UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

IN RE NUVARING® PRODUCTS LIABILITY LITIGATION	)	Case No. 4:08-MD-1964 RWS
	)	
	)	ALL CASES
	)	

MEMORANDUM AND ORDER

Defendants ("Organon") have moved to exclude all testimony during the course of this multi-district litigation ("MDL") that NuvaRing and other combined hormonal contraceptives ("CHCs") containing third-generation progestins should be taken off the market. Organon asks me to find, as a matter of law, that any opinion on this subject from any expert would be so unreliable and so irrelevant that it should be excluded from being tested by any cross-examination at trial, being weighed by any jury, or even limited in any respect by any trial judge. After reading the voluminous briefs and exhibits filed by both sides on this issue, I am not persuaded that I should enter a global order that all experts should be prohibited as a matter of law from testifying that NuvaRing and other third-generation CHCs should be taken off the market. However, I do find that Plaintiffs have failed to demonstrate the reliability of Dr. Scott Roseff's opinion that NuvaRing should be taken off the market. I will grant Organon's motion to exclude Dr. Roseff's proffered testimony that NuvaRing should be taken off the market.

I. BACKGROUND

This MDL relates to the manufacture, marketing, and sale of the prescription pharmaceutical known as NuvaRing. NuvaRing, which is manufactured, marketed, and sold by Organon, is a member of a class of prescription drugs known as combined hormonal contraceptives ("CHCs"). Unlike oral CHCs, NuvaRing takes the form of a flexible ring which

releases hormones over the course of treatment. The ring is vaginally inserted by women for birth control. Each month, the ring is removed and a new ring is inserted.

CHCs contain an estrogen, typically ethinyl estradiol ("EE"), and a progestin. The "generation" of CHC depends upon the type of progestin. Each "generation" of CHC typically uses the following progestins: first-generation contains norethynodrel; second-generation contains levonorgestrel; and third-generation CHCs contain desogestrel, gestodene, or norgestimate. NuvaRing uses the active metabolite of desogestrel, etonogestrel, and is therefore considered a third-generation progestin.

First-generation CHCs use high levels of EE and are associated with high incidence rates venous thromboembolism ("VTE"), including deep vein thrombosis and pulmonary embolism.[1] Second-generation CHCs use a reduced amount of EE and are associated with less risk for VTE. It is generally accepted that risk of thrombosis is correlated with estrogen dose.

Third-generation CHCs use lower amounts of estrogen than prior generations; however, some studies have found an increased risk for VTE with some third-generation CHCs as compared to second-generation CHCs. Plaintiffs claim that the third-generation progestin used in NuvaRing, etonogestrel, has been linked to undisclosed higher risk for VTE, including both deep vein thrombosis and pulmonary embolism. Plaintiffs have asserted the following claims: strict products liability for defective manufacturing, defective design, failure to test, and inadequate warnings; breach of express / implied warranties; and negligence.

One of Plaintiffs' experts, Dr. Scott Roseff, M.D., stated in his deposition that the risk for VTE presented by NuvaRing and other third-generation CHCs is so great that the entire

[1] Venous thromboembolism is a blood clot that forms within a vein. Deep vein thrombosis is a blood clot that forms in a vein not externally visible, typically in the veins of the lower extremities. A pulmonary embolism forms when part or all of a blood clot breaks free and lodges in one of the lungs. These conditions have varying severity and can be life threatening.

generation of contraceptives should be removed from the market. Organon alleges that this testimony is the result of unreliable methods and should be excluded from trial.

II. LEGAL STANDARD

Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), govern the admissibility of expert testimony. The Daubert standard applies to all expert testimony, whether based on scientific competence or other specialized or technical expertise. See Polski v. Quigley Corp., 538 F.3d 836, 838 (8th Cir. 2008). 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.

"[I]t is the responsibility of the trial judge to determine whether a particular expert has sufficient specialized knowledge to assist jurors in deciding the specific issues in the case." Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc., 254 F.3d 706, 715 (8th Cir. 2001). "Once initial expert qualifications and usefulness to the jury are established, however, a district court must continue to perform its gatekeeping role by ensuring that the actual testimony does not exceed the scope of the expert's expertise, which if not done can render expert testimony unreliable . . . ." Id.

"When faced with a proffer of expert scientific testimony, the trial court must make 'a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.'" Polski, 538 F.3d at 838 (quoting Daubert, 509 U.S. at 592–93). Thus, under

Rule 702, the trial judge also acts as a gatekeeper by screening evidence for relevance and reliability. Daubert, 509 U.S. at 589.

The district court applies a three-part test when screening expert testimony under Rule 702:

> First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires.

Polski, 538 F.3d at 839 (quoting Lauzon v. Senco Prods., Inc., 270 F.3d 681, 686 (8th Cir. 2001)).

"Rule 702 reflects an attempt to liberalize the rules governing the admission of expert testimony. The rule clearly is one of admissibility rather than exclusion." Lauzon, 270 F.3d at 686 (internal quotations and citations omitted). "The exclusion of an expert's opinion is proper only if it is so fundamentally unsupported that it can offer no assistance to the jury." Wood v. Minn. Mining & Mfg. Co., 112 F.3d 306, 309 (8th Cir. 1997) (internal quotations and citation omitted).

When assessing the reliability of expert testimony, a trial court should consider several factors, including: "(1) whether the concept has been tested, (2) whether the concept has been subject to peer review, (3) what the known rate of error is, and (4) whether the concept is generally accepted by the community." Miller v. Baker Implement Co., 439 F.3d 407, 412 (8th Cir. 2006) (citing Daubert, 509 U.S. at 593–95). 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 Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 150 (1999) (quoting Daubert, 509 U.S. at 591).

"[T]he rejection of expert testimony is the exception rather than the rule." Robinson v. GEICO General Ins. Co., 447 F.3d 1096, 1100 (8th Cir. 2006) (citing Fed. R. Evid. 702 advisory comm. note). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Daubert, 509 U.S. at 595.

III. ARGUMENT AND ANALYSIS

Organon presents this Court with a motion to exclude the testimony of Dr. Roseff that NuvaRing and other third-generation CHCs should be taken off the market. Organon also asks me to rule, as a matter of law, that no expert could reliably reach the same conclusion. However, I decline to reach that second issue. The parties have not identified any other expert who has offered an opinion that NuvaRing and other third-generation CHCs should be taken off the market. I cannot apply the Daubert factors to an unidentified expert. On the other hand, if none of the previously identified experts have offered the opinion, it is too late under the scheduling order and the federal rules of civil procedure to supplement their reports with such an opinion.

Organon presents four arguments that it asserts render Dr. Roseff's methodology unreliable. First, Organon asserts that Dr. Roseff employs personal standards rather than applying the proper methods of the field; second, Dr. Roseff lacks knowledge of the most fundamental data points; third, Dr. Roseff ignores the vast majority of relevant studies; and finally, Dr. Roseff reaches conclusions that exceed the bounds of the studies upon which he relies. Because I find Organon's first argument meritorious, I need not reach its remaining arguments.

Dr. Roseff asserts that NuvaRing, like all third-generation CHCs, should be taken off the market because the VTE risk presented by those drugs outweighs their benefits. (Doc. 1377,

Plaintiffs' Opp. 12). Dr. Roseff testified that when reaching this opinion, it is important to consider all available epidemiology data and, specifically, to evaluate all of the potential risks. (Doc. 1377-3, "Roseff Depo.," Oct. 10, 2011, at 71, 99).

Dr. Roseff testified that third-generation CHCs have approximately double the risk for VTE as second-generation CHCs. (Roseff Depo. at 18). He further stated that third-generation oral CHCs have no advantages over second-generation oral CHCs with regard to bleeding control, nausea, breast tenderness, metabolic issues, lipid profile, and insulin resistance. (Roseff Depo. at 96–97). When asked what types of risk he took into account for his analysis, Dr. Roseff admitted that he only evaluated VTE risk:

> Q: . . . What I want to know is, you have not looked at the comparative risk in any other aspect other than VTE, true?
> A: True.

(Roseff Depo. at 106).

> Q: And as I understand what you are saying is the reason and the only reason you think it should be off the market is because of the increased risk of VTE?
> A: Compared to second-generation pills?
> Q: Right.
> A: Yes.
>
> Q: But just so I'm clear, the sole basis that you're stating the opinion that you have today that third-generation pills and NuvaRing should be removed from the market is because of the VTE risk, right?
> A: Yes.

(Roseff Depo. at 168, 170).

Dr. Roseff testified that heart attack and arterial stroke are more serious events in general than a VTE. (Roseff. Depo. at 101). He admitted, however, that he had not conducted any inquiries into and was not aware of any literature discussing the comparative risk for heart attack, arterial stroke, or myocardial infarction between third- and second-generation CHCs. (Roseff Depo. at 99, 102, & 105).

I find that Dr. Roseff's opinion that NuvaRing and third-generation CHCS should be taken off the market is the product of unreliable methodology. Dr. Roseff testified that this opinion is based on a weighing of the relative risks and benefits of the drug and that it is important to consider all risks when conducting the evaluation. However, Dr. Roseff failed to consider several potential risks that he considers to be generally more serious than VTE, the risk that formed the sole basis for his opinion. As a result, I will grant Organon's motion to exclude Dr. Roseff's opinion that NuvaRing and third-generation CHCs should be taken off the market.

Organon also seeks to exclude any other expert from offering testimony that NuvaRing should be taken off the market. However, none of Plaintiffs' experts have expressed that opinion. Because Rule 702 must be applied to each particularized expert opinion at issue, this inquiry is inappropriate at this time.

IV. CONCLUSION

For the foregoing reasons, I find Dr. Roseff's opinion that NuvaRing and third-generation CHCs should be taken off the market to be the product of unreliable methodology. I decline to apply this ruling prospectively against all testimony that NuvaRing and third-generation CHCs should be taken off the market.

Accordingly,

IT IS HEREBY ORDERED that Organon's motion to exclude testimony regarding opinion that NuvaRing should be taken off the market [Doc. 1305] is **GRANTED in part and DENIED in part.**

RODNEY W. SIPPEL
UNITED STATES DISTRICT JUDGE

Dated this 22nd day of March, 2013.