine about the meaning of specific FDA regulations or whether Bayer violated those regulations because such testimony would usurp the role of the Court in instructing the jury on the law and invade the province of the jury in applying the law to the facts of the case. Plaintiffs contend that Dr. Parisian does not seek to offer any impermissible legal opinions, but rather Dr. Parisian seeks provide statements of her understanding, as an expert working in the field, of what the applicable regulations require and her expert analysis of the facts. Moreover, plaintiffs argue that these issues require the specialized knowledge and expertise of an FDA regulatory expert who will assist the jury with understanding these regulations, requirements, and procedures, and defendants' compliance or non-compliance with them.

Here, the Court finds that Dr. Parisian's testimony is permissible because of the complex nature of the process and procedures and the jury needs assistance understanding it. As the court in *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164 (S.D. N.Y. 2009), observed based upon a similar objection and directly involving Dr. Parisian:

A lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care in the pharmaceutical industry. [The expert's] assessment of the reasonableness of Merck's conduct in light of her experience and her understanding of FDA regulations will be helpful to the jury. An expert may offer testimony embracing an ultimate issue of fact that the jury will decide. Fed. R. Evid. 704(a). Cross-examination and competing expert testimony by Merck's regulatory experts will ensure that the jury carefully weighs her testimony.

*Id.* at 190-91. Similarly here, Dr. Parisian's testimony will assist the trier of fact in understanding the federal regulations, and the jury will be instructed that that the Court, not Dr. Parisian nor any other witness, will instruct the jury on the law in this case.

### **Lack of Expertise**

Defendants also proffer that Dr. Parisian lacks expertise to offer opinions related to epidemiology, hematology, or pharmacokinetics. Plaintiffs argue that Dr. Parisian does not hold herself out as an expert in epidemiology, hematology, and pharmacokinetics, but rather holds herself out as a highly trained pathologist and FDA expert who has a substantial experience and background in each of those areas. Further, plaintiffs suggest that while Dr. Parisian does not need to rely on epidemiological, hematological, and pharmacokinetic experts to support her opinions, if she did, she would be qualified to rely on such experts.

Here, plaintiffs contend that Dr. Parisian does not need to rely on epidemiological, hematological, and pharmacokinetic experts to support her

opinions and does not hold herself out as an expert in epidemiology, hematology, and pharmacokinetics. Thus, defendants argument appears to be moot. Nevertheless, based upon Dr. Parisian's education and experience, including training in epidemiology while at the FDA, it would appear reasonable for Dr. Parisian to rely on epidemiological, hematological, and pharmacokinetic experts to support her opinions. See, e.g., *Doe*, 971 F.2d at 385 ("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*, 388 F.3d at 978-79; *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)).

### **Foreign Regulatory Matters**

Defendants further suggest that Dr. Parisian cannot testify about foreign regulatory matters because this testimony is beyond the scope of her expertise and is irrelevant. Plaintiff disputes this, arguing that Dr. Parisian may testify about foreign regulatory events because these events – which do not require Dr. Parisian to be an expert in foreign regulatory matters – are highly relevant to show

what Bayer knew and what it could have, and should have done in the United States. The Court agrees with plaintiffs.

Dr. Parisian can give opinions within her area of expertise about what she has reviewed in this case, including facts, i.e., foreign regulatory matters that have occurred, that are relevant to her opinions. 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.”). “[A]ny questions or problems concerning the expert’s testimony may be thoroughly explored during cross-examination of the witness.” *Gonzalez*, 933 F.2d at 429. 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.

### ***Buckman***

Finally, defendants contend that Dr. Parisian may not testify about inadmissible issues or matters for which she lacks expertise. Specifically, defendants argue that Dr. Parisian’s testimony that Bayer failed to disclose information properly to the FDA is foreclosed by *Buckman* and 21 U.S.C. § 337. Plaintiffs disagree, contending that *Buckman* does not pre-empt evidence of Bayer’s failure to timely inform the FDA of information relating to Yasmin and YAZ. Rather, plaintiffs’ position is that this evidence is not offered in support of any claim that Bayer defrauded the FDA, but rather the evidence is used to prove

Bayer's knowledge and is relevant to prove Bayer's violations of FDA regulations, which may be proved in support of plaintiffs' product liability claims.

In *Buckman*, patients claimed to have suffered injuries from implantation of orthopedic bone screws into their spines. The patients brought suit alleging that a regulatory consultant to the manufacturer made fraudulent representations to the FDA in the course of obtaining approval to market the screws. The Supreme Court held that state-law fraud-on-the-FDA claims were pre-empted by federal law, specifically the FDCA, as amended by the MDA, 21 U.S.C. § 301. 531 U.S. at 348. The Court found that the FDA was empowered to punish and deter fraud against the FDA, and that by allowing fraud-on-the-FDA claims under state tort law, the FDA's authority might be skewed. *Id.*

Here, *Buckman* does not pre-empt evidence of when Bayer informed the FDA of information relating to Yasmin and YAZ. *Buckman* is a claim preemption case focusing on fraud-on-the-FDA claims, not an evidence preemption case. See *Bausch*, 630 F.3d at 557 ("But the *Buckman* court specifically distinguished such 'fraud-on-the-agency' claims, i.e., claims not related to a field of law that states had traditionally occupied, from claims based on state law tort principles . . ."). Further, a comparison between *Buckman* and the landmark case *Wyeth v. Levine*, 555 U.S. 555 (2009), demonstrates exactly why *Buckman* is completely distinguishable from this case and why there is no way to analyze *Buckman* to

have any impact on this case. The Supreme Court made clear in *Wyeth* that federal law does not prevent judges and juries in failure to warn cases from considering a drug companies compliance with FDA regulations. *Wyeth*, 555 U.S. at 568-73.

### **Conclusion**

For the reasons stated above, defendants' motion to exclude the expert testimony of Dr. Parisian (Doc. 2026) is denied.

### **D. Motion to Exclude the Testimony of Cheryl D. Blume**

#### **Defendants' Position**

Defendants contend (1) that Dr. Blume's legal conclusions about federal law usurp the role of the court to instruct on the law and the province of the jury to apply that law to the facts; (2) that Dr. Blume's labeling opinions are not grounded in objective standards of expertise but rather, her own narrative interpretation of the facts; (3) that Dr. Blume's marketing opinions invade the province of the Court and jury and are unreliable; (4) that Dr. Blume's testimony that Bayer failed timely to provide information to the FDA is foreclosed by *Buckman*; and (5) that Dr. Blume's testimony regarding foreign regulatory actions is not grounded in relevant expertise and is irrelevant.

### **Plaintiffs' Position**

Plaintiffs contend that in her report, Dr. Blume expresses, explains, and meticulously substantiates her opinion that, by promoting their products for unproven uses and also neglecting to warn of escalating safety signals, Bayer failed to properly advise healthcare providers and their patients of the escalating negative benefit-risk properties associated with YAZ and Yasmin.

### **Dr. Blume's Proffered Testimony**

While it would have been helpful for plaintiffs to point out specifically what Dr. Blume was being tendered to testify about rather than just generally defending the expert's report, Dr. Blume's report is insightful on this issue. In her report, Dr. Blume states that based on her education, training, and experience, she has been asked to address 1) Bayer's actions (or failures to act) regarding the notification of prescribers and patients of pertinent safety information bearing on the risk of thrombotic/thromboembolic events associated with the use of their marketed Yasmin and YAZ; 2) Bayer's marketing efforts to promote Yasmin/YAZ for indications not approved by the FDA; and 3) that by promoting their products for unproven uses and also neglecting to warn of escalating safety signals, Bayer failed to properly advise healthcare providers and their patients of the escalating negative benefit-risk properties associated with YAZ and Yasmin.

Moreover, Dr. Blume gave the following conclusions in her report:

Evidence supporting an increased risk of venous thromboembolic events associated with the drospirenone-containing oral contraceptives Yasmin and Yaz relative to second generation products has steadily accumulated subsequent to the 2001 United States approval of Yasmin. Support for this increased risk has come from a number of sources, including clinical trial reports of venous thromboembolism, concerns expressed by drug regulatory agencies regarding the potential increased risk of venous thromboembolism, pharmacokinetic studies demonstrating procoagulatory changes in hemostatic parameters, spontaneous adverse event reports of thrombotic and thromboembolic events contained in postmarketing safety databases, and a prescription event monitoring study demonstrating an increased reporting rate for Yasmin. These results have been further supported by subsequent epidemiologic investigations noting that the risk of venous thromboembolism associated with drospirenone-containing contraceptives is more than double the risk of second generation products. Despite this mounting evidence, which supported a product labeling update (Yasmin) regarding venous thromboembolism as early as 2003, Bayer failed to properly incorporate new information concerning the increased risks of venous thromboembolism in the Yasmin/Yaz product labeling.

Though oral contraceptives as a class have been associated with an increased risk of venous thrombotic events, the labeling for particular products has been differentiated to highlight greater risks in those products where information suggests greater cause for concern. For example, so-called third generation agents have wording specifying an increased risk associated with their products. Relatedly, individual products have been differentiated based on information specific to those products. For example, the product labeling for the contraceptive Depo-Provera (medroxyprogesterone acetate injectable suspension) was updated (addition of a Boxed Warning ) in 2004 based on the results from two Postmarketing studies (Pfizer, November 18, 2004 Dear Healthcare Professional Letter). Moreover, the thrombotic-related risks associated with Ortho Evra are discussed in their 2006 labeling and note varying epidemiology study results. As information developed in the marketed use of Yasmin and later Yaz, Bayer could have (and should have) submitted a CBE for a changed label to reflect information concerning increased risk of venous thromboembolic events associated with Yasmin and Yaz.

Bayer's failure to update the respective labeling for Yasmin and YAZ occurred during a period in which the company was repeatedly cited by FDA for violative marketing practices, including off-label promotions. This lack of proper warning information in the Yasmin and YAZ product labeling is especially concerning because use was being promoted, and patients were receiving the drugs, for unproven and off-label uses. Prescribers and their patients should have been provided with up to date information concerning thrombotic and thromboembolic risks as the evidence became available. Unfortunately, a number of actions undertaken by Bayer, including delayed communication of safety data, had the effect of minimizing the serious potential risks associated with Yasmin and YAZ. The opinions in this report are held to a reasonable degree of scientific certainty.

Because many of defendants arguments do not involve a *Daubert* analysis at all, but rather go to objections that may be raised at trial or to issues that would have been more properly brought in motions limine, the Court begins by conducting a *Daubert* analysis generally, and then will address each of defendants' arguments specifically.

### **Whether Dr. Blume Qualifies as an Expert?**

First, the district court must determine whether Dr. Blume is an expert through "knowledge, skill, experience, training or education." *Ervin*, 492 F.3d at 904 (citing FED. R. EVID. 702). Dr. Blume received her Ph.D. in pharmacology and toxicology from the West Virginia Medical Center where she was a recipient of a predoctoral fellowship from the National Institute of Health. Currently, she is president of Pharmaceutical Development Group, Inc., a consulting firm specializing in pharmaceutical development and registration activities. Prior to

that, Dr. Blume held several executive positions in pharmaceutical companies for over twenty years, including serving as vice president of scientific affairs for Mylan Laboratories, Inc. and as the executive vice president and chief operations officer for Somerset Pharmaceuticals, Inc., where she was a member of the board of directors. Dr. Blume has been responsible for preclinical and clinical programs associated with pharmaceutical product development and the securing of pre-marketing approvals for over 100 prescription drugs from the FDA, including the design, execution, and interpretation of pivotal preclinical and clinical trials. She also directed all phases of interactions with the FDA relating to the prosecution of New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), Supplements to New Drug Applications (sNDAs), and the approval process, including the collection and evaluation of post marketing adverse medical events, the preparation of amplified product labeling, and the dissemination of updated product information to health care providers, patients, and consumers. Dr. Blume has also been responsible for the regulatory review of promotional and educational materials for both brand-name and generic drug products. Based upon Dr. Blume's extensive experience, as well as her knowledge, skill, education, and training, the Court finds that Dr. Blume is qualified to testify as an expert for things she states she was asked to address in her report. See also *Daniel v. Wyeth Pharms., Inc.*, 15 A.3d 909, 926 (Pa. Super Ct. 2011) (finding sufficient evidence of record to permit the trial court to find that Dr. Blume qualified as a

satisfactory “medical expert” and “labeling expert”); *In re Neurontin Mktg., Sales Practices, & Prods. Liab. Litig.*, 612 F. Supp. 2d 116, 163 (Mass Dist. 2009) (concluding that Dr. Blume is amply qualified at least to evaluate the adverse event data and other resources of information regularly used by the FDA and industry professionals); *Wright v. Am. Home Prods. Corp.*, 557 F. Supp. 2d 1032, 1038 (W.D. Mo. 2008) (finding that Dr. Blume is clearly qualified to testify about the risks and benefits of Pondimin as it relates to general industry practice and she is qualified as to any general industry standards Wyeth followed or failed to follow prior to marketing and distributing Pondimin, but she was not permitted to testify as to Wyeth’s intent in failing to abide by industry standards, unless she had specific knowledge related to Wyeth’s specific intent, which would be addressed at trial).

**Whether Dr. Blume’s Reasoning or Methodology is Reliable?**

Second, the Court must determine whether Dr. Blume’s reasoning or methodology is reliable. Dr. Blume bases her reasoning based upon her education, training, and experience, and after the review of countless articles, studies, documents, depositions, and exhibits relevant to this case. Specifically, Dr. Blume refers to number of sources in her report, including clinical trials, studies, epidemiologic investigations, events contained in post marketing databases, and more. She then combines this with her knowledge, training, and experience in the industry to form her opinions. The Court finds that Dr. Blume’s

method of forming her opinions is reliable. The Court does not comment as to the correctness of Dr. Blume's opinions, but finds that Dr. Blume bases these opinions on a reliable reasoning.

### **Whether the Proposed Testimony Will Assist the Trier of Fact?**

Lastly, the Court must determine whether the testimony will assist the trier of fact with its analysis of any of the issues involved in the case. *Smith*, 215 F.3d at 718. In doing so, "the trial court is not compelled to exclude the expert just because the testimony may, to a greater or lesser degree, cover matters that are within the average juror's comprehension." *Ancho*, 157 F.3d at 519 (quoting *Hall*, 93 F.3d at 1342). Still, if the expert testimony is obvious to a layperson, expert testimony would be useless. *Ancho*, 157 F.3d at 519.

Here, the Court finds that Dr. Blume's testimony would not be useless to the jury, and will assist the trier of fact. Dr. Blume has been asked to testify about Bayer's actions associated with Bayer's marketing efforts of Yasmin/YAZ based upon her experience in the pharmaceutical industry for over twenty years. Her expertise and experience will certainly be helpful to the jury's understanding of this complicated industry. See *Tyus*, 102 F.3d at 263 (finding it error to exclude the testimony of the expert prepared to testify about the way an advertising campaign sends a message to its target market and how an all-White campaign affects African Americans when "[t]his kind of social research, which

would demonstrate the way one of the most important industries in our country actually operates, would have given the jury a view of the evidence well beyond their everyday experience.”).

### **Legal Conclusions**

Defendants contend that Dr. Blume’s legal conclusions about federal law usurp the role of the Court to instruct on the law and the province of the jury to apply that law of the facts. Specifically, defendants argue that Dr. Blume offers a series of legal conclusions about the meaning and scope of the FDA regulations, about Bayer’s federal law duties, including FDA regulations, and about the duties of pharmaceutical companies under FDA regulations. Plaintiff disagrees, contending that Dr. Blume does not seek to offer any impermissible legal opinions. Rather, plaintiffs argue Dr. Blume’s statements are not legal conclusions, but are merely Dr. Blume’s statements of her understanding, as an expert working in this field, of what the applicable regulations require.

The Court agrees with plaintiffs. At her deposition, Dr. Blume testified to what she believed to be required from a regulatory perspective and from industry standards through her experience, not from a legal perspective. To the extent, Dr. Blume does offer legal conclusions, the Court finds that Dr. Blume’s testimony is permissible because of the complex nature of the process and procedures and the jury needs assistance understanding it. Dr. Blume’s testimony will assist the trier

of fact in understanding the federal regulations, and the jury will be instructed that that the Court, not Dr. Blume nor any other witness, will instruct the jury on the law in this case.

### **Narrative/Marketing Testimony**

Defendants next quarrel with Dr. Blume's proposed testimony criticizing Bayer's FDA-approved labeling and opine that a number of "events should have prompted Bayer to strengthen the respective Yasmin and YAZ labels regarding thromboembolic events in a timely manner." Defendants suggest that these opinions are inadmissible because they are not grounded in FDA regulations or other established standards but instead are based upon Dr. Blume's narrative description of documents that she lacks the expertise to evaluate or analyze under the relevant regulatory standards. In detail, defendants seeks to have Dr. Blume's labeling opinions excluded because they are not grounded in expert analysis and because she lacks the expertise to evaluate scientific data as part of her labeling opinions. Defendants base this argument in part on the fact that Dr. Blume's labeling opinions purport to assess scientific evidence, including adverse event reports, epidemiological studies, and case reports from the scientific literature, but Dr. Blume is not a medical doctor, an epidemiologist, or a statistician, and she admits to relying on a trained epidemiologist and statistician hired by her

office. Defendants further argue that Dr. Blume's factual narrative and speculation about Bayer's knowledge, motives, or intent should be excluded.

Defendants also argue that Dr. Blume's marketing opinions are inadmissible because she applies no objective standards, but instead gives a narrative summary of regulatory and Bayer documents for which she is particularly ill-suited given her lack of sales and marketing experience. First, defendants assert that Dr. Blume's proposed marketing testimony consist largely of an impermissible narrative summary of Bayer documents and communications between Bayer and the DDMAC, peppered with Dr. Blumes' personal views of Bayer's motive and intent and what the documents show. Second, defendants argue that Dr. Blume's marketing opinions are unreliable because they are not based on any expert analysis. Third, defendants propose that Dr. Blume's summary of DDMAC letters and Bayer documents is particularly inappropriate given that her lack of experience in the sales and marketing of prescription drugs and her limited interaction with DDMAC render her unqualified to draw conclusions about Bayer's alleged off-label marketing of Yasmin and YAZ.

First, as the Court has previously found, Dr. Blume's education, training, and experience qualify her to provide expert testimony regarding marketing opinions in this case. While Dr. Blume is not a medical doctor, she does have a Ph.D. in pharmacology and toxicology and has more than twenty years' experience

in the pharmaceutical industry, specifically dealing with the marketing for over 100 prescription drugs.

Second, as to defendant's argument regarding narrative testimony, the Court has broad discretion over the mode and order of examining witnesses and presenting evidence and may allow testimony in narrative form at trial if the Court finds that it would be helpful to the jury. See FED. R. EVID. 611; *Pless*, 982 F.2d at 1123 ("Fed. R. Evid. 611(a) provides district judges with authority to allow testimony in narrative form rather than as answers to specific questions [citations omitted], and we ourselves have said that 'there is . . . nothing particularly unusual, or incorrect, in a procedure of letting a witness relate pertinent information in a narrative form as long as it stays within the bounds of pertinency and materiality' (*United States v. Garcia*, 625 F.2d 162, 169 (7th Cir. 1980))."); *Hutter N. Trust*, 467 F.2d at 1078 (finding the denial of a *pro se* plaintiff's request to testify in the narrative form well within the proper exercise of the judge's discretion). Such matters will be decided at trial in context specific situations and will be ruled upon then.<sup>6</sup> The Court's rulings on these matters will likely be impacted by whether the evidence that the narrative relates to is admitted. Moreover, if evidence is admitted in narrative form, defendants will have an

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<sup>6</sup> This also applies to defendants' arguments about whether Dr. Blume is testifying about someone else's state of mind. Plaintiffs dispute that Dr. Blume testifies or is going to testify about these matters, and if such testimony is elicited at trial, defendants may object to it at that time.

opportunity during cross-examination or presentation of its own evidence to address any concerns defendants might have. See *Pree*, 408 F.3d at 871 (“Where . . . the defense conducted a thorough cross examination of the witness concerning the disputed matters, and also had the opportunity to present its own version of those matters, the likelihood of any error in admitting summary evidence diminishes.”) (quoting *Norton*, 867 F.2d at 1363).

Third, the Court rejects Bayers’ argument that Dr. Blume may not ground any of her opinions on the opinions of others. Rule 702 states that an expert’s testimony must be “based on sufficient facts or data.” FED. R. EVID. 702. Dr. Blume may rely on the epidemiological opinions and statistics of other experts employed by her office. 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.”

## ***Buckman***

Defendants contend that Dr. Blume's testimony that Bayer failed to timely provide information to the FDA is foreclosed by the Supreme Court's decision in *Buckman*. Specifically, defendants argue that Dr. Blume proffered legal conclusions that Bayer failed to provide timely information to the FDA in violation of the FDCA and that these conclusions should be excluded because they contravene the holding in *Buckman* and 21 U.S.C. § 337. Plaintiffs argue that contrary to Bayer's arguments, *Buckman* does not preempt evidence of Bayer's failure to timely inform the FDA of information relating to Yasmin and YAZ. Plaintiffs suggest that this evidence is not offered in support of any claim that Bayer defrauded the FDA. Rather, the evidence is relevant to prove Bayer's knowledge, and it is relevant to prove Bayer's violations of FDA regulations which may be proved in support of plaintiffs' product liability claims.

In *Buckman*, patients claimed to have suffered injuries from implantation of orthopedic bone screws into their spines. The patients brought suit alleging that a regulatory consultant to the manufacturer made fraudulent representations to the FDA in the course of obtaining approval to market the screws. The Supreme Court held that state-law fraud-on-the-FDA claims were pre-empted by federal law, specifically the FDCA, as amended by the MDA, 21 U.S.C. § 301. 531 U.S. at 348. The Court found that the FDA was empowered to punish and deter

fraud against the FDA, and that by allowing fraud-on-the-FDA claims under state tort law, the FDA's authority might be skewed. *Id.*

Here, *Buckman* does not pre-empt evidence of when Bayer informed the FDA of information relating to Yasmin and YAZ. *Buckman* is a claim preemption case focusing on fraud-on-the-FDA claims, not an evidence preemption case. See *Bausch*, 630 F.3d at 557 (“But the *Buckman* court specifically distinguished such ‘fraud-on-the-agency’ claims, i.e., claims not related to a field of law that states had traditionally occupied, from claims based on state law tort principles . . . .”). Further, a comparison between *Buckman* and the landmark case *Wyeth v. Levine*, 555 U.S. 555 (2009), demonstrates exactly why *Buckman* is completely distinguishable from this case and why there is no way to analyze *Buckman* to have any impact on this case. The Supreme Court made clear in *Wyeth* that federal law does not prevent judges and juries in failure to warn cases from considering a drug companies compliance with FDA regulations. *Wyeth*, 555 U.S. at 568-73.

### **Foreign Regulatory Testimony**

Defendants also argue that Dr. Blume seeks to testify about foreign regulatory standards and to opine that certain actions taken by foreign regulatory bodies related to Yasmin and YAZ should have influenced the labeling of those drugs in the United States. Defendants contend that this testimony is

inadmissible because it is beyond the scope of Dr. Blume's expertise and is irrelevant. Plaintiff counters that Dr. Blume is not and does not claim to be an expert in foreign regulatory matters, but that does not mean that she is unqualified to rely on events concerning Yasmin and YAZ, such as labeling actions, that took place in other countries. The Court agrees.

Dr. Blume does not claim to be an expert in foreign regulatory matters, but rather refers to foreign events that she has reviewed. Dr. Blume can certainly testify about any reliable and relevant foreign events that she has reviewed. See FED. R. EVID. 703 ("An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed."). "[A]ny questions or problems concerning the expert's testimony may be thoroughly explored during cross-examination of the witness." *Gonzalez*, 933 F.2d at 429. 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.

### **Conclusion**

For the reasons stated above, defendants' motion to exclude the testimony of Dr. Blume (Doc. 2016) is denied.

## **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. 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.

**IT IS SO ORDERED.**

Signed this 16th day of December 2011.

  David R. Herndon  
2011.12.16  
17:11:50 -06'00'

**Chief Judge**  
**United States District Court**