**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLORADO**
**Chief Judge Marcia S. Krieger**

**Civil Action No. 13-cv-02070-MSK-CBS**

**JENNIFER HEINEMAN; and**
**ERIC ALLEN HEINEMAN,**

**Plaintiffs,**

**v.**

**AMERICAN HOME PRODUCTS CORPORATION;**
**WYETH-AYERST PHARMACEUTICALS, INC;**
**WYETH-AYERST INTERNATIONAL, INC.; and**
**WYETH-AYERST LABORATORIES DIVISION OF AMERICAN HOME PRODUCTS CORPORATION,**

**Defendants.**

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**OPINION AND ORDER GRANTING IN PART AND DENYING IN PART MOTION FORRECONSIDERATION**

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**THIS MATTER** comes before the Court pursuant to the Plaintiffs' Motion for Reconsideration **(# 81)**, the Defendants' response **(# 90)**, and the Plaintiffs' reply **(# 93)**. The motion seeks reconsideration of the Court's November 14, 2014 oral ruling **(# 78)** excluding certain opinions proffered by the Plaintiffs' expert, Cheryl Blume, pursuant to Fed. R. Evid. 702.

## FACTS

The Court assumes the reader's familiarity with the proceedings to date. Greatly summarized, the Plaintiffs bring a variety of product liability and other tort claims against the Defendants, arising from the Defendants' manufacture and sale of weight-loss drugs called Pondimin and Redux. The Defendants eventually withdrew the drug from the market after studies revealed that it caused harmful side effects. Ms. Heineman used Pondimin and Redux

while they were being actively marketed by the Defendants and claims that she suffered permanent injuries as a result.

Both sides designated expert witnesses who they intended to call at trial and, consonant with this Court's procedures, sought a pre-trial determination as to whether certain opinions proffered by the other side's expert conformed to the foundational requirements of Fed. R. Evid. 702. The Court held a Rule 702 hearing on November 4, 2014 and ruled on the various objections to the proffered opinions. Pertinent here are the Plaintiffs' proffer of two opinions by Dr. Cheryl Blume. As denominated in the Rule 702 Motion: (i) Opinion 2, that "the risks associated with ingesting diet drugs manufactured by [the Defendants] outweighed the benefits to patients by 1995"; and (ii) Opinion 3, that "corporate documents demonstrate that [the Defendants] failed to conform to the standard of care for post-market safety surveillance of its diet drugs" (along with certain additional opinions discussed below). As explained in more detail below, the Court excluded Opinion 2 on the grounds that Dr. Blume lacked the requisite knowledge or experience to render such an opinion, and the Court excluded the second opinion on the grounds that the opinion was not the product of a reliable methodology.

The Plaintiffs have moved **(# 81)** for reconsideration of that ruling, arguing that Dr. Blume's opinions do indeed meet the foundational requirements of Rule 702.

## ANALYSIS

### A. Standard of review

The Plaintiffs' motion is considered under Fed. R. Civ. P. 59(e). Relief under that rule is appropriate where there has been an intervening change in the law, newly discovered evidence, or where necessary to correct clear error or prevent manifest injustice. *Servants of the Paraclete v. Does*, 204 F.3d 1005, 1012 (10th Cir. 2000). This last category is typically reserved for

situations in which the Court misapprehended the facts, misunderstood a party's position, or failed to recognize the controlling law. *Id.* However, Rule 59(e) is not an appropriate means for a party to re-argue previously-asserted and rejected positions, nor does it grant a party an opportunity to present arguments that could have been made earlier but were not. *Id.*

**B. General principles of Rule 702**

Fed. R. Evid. 702 sets out **foundational requirements** that the proponent of expert testimony must satisfy to ensure that the testimony is reliable. Under the current version of Rule 702, the proponent must demonstrate that: (i) the witness' specialized knowledge or expertise will help the trier of fact to understand and evaluate the evidence; (ii) that the witness' testimony is the product of reliable principles or methods; (iii) the witness obtained sufficient facts and data to apply to the methodology; and (iv) the witness reliably applied the methodology to those facts. Fed. R. Evid. 702(a)-(d); *see generally Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993); *U.S. v. Crabbe*, 556 F.Supp.2d 1217, 1220 (D.Colo. 2008).

The touchstone of the Rule 702 inquiry is whether the testimony has a "reliable basis in the knowledge and experience of [the relevant] discipline." *Kumho Tire Co. v. Carmichael,* 526 U.S. 137, 149 (1999). Thus, a court's focus is on the proffered expert testimony or opinion, rather than simply on the witness' credentials. It is no longer sufficient to "qualify an expert" based on his/her credentials and then to expect that the witness can express any opinion within the area of his/her expertise.

Rule 702 requires the court to focus on the expert's opinion or testimony to ensure its reliability. Such focus is not on the merits or persuasiveness of the opinion or testimony, but rather on the method by with the opinion or testimony was derived. *Dodge v. Cotter Corp.*, 328 F.3d 1212, 1222 (10th Cir. 2003). Rule 702 requires that the proponent must demonstrate that the

testimony is "ground[ed] in the methods and procedures of science," not "subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590. Put another way, Rule 702 is testimony-centric rather than expert-centric.

As explained in more detail below, the Court's focus here is on two opinions by Dr. Blume. [1] The question presented is whether the record is sufficient to satisfy Rule 702(a) and 702(c).

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[1] At this juncture, the Court note that the Plaintiffs lean largely toward hyperbole in their arguments, and in doing so misinterpret the rulings of this Court and prior courts. For example, the Plaintiffs argue that "not a single court in the country – state or federal – has completely prohibited Dr. Blume from testifying, despite her appearances in multiple diet drug and hormone therapy cases."

This statement is fallacious for several reasons. First, it suggests that this Court prohibited Dr. Blume from testifying. That simply is not the case – the Rule 702 process focuses on opinions/testimony not on the witness, and the Court focuses only on the opinions challenged. Even if the statement is understood to mean that the Court excluded all opinions by Dr. Blume, it is not accurate. The parties designated only 3 opinions by for Dr. Blume to test under Rule 702. **[35]**. Presumably there were other opinions about which there was no foundational dispute. As to the three opinions at issue, only two are excluded for lack of adequate foundation. Even with regard to those opinions, the Court has pointed out in this decision and in the oral ruling how components of the opinions might be admissible. Finally, the statement fails to acknowledge multiple decisions that have limited Dr. Blume's testimony in precisely the way that this Court has. See: *Wilson v. Wyeth Inc.* (*In re Prempro Prods. Liab. Litig.*), MDL No. 4:03CV01507-WRW, No. 3:05CV00078-WRW, slip op. at 4-6 (E.D. Ark. Sept.16, 2010) (excluding opinions on the existence of a reasonable standard of care or a custom and practice regarding a duty to test);  *Ingram v. Wyeth Inc.* (*In re Prempro Prods. Liab. Litig.*), MDLNo. 4:03CV01507-WRW, No. 4:05CV00718-WRW, 2010 U.S. Dist. LEXIS142558, at *5-9 (E.D. Ark. Sept. 16, 2010) (excluding opinions on the existence of a reasonable standard of care or a custom and practice regarding a duty to test); *Lea v. Wyeth LLC*, No. 1:03-CV-01339, slip op. at 8-10, 14 (E.D. Tex. Oct. 6, 2011) (excluding opinions on defendants' intent or motive based on review of corporate documents, what a reasonable pharmaceutical company would have done or should have known or done, and breach of a purported standard of care based on a failure to perform additional testing);  *Chandler v. Greenstone Ltd.*, No. C04-1300RSL, 2012 WL 882756, at *1 (W.D.Wash. Mar. 14, 2012) (excluding opinions on defendants' state of mind, intent, or knowledge based on review of corporate documents and whether a prudent pharmaceutical company would have performed additional testing to ensure the safety of its products);  *Johnson v. Wyeth LLC*, No. CV 10-02690-PHX-FJM, 2012 WL 1204081, at *2-3 (D. Ariz. Apr. 11, 2012) (excluding opinions on defendants' motive, intent, knowledge, or other state of mind based on review of corporate documents, defendants' failure to act as a reasonable pharmaceutical company, and breach of

Rule 702(a) requires the proponent of the opinion to show that "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or determine a fact in issue". In assessing whether a proffered opinion meets this standard, courts "consider several factors, including whether the testimony is within the juror's common knowledge and experience, and whether it will usurp the juror's role of evaluating a witness's credibility." *U.S. v. Gutierrez de Lopez*, 761 F.3d 1123, 1136 (10th Cir. 2014). The court engages in a "common-sense inquiry into whether a juror would be able to understand certain evidence without specialized knowledge." *Id.* An expert opinion that simply "compar[es] a [defendant's] actions to the industry standard" may be excluded where "the jury was fully capable of deciding this [issue] without expert testimony." *North American Specialty Ins. Co. v. Britt Paulk Ins. Agency, Inc.*, 579 F.3d 1106, 1112 (10th Cir. 2009).

Rule 702(c) requires that "the testimony is the product of reliable principles and methods". This requirement can be satisfied in two ways. If the testimony is based on a scientific or another analytical approach, the court may consider a variety of factors set out *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), *Kuhmo Tire Co., v. Carmichael*, 526 U.S. 137 (1999) and their progeny. These factors include: (1) whether a theory has been or can be tested or falsified – that is, whether the expert's theory can be challenged in some objective sense or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) whether the theory or technique has been subject to peer review and publication; (3) whether there are known or potential rates of error

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a purported standard of care based on a failure to perform additional testing); and *Romero v. Wyeth Pharm., Inc.*, No. 1:03-cv-1367, slip op. at 5-9, 12 (E.D. Tex.Apr. 26, 2012) (excluding opinions on defendants' intent or motive based on review of corporate documents, what a reasonable pharmaceutical company would have done or should have known or done, and breach of a purported standard of care based on a failure to perform additional testing).

with regard to specific techniques; and (4) whether the theory or approach has "general acceptance" in the scientific community; (5) whether the expert employed the same degree of intellectual rigor in testifying as he would be expected to employ in his professional life; (6) whether the expert proposes to testify about matters growing naturally and directly out of research he or she conducted independent of the litigation or whether the expert developed opinions expressly for purposes of testifying; (7) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion (*i.e.,* whether there is too great an analytical gap between the data and the opinion proffered); (8) whether the expert adequately accounted for obvious alternative explanations; (9) whether the expert was as careful as he or she would be in regular professional work outside of paid litigation consulting; (10) whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give; (11) the extensiveness of the expert's credentials; (12) the expert's ability to articulate a process that he or she applied; (13) whether the industry adheres to a particular practice; and (14) whether the opinion consists of summary conclusions or broad generalizations based on perfunctory analysis with no supporting specifics.

Alternatively, if the testimony is the product of the only the witness' experience, the Comments following Rule 702 instruct that "the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts". The trial court's gatekeeping function requires "more than simply taking the expert's word for it." *Daubert*, 43 F3d 1311, 1319 (9th Cir 1995). "The more subjective and controversial the expert's inquiry the more likely the testimony should be excluded as unreliable. See O'Conner v. Commonwealth Edison Co., 13 F3d 1090 (7th Cir 1994) (expert testimony based on a completely subjective methodology held properly excluded)."

**C. Dr. Blume's opinions**

1. Opinion 2

Dr. Blume's Opinion 2 is that "[t]he risks associated with ingesting diet drugs manufactured by [the Defendants] outweighed the benefits to patients by 1995."

Dr. Blume is a pharmacologist. She worked with pharmaceutical corporations from 1977 to 1998, focusing her efforts on regulatory affairs. Since that time, she has assisted various clients applying for FDA approval of drug products, including preparing New Drug Applications, developing product labeling (including identification of the risks and benefits of drugs), and post-marketing evaluation of a drug's safety. She explained that the first "risk-benefit" examination of a drug occurs prior to FDA approval, during "Phase II" testing of a drug. At that point in time "you must demonstrate [to the FDA] that the product has clinical effect, and that the benefit of the product exceeds the risk." Once a drug is approved by the FDA (as Pondimin was), drug makers continue to look for "signals" of new or enhanced adverse effects. If such signals appear, drug makers may conduct "Phase IV" studies to further assess the situation or otherwise examine the additional data. The drug maker must then determine "whether the benefit of their product is such that it can justify all of the new risks that were observed following the launch of the product." If not, the drug maker might attempt to fix the situation with additional label warnings, but "if your post-marketing experiences demonstrate that the benefit of the drug can never justify the new adverse effects that you're seeing, that the benefit-risk relationship can never be positive, then the product is to be removed from the marketplace." Much of Dr. Blume's testimony focused on the "risk" side of that calculation –

that is, the drug maker's duties of "pharmacovigilance" or "scientific and data-gathering activities relating to detection, assessment, and understanding of adverse effects."

After several hours of general direct examination of Dr. Blume, the Court called counsel to the bench and observed that, thus far, the Plaintiffs' questioning of Dr. Blume, though extensive, had not begun to approach the Defendant's foundational challenges to the recited opinions. With the consent of counsel, the Court took over the examination of Dr. Blume.

The Court began by clarifying that Dr. Blume's opinion was that "the risks associated with ingesting diet drugs manufactured by [the Defendants'] outweighed the benefits to patients" during a time frame that Dr. Blume defined as "by the first half of 1995" until the drugs were withdrawn from the market in 1997. The Court then asked how Dr. Blume formulated that opinion.

Dr. Blume responded that she "asked for all the same documents . . . for which I would do it if I were conducting a new product review or safety assessment for a drug company." She assembled the documents she obtained chronologically, reviewed them, reviewed the relevant FDA regulations, and then reviewed "internal databases" maintained by the Defendants "to get a handle on how many [adverse] events were coming in." She then looked at benefit side of the risk-benefit equation:

> I felt I had enough knowledge of what happened in the early years to be able to look at the benefit versus the product. At that time when I first stated, it was Pondimin. The weight loss with Pondimin when used according to its labeling is very minor, it's a couple of pounds, when used just for the couple of months that is in their insert, the product was only recommended within their insert for a very short period of time. So my numerator became a couple of pound weight loss. They had done some independent studies that showed if you combined Pondimin with [unknown] you might actually have a total of 6-kilo weight loss over a period of time. 6 kilos, twelve to fifteen pounds, that's the benefit. The benefit, I learned, was not long-lasting. You had to [unknown] the

> drug, and when you discontinued the drug, the weight loss came back – the weight loss was lost. So I had a picture in my head of the total benefit of the product, anywhere between 3-pound weight loss if used the way you're supposed to with labeling, compared to up to 12 pounds if you used it if you used the way an independent study supporting in part by Wyeth had demonstrated. Either way, not long-term loss, rebounds after you go off the drug.

Dr. Blume testified that she balanced this benefit against evidence that, by 1995, indicated the potential for side effects causing heart disease or preliminary pulmonary hypertension. She stated that "in my mind for that de minimis and temporary and transitory weight loss, that is confirmed in the literature and in their own FDA regulations files for Pondimin alone and although not approved for Pondimin plus [unknown], that combination, that weight loss, that benefit cannot justify two very serious cardiovascular events . . ., one of which is always fatal. So that formed my opinion."

Dr. Blume then performed a similar task with the drug Redux (which the Defendants also manufactured and which Ms. Heineman used). Although "the weight loss with Redux was somewhat better than with Pondimin, [it] was of the same magnitude I mentioned earlier," and the same side effects were present, leading Dr. Blume to reach the same opinion regarding it. Simply put, Dr. Blume concluded that "I felt the weight loss that was seen, you couldn't justify marketing it . . . in lieu of those adverse events."

The Court inquired whether this retrospective risk-benefit review was something that Dr. Blume typically did. Dr. Blume responded that this was the first time she had done such a review in order to testify as an expert witness, but that in corporate practice, she would occasionally conduct retrospective risk-benefit reviews for existing drugs, such as when her company purchased the rights to domestically distribute a drug that was already in use overseas. She explained that "we would be given opportunities to license products, the same drill that I

gave you in such detail was also undertaken, and at the end of it, the pencil went down and we said 'we can't take the risk.' The benefits sometimes were great, but for our size company and the goals of our company, we couldn't take the risk of what we saw lurking in there."

The Court then asked whether "there [was] a regulation or policy or a standard of care or an industry standard that compels your conclusion". As to the benefit side of the equation, Dr. Blume explained "the efficacy component of it – I would assess the efficacy. . . For most products that are approved in the United States, it did not require [consultation with specialists]. I conducted it." Exploring that issue further, the following exchange occurred:

> THE COURT: Historically in your experience, when you made an efficacy decision, that efficacy decision was based on your assessment?
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> DR. BLUME: It was. It was. But I do say that – now, for something like weight loss, I would be able to do that assessment, and for those types of issues, I would not access others. . . .
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> THE COURT: When you assessed the risk, you were looking at it as, as you say, as a corporate officer, as a business decision: 'how much risk can we take if we bring this drug to the United States?,' is that right?
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> DR. BLUME: . . . First I have to look at it as a scientist. I'm a pharmacologist, toxicologist, and I would look at the safety data, and for those products that were already marketed in Europe, I would then have to look at the risk that they had in their labeling and would our company be able to tolerate that kind of risk. So the first was a scientific decision, the risk outweighs the benefit or I would look at it and say FDA regulations would never ever look at this data and allow the labeling used in Europe. . . . .
>
> THE COURT: Then let me go back to your opinion and make sure I understand. When you say the risks associated with ingesting diet drugs, here you're talking about the same kinds of risks that you assessed historically, which would be both business risks, safety risks, and labeling risks. Is that right?
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> DR. BLUME: Well, in this case, they had made the decision they were going to market these products, so that business decision had

already been made by Wyeth. What I was looking as was science. I was looking – the product is on the market, Pondimin is on the market, I'm going to pretend I'm working there and I'm going to look at the benefit of the drug versus the escalating risks of the drug. And all that was done within the platform of the labeling. My report notes labeling iteration after labeling iteration, and the goal was, in a drug company, you're looking at a moment in time and saying, here is my benefit data, here is the risk factor as of today, here is my labeling today, still adequate or not adequate? That's how I approached this because the product was already on the market. I wasn't making a decision for Pfizer whether they should have stayed on the market with it. I was looking at it just from the adequacy of the labeling in light of the escalating risks.

THE COURT: But your prior experience was limited to putting product on the market, is that right?

DR. BLUME: In general, it was a product that we wanted to put on the market in the United States. I recall a couple of instances where the company was thinking of purchasing the rights to a product . . . so and so is thinking of divesting, they can't detail it, they can't afford it, whatever it is. I would be asked to look at 'what do you think of the safety?', 'what do you think of its FDA regulations positioning?,' FDA records compliance, 'do you see any opportunities where we could go out and maybe do a combination product?' Those types of issues. I did have those types of experiences as well, where the product was being marketed, did we see benefit in marketing the product.

THE COURT: The benefit was a business benefit as well as a benefit to patients, is that right?

DR. BLUME: It was for the existing product, but the benefit of doing a combination product or increasing indications would have been both a benefit for patients – 'do I see a benefit in patients if I combine this product,' similar to what Maxzide. The two components already existed in the United States. They were marketed separately. Smith Klein and French had the rights and we had the combination. But we knew the combination wasn't adequately performing. The product was already marketed, it was a patient decision. We looked and said the product is so poorly made, studies so ancient, we have no idea the correct dose. We went to FDA regulations and said here is the data with the products, we want to do a combination that we think will be lower dosed . . . That's how that merger came together on that product.

> THE COURT: Thank you. Is there anything else about your knowledge, experience, skill, training, expertise, or education that you believe you drew upon in formulating this opinion?
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> DR. BLUME: The only other thing I think I can add is that I have experience in, as you saw on some of the exemplars, in disseminating information when new safety information becomes available . . . I have years of experience in identifying potential signals, doing the work to see if it is truly a signal, and then making the decision how is the best way to disseminate that information. . .
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> THE COURT: How does that inform your conclusion that the risks associated with ingesting diet drugs outweighed the benefit to these patients?
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> DR. BLUME: Well, my opinion that the risks outweighing the benefits were linked with the escalating risks – the benefits never change. The risks escalated. And one of the main points that I make is that while the product was on the market, that information . . . would have been to change the labeling to reflect the escalating information and to share that information with prescribers. . . .

Both parties were offered the opportunity to ask additional questions. The Defendants' cross-examination of Dr. Blume focused, in part, on the fact that Dr. Blume is not a medical doctor and had no particular knowledge or experience regarding the care of obese patients or the risks and benefits of bariatric surgery or other non-pharmaceutical treatments for obesity.

The Court found that the Plaintiffs failed to show that Dr. Blume had the necessary expertise to express Opinion 2. The Court explained as follows:

> . . . the opinion, as Dr. Blume explained, is a balancing between risk and benefit. The methodology here did not have a singular definition of "risk" and "benefit." It was not a quantitative determination. It was a qualitative determination. And as she explained, she studied substantial documentation from Wyeth with regard to Pondimin and also Redux.
>
> Her assessment with regard to Pondimin was that the benefit was a potential loss of 2 to 3 pounds of weight, as compared to three very serious heart events. She concluded that the risks outweighed the benefits. She engaged in a similar analysis with regard to Redux.

And there is no dispute that she considered a substantial body of information that included opinions given by other experts and assessments and studies prepared by others.

But as she explained, there are at least three different kinds of risk-benefit assessments. There is the risk-benefit assessment for an individual patient, and that is what Dr. Blume concedes should be made by a doctor.

There is the risk-benefit associated with a new drug, either in development or arguably, as she explained, when you might acquire the rights to produce and sell drugs. And then there is the risk-benefit analysis that occurs after the drug has been sold, post-approval, post-marketing. And as she explains, the populations are different, because you have a population prior to sale of a drug, and then you have a population that is different after the drug is marketed.

Her assessment as to risk-benefit is not tied to any objective standard. It is, instead, a function of her experience and expertise. And it's not impossible for an expert to rely upon experience and expertise in formulating an opinion. . . .

[But Rule 702] goes on to explain that if the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.

Dr. Blume explained that her experience occurred in a number of different circumstances where she was involved in assessing the risk-benefit to acquisition of a particular drug for marketing or taking it from Europe here to the United States. And that is consistent with her experience as an executive in drug companies. But that assessment is [ ] partially an economic assessment. The definition of risk to a drug company in marketing a product may be very different than the definition of risk to a particular plaintiff or patient.

Now, I inquired if there were other circumstances in which she had engaged in this balancing approach and she explained that she had given opinions to clients, drug companies, who she advises as to the safety requirements and the labeling requirements. And that falls within her extensive expertise as well. But this opinion is an opinion that assesses risks and benefits to patients as of 1995. And I agree with the Defendants that the record does not show that Dr.

> Blume has knowledge, experience, skill, training, expertise, or education to testify as to that opinion.

Having had the opportunity to study the entire record, as well as to reflect upon the arguments made by the Plaintiffs in their motion, the Court believes its prior ruling to be correct. To the extent it was unclear, or incomplete, the Court thus takes this opportunity to clarify and amplify that ruling.

The Court returns to the statement of Opinion 2 - "The risks associated with ingesting diet drugs manufactured by [the Defendants] outweighed the benefits to patients by 1995." Because Dr. Blume concedes that she cannot make an assessment for any particular patient, the Court understands this opinion to be an assessment for a population of patients or potential patients. In addition, the Court is satisfied that Dr. Blume has extensive experience and expertise in evaluating the risks of drug products and articulated a clear methodology she follows in evaluating "signals" of new risks as they arise.

The difficulty with the opinion is with the determination of the "benefits" in the risk-benefit comparison and in the means by which Dr. Blume compared the risks and benefits. Dr. Blume testified that in the case of drugs like Pondimin and Redux, she looked at the evidence of weight loss and evaluated the benefits relying on her own knowledge. She offered no standards or referents that guided her in characterizing the weight loss as de minimis. In the case of Pondimin, she apparently consulted existing studies or material that indicated that the drug was likely to result in weight loss of "a couple of pounds" (perhaps as much as 12-15 pounds when Pondimin was used in combination with another drug) and that such results would be maintained only so long as the patient continued taking the drug. Her testimony was that Redux offered somewhat more favorable weight loss results, but she was not specific, other than observing that such results were "of the same magnitude" as Pondimin. Dr. Blume's factual

basis for this assertion – that the expected weight loss for a Pondimin user was "a couple of pounds" – was unchallenged, and thus, the Court will assume it to be accurate.

The problem lies with nature of the opinion – a comparison or weighting of risks and benefits. An adequate and demonstrable method for assessment of the risks is not sufficient to address the other components of the opinion – assessment of the benefits and comparison of the risks and benefits. At the most abstract level, Dr. Blume did not identify any scientific or generally accepted measure that she and other experts in the field use to quantify the "benefit" associated with a drug, or how "benefits" and "risks" are compared. At the next level of specificity, Dr. Blume did not articulate how she quantified the particular "benefit" of using Redux and Pondimum as "de minimus" or how she compared that measure of "benefit" with her measure of "risk". And as noted, on the most specific level, Dr. Blume conceded that she could not assess the benefits and risks to Ms. Heineman.

Without a scientific methodology for the characterization of the "benefits" as de minimus, the question becomes whether Dr. Blume's relied on her experience and expertise and whether they would provide sufficient foundation to make her opinion reliable. Although it appears that Dr. Blume relied upon her experience as a pharmacologist in gathering information about the weight loss effects of the drugs, it does not appear that her expertise was used in assessing the information. For example, she did not compare the weight loss benefits offered by Pondimin or Redux to other weight loss drugs she evaluated during her career. She did not consult with other experts about the medical benefits of the weight loss in various ranges or attempt to identify the situations in which physicians might conclude that these weight loss amounts might nevertheless have beneficial medical purpose. Rather, it appears that Dr. Blume simply made her own value judgment that the benefit of "a couple of pounds" of weight loss for

as long as one took the drug was "de minimis". ." Characterizing the benefit of the drugs that way ensured that any risk would outweigh the benefit.

Quantification of the benefits of the drugs is a necessary component to Opinion 2 because it compares the benefits of the drugs to their risks. In determining the benefits of the drugs, it does not appear that Dr. Blume brought any more expertise to bear on the question than would any layperson (or, at least, any layperson advised of the weight loss data for the drugs). In such circumstances, Dr. Blume's evaluation of the benefits of Pondimin and Redux does not seem to be an opinion informed by Dr. Blume's specialized training, knowledge, or experience, and thus, fails to satisfy the foundational requirements of Rule 702(a).

In addition, the opinion lacks the necessary foundation under Rule 702(c). Without a methodology or use of experience, training etc. to formulate the benefit component of the risk-benefit comparison, the comparison is not a product of a reliable methodology. As note, the characterization of a de minimus benefit ensures that any risk will outweigh it.

However, absent the problem with the quantification of the benefit, there is a second deficiency – in methodology for comparing risk and benefit. As the Court's oral ruling discussed to some degree, it is not entirely clear from her testimony that the risk-benefit evaluation she performed necessarily yields a reliable opinion here. When performing her risk-benefit evaluations, it appears that Dr. Blume is engaging in a business decision as to the economic benefits of marketing a drug, rather than a population specific assessment as to the benefits of using a drug. Although questions of whether and to what extent the public as a whole would benefit from a particular drug being brought to market, Dr. Blume made clear that in her professional experience the particular characteristics of the companies she worked for would then shape that benefit assessment. As Dr. Blume explained: "The benefits [of manufacturing

and marketing a drug] sometimes were great, but for our size company and the goals of our company, we couldn't take the risk of what we saw lurking in there." In other words, Dr. Blume is saying that there have been products that offered "great" benefits to the public, but because of the particular size and risk-tolerance of the company she was advising, the company would conclude that the risk-benefit equation tipped against bringing that product to market. This may be a sound business approach, but it is a different risk-benefit analysis than that directed to the risk and benefit to a population who used the drug.

Accordingly, although the Court has reconsidered its oral ruling in light of the Plaintiffs' motion, the Court nevertheless finds upon reconsideration that the same outcome is warranted. Opinion 2 is excluded under Rule 702(a) and (c).

2. Opinion 3

The precise content of Opinion 3 varied prior to and during the hearing. Originally, that opinion was stated as "corporate documents demonstrate [the Defendant's] misconduct and failure to act as a reasonable pharmaceutical company." Later, the Plaintiffs articulated Opinion 3 as the following:

> corporate documents demonstrate that [the Defendants] failed to conform to the standard of care for post-market safety surveillance of its diet drugs. The standard of care is known as pharmacovigilance and these standards of care come from FDA regulations, FDA guidances, and the custom and practice in the drug manufacturing industry. Based on a review of these documents, Wyeth knew or should have known or at least was put on notice that . . . that the risk and benefits of the diet drugs that they were distributing were not adequately expressed in the labeling, distributed to physicians and otherwise communicated to the medical industry.

The Court did not address the factual statements with regard to the sources and definitions of the standard of care, but understood there to be two, separate opinions: (i) that "corporate documents

demonstrate that [the Defendants] failed to conform to the standard of care . . .," and (ii) that "based on a review of these documents, [the Defendants] knew or should have known . . . that the risk and benefits of the diet drugs that they were distributing were not adequately expressed . . . ."

The Court began by asking Dr. Blume how she came to the conclusion regarding the first component ("corporate documents demonstrate . . ."). She explained that her company was "given databases as part of the materials provided," and she had a biostatistician examine that database to ascertain "the total number of [adverse event] reports provided to the company over the years." She stated that she was also provided with "exhibits and depositions" that included statements from "people in their safety surveillance department" who had expressed concerns about the completeness of the drugs' labeling. She explained that she couldn't "talk to the people, go back down memory lane," so she used what she learned from these documents to "fill[ ] in that gap, what was going on inside the company as all of these events were being reported, did everybody miss it that the labeling needed to be changed or did some people see that it needed to be changed and noted, made an effort to make the change, although it was eventually blocked."

The Court rejected the two opinions, finding that the Plaintiffs had not satisfied Rule 702(c) – that there was no demonstration that Dr. Blume used a reliable methodology to formulate either opinion. As to the first component, the Court found that:

> the opinion really isn't that [the Defendants] failed to conform with the standard of care; it is that <u>corporate documents demonstrate</u> that [the Defendants] failed to conform to the standard of care. . . I find that Dr. Blume has no methodology that is reliable for determining what the documents demonstrate. Ultimately, the plaintiffs will be able to put on the documents at trial, and the jury will decide what the documents demonstrate. She can testify as to her opinion as to whether [the Defendants] comply with binding

> provisions of law, but she cannot offer a global opinion that corporate documents demonstrate something.

In retrospect, it may not have been necessary to address the methodology issue of Rule 702(c), because this portion of Opinion 3 is properly excluded on the more basic grounds that the Plaintiffs have not demonstrated that Dr. Blume's "specialized knowledge will help the trier of fact to understand" the corporate documents themselves. Fed. R. Evid. 702(a). In this regard, the Court again emphasizes that the opinion being proffered by Ms. Blume is not "the Defendants failed to conform to the standard of care" but instead that "corporate documents demonstrate that [the Defendants] failed to conform to the standard of care."

Dr. Blume describes deriving her opinion by performing two tasks (directly or with assistance): (i) culling through a database to extract instances of reports of adverse effects, and (ii) examining "exhibits and depositions" in which employees of the Defendants expressed concerns about the products' labeling. It may very well be that Dr. Blume's experience and knowledge was essential to performing the identified tasks – that only a person with Dr. Blume's expertise would be able to locate and extract the relevant information from the entirety of the databases and records she was given. But once Dr. Blume extracted those records, the Plaintiffs have not demonstrated that the extracted records themselves are so opaque or incomprehensible that the trier of fact requires Dr. Blume's assistance to parse them. (Indeed, one would assume that, for example, deposition testimony by the Defendants' employees would be rendered in language comprehensible to the non-expert attorneys taking the depositions.) Put differently, Dr. Blume's expertise was used in the sifting of the documents, not the record does not show whether or how her expertise was essential in their interpretation. But the opinion as proffered is one relating to interpretation – the opinion is that the extracted documents "demonstrate" a certain thing. Because the Plaintiffs have not shown that the documents extracted by Dr. Blume

cannot otherwise be understood by the trier of fact – that is, that Dr. Blume's specialized knowledge is necessary to interpret them for the factfinder -- the first portion of Opinion 3 does not satisfy Rule 702(a). The Plaintiffs may introduce the relevant documents (and may even ask Dr. Blume to place them in context or to explain unfamiliar references), but the trier of fact can ultimately determine whether those documents "demonstrate" any particular fact or not. In their motion, the Plaintiffs argue that this is error because "highly-technical documents, like [adverse drug effect reports], should be interpreted by someone with a proven expertise in the science of pharmacovigilance."

This argument is misplaced for several reasons. First, nothing in the record supports this contention as a factual matter. At no time during the Rule 702 hearing did Dr. Blume, for example, testify that adverse drug effect reports are somehow incomprehensible to non-pharmacologists.[2] Second, the contention that these reports "should be interpreted by" Dr. Blume is orthogonal to the Court's ruling that Dr. Blume cannot give the opinion that the documents "demonstrate that [the Defendants] failed to conform to the standard of care." Certainly, if an adverse effect report contains medical terminology unfamiliar to the layperson (*e.g.* a report that

[2] Although the parties supplied the Court with several exhibit binders in advance of the hearing, the record does not indicate that any party moved for admission of any exhibit. Nevertheless, the Court has briefly reviewed the tendered exhibits and finds little to support the Plaintiffs' contention. For example, Exhibit 8 is a document on the Defendants' letterhead, entitled "ADE [adverse drug effect] Periodic Report" for Pondimin dated July 1994. The document is primarily a compendium of form incident reports in which doctors have reported to the Defendants side effects that patients taking Pondimin have experienced. Although some reports contain medical terminology that might be unfamiliar to laypeople ("Patient with refractory depression was receiving Pondimin for potentiation of Prozac . . ."), most reports are readily understandable without any medical knowledge: "Patient reported she experienced profuse sweating from her face while receiving Pondimin," "Patient developed right eye pain and ear pain after one day of Pondimin therapy. He subsequently developed small vesicles on the right side of his face," "After four months of Pondimin therapy, patient developed hair problems including thinning, 'splitting,' loss of 'body,' and inability to retain permanent curling treatment."

states that a patient reported "a worsening of symptoms of [myasthenia gravis] upon initiating Pondimin therapy"), the Plaintiffs might be able to ask Dr. Blume to explain the meaning of the unfamiliar terms and possibly explain what conclusions she might draw from the fact that a patient reported a worsening of those symptoms when taking Pondimin. But this opinion goes far beyond such explanations. This opinion attempts to summarize all of the Defendant's records both proffered opinion was that the documents "demonstrate the Defendants' failure to conform to the standard of care," and for the reasons stated above, the Plaintiffs have not shown that specialized knowledge is necessary for the trier of fact to eventually draw that conclusion from the documents and testimony that the Plaintiffs can offer.[3]

The second part of Opinion 3 is Dr. Blume's opinion that "[the Defendants] knew or should have known . . . that the risk and benefits of the diet drugs that they were distributing were not adequately expressed." The Court asked about this opinion in three stages. First, it asked "how did you determine that [the Defendants] knew that the labeling was inadequate?".

[3] The Court observes that the opinions that the Plaintiffs wish to have Dr. Blume present are classic examples of a party attempting to have their expert "say too much." It might be sufficient for Dr. Blume to explain the standards of care that apply in the field of pharmacology and to walk the factfinder through the evidence demonstrating the Defendants' failure to conform to that standard of care, leaving it to the jury to determine whether the Defendants did indeed deviate from that standard. However, attorneys often want the expert to go one step further and explicitly state the particular conclusion that the attorney wants the factfinder to make. In other words, some attorneys not only want the expert to show that, for example, the defendant failed to observe a standard of care; they want to have the expert expressly say that the defendant failed to observe that standard.

Traditionally, such expert testimony as to the "ultimate issue" was inadmissible. In 1972, Fed. R. Evid. 704(a) abrogated that rule, allowing such testimony if otherwise admissible. But the Advisory Committee notes to that Rule note that standards such as Rule 702's requirement that an opinion be helpful to the trier of fact "afford ample assurances against the admission of opinions which would merely tell the jury what result to reach." And, in this Court's experience, Rule 702(a) often operates to permit an expert to provide all of the testimony necessary to permit a factfinder to reach a conclusion, but precludes the expert from taking that last step of testifying as to the conclusion itself.

Dr. Blume responded that:

> the example that comes to my mind immediately, specific to their records, is that requests were generated by lower-level safety surveillance people to change the labeling, to amplify it, to better represent that assembly of data that were in their databases and it was blocked by higher officials in the company. . . So the fact that they didn't want [a black box warning] and actively exercised efforts to block it and forbade people who had requested to make label changes all came together . . . to suggest that the company, first, knew about the events, these various safety events, and secondly, there was an effort undertaken at these levels to block the dissemination of those events in the labeling.

The Court then inquired "How about that [the Defendants] should have known that the diet drug they were distributing was not adequately being labeled?". Dr. Blume stated "Well, I think because they did know, I was not as concerned of saying they should have known, because the documents clearly evidenced to me that they did know." Finally, the Court asked "And how about 'at least was put on notice' – does that fall into the same category?". Dr. Blume responded "They were put on notice in a variety of ways to this. Not only did they have – all that I've just talked about, but they also had direct contact with leaders in the field on this . . . [Doctors specializing in pulmonary hypertension] are all through their documents, but those gentlemen had direct contact with leadership at [the Defendants] to discuss those issues and did discuss those issues. So they were put on notice, not only by information available from their own people and available provided to them in studies they sponsored, but also by contacts they directly had with these people, talking about the escalating risks."

As to the second component of the opinion, the Court ruled:

> The second part of this is that [the Defendants] failed to conform with the standard of care for post-market safety surveillance of its diet drugs. And I asked [Dr. Blume] what standard of care did she apply? And she said, her own view, she looked at the audit letter, and she looked at the extent to which labels changed or did not change based upon information that [the Defendants] had. . .

> I find that the methodology used here – 'I'm reviewing the documents that are supplied to me by plaintiff's counsel, I'm looking at depositions, I am looking at information that [the Defendants] had and I'm formulating a view, looking at an audit letter and considering my experience' -- to not be a reliable methodology. Not because the conclusion is wrong. I'm not looking at the conclusion. But because the methodology is not subject to general acceptance, with a known rate of error, duplicable by anyone else. In other words, it is simply Dr. Blume's opinion . . . it is an extrapolation based on her assessment of information without any objective measurable repeatable process.
>
> I join a number of other courts in finding that Dr. Blume may not testify as to what [the Defendant] knew or didn't know. That does not mean that the plaintiffs cannot present the evidence that Dr. Blume considered or that she may offer an opinion as to what that might have meant to her in her role as an executive of a drug company. But she may not testify that [the Defendants] knew or should have known , or was put on notice that . . . the risks and benefits [of its diet drugs] had not been adequately expressed in the labeling."

Upon reconsideration, it is clear to the Court that it erred in addressing the part of Opinion 3 referring, instead, to the evidence supporting the first part of Opinion 3. Nevertheless, the second component of Opinion 3 is properly excluded for the same reasons as the first component: that Dr. Blume's specialized training and knowledge are not necessary or helpful in assisting the factfinder in understanding the evidence. Dr. Blume's opinion that the Defendants "knew" that the labeling of their drugs was inadequate was, by Dr. Blume's own testimony, based on the fact that there were records of the Defendants' safety surveillance employees stating that the labeling was inadequate. Once again, it may be necessary for Dr. Blume to explain the meaning or significance of certain words or concepts that might appear in such records – she may have to explain what a safety surveillance employee does, the hierarchy that oversees such employees, or the typical consequences of the event the record reflects – but

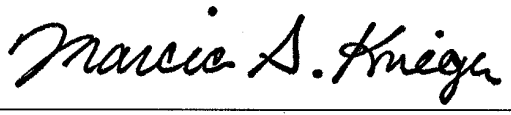
the Plaintiffs have not shown that, armed with such records and Dr. Blume's explanations thereof, the trier of fact would be unable to reach a conclusion about the Defendants' knowledge of any labeling deficiencies without Dr. Blume's say-so. Because Dr. Blume's expression of either component of Opinion 3 does not assist the trier of fact, it does not meet the requirements of Rule 702(a). Opinion 3 was properly excluded in its entirety.

## CONCLUSION

For the foregoing reasons, the Plaintiffs' Motion for Reconsideration **(# 81)** is **GRANTED IN PART**, insofar as the Court has reconsidered its oral ruling in light of the arguments presented by the Plaintiffs, and **DENIED IN PART**, insofar as, upon such reconsideration, the Court reaches the same conclusions that it previously had. Opinions 2 and 3 by Dr. Blume do not satisfy the foundational requirements of Fed. R. Evid. 702.

Dated this 11th day of March, 2015.

**BY THE COURT:**



Marcia S. Krieger
Chief United States District Judge