

This Order has been prepared and filed by the Court.

IN RE: NUVARING® LITIGATION

SUPERIOR COURT OF NEW JERSEY

LAW DIVISION

BERGEN COUNTY

DOCKET NO. BER-L-3081-09

CIVIL ACTION

ORDER

**FILED**

**JUN 01 2012**

**BRIAN R. MARTINOTTI, J.S.C.**

*THIS MATTER* having been opened to the Court upon the Defendants', Organon USA Inc., Organon Pharmaceuticals USA Inc., and Organon International Inc.'s (hereinafter "Defendants"), Motion for Protective Order, pursuant to *New Jersey Court Rule* 4:10-3, relieving them of any obligation to provide formal expert reports as to Dr. Titia Mulders, Mr. Wouter de Graaff and Dr. Hans Rekers (hereinafter "the company witnesses");

For the reasons set forth in the accompanying Opinion;

*IT IS* on this 1st day of June, 2012,

**ORDERED:**

1. Defendants' Motions is GRANTED;
  - a. Without providing formal expert reports, the company witnesses may only testify as to facts and historical accounts relating to their

personal involvement in the research and development of NuvaRing®;

- b. If Defendants intend to offer any opinion testimony from these witnesses, expert reports must be served on plaintiffs;
- c. Even if expert reports are served for these company witnesses, certain opinion testimony may nevertheless be barred at trial pursuant to *N.J.R.E.* 403;

- 2. A copy of this Order shall be served upon all counsel of record within seven (7) days of counsel's receipt thereof, and shall be posted on the Judiciary's website.

A handwritten signature in black ink, appearing to read 'B. Martinotti', is written over a horizontal line.

BRIAN R. MARTINOTTI, J.S.C.

NOT TO BE PUBLISHED WITHOUT  
THE APPROVAL OF THE COMMITTEE ON OPINIONS

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**BRIAN R. MARTINOTTI, J.S.C.**

Submitted: May 16, 2012<sup>1</sup>

Decided: June 1, 2012

On the Briefs:

For Plaintiffs: Hunter J. Shkolnik, Esq. (Napoli Bern Ripka  
Shkolnik & Associates, LLP)

For Defendants: Melissa Geist, Esq., Daniel Winters, Esq.  
(Reed Smith, LLP)

**MARTINOTTI, J.S.C.**

Before the Court is Defendants' Motion for a Protective Order, pursuant to *Rule* 4:10-3, relieving them of any obligation to provide formal expert reports as to Dr. Titia Mulders, Mr. Wouter de Graaff and Dr. Hans Rekers (hereinafter referred to as the "company witnesses"). Plaintiffs have **OPPOSED** this Motion.

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<sup>1</sup> By way of e-mail correspondence dated May 18, 2012, all counsel waived oral argument on this Motion.

## FACTS<sup>2</sup>

On March 26, 2012, Defendants served Plaintiffs with their Amended Generic Expert Disclosures (“Amended Disclosures”) in this litigation. (Winters Cert. Ex. A). The disclosures list the names of eleven retained generic expert witnesses and state that, in addition, the Defendants may call some of their employees as witnesses. *Id.* The disclosures specifically note that “Defendants do not regard the following employees’ expected testimony as expert opinion testimony pursuant to [New Jersey Court] Rule 4:10-2, but rather as factual, historical and state of mind testimony regarding Defendants’ involvement with NuvaRing® and hormonal contraceptives generally.” *Id.*

The Amended Disclosures listed Titia Mulders, Wouter de Graaff, and Hans Rekers as the company witnesses who may testify. For each company witness, the Amended Disclosures contain a lengthy listing and explanation of the potential topics of testimony. For example, the Amended Disclosures state, in part, the following as to Titia Mulders, Ph.D:

Titia Mulders, Ph.D is a current Merck employee and is both a fact witness and a witness designated knowledgeable about certain topics related to the research and development of NuvaRing® and hormonal contraceptives generally pursuant to New Jersey Court Rule 4:14-2(c). Dr. Mulders has served as senior project team leader in the field of contraceptive development at Merck. Further information regarding Dr. Mulders’ qualifications and experience is outlined in her curriculum vitae, which was provided to Plaintiffs at the time of her depositions.

Dr. Mulders is expected to provide testimony regarding Defendants’ involvement with NuvaRing® and hormonal contraceptives generally, including (1) the research and development of NuvaRing®; (2) the NuvaRing® New Drug Application (NDA); (3) the efficacy and safety of hormonal contraceptives; (4) interactions about NuvaRing® with

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<sup>2</sup> The Court focuses only on those facts relevant to the instant application.

regulatory bodies including the U.S. Food and Drug Administration (FDA) pertaining to the approval and subsequent regulation of NuvaRing®; (5) the regulatory approval process for NuvaRing® by regulatory bodies including the FDA; (6) the drafting and content of NuvaRing® package inserts and patient information sheets; (7) the design, scope and execution of the NuvaRing® clinical trial program and each study therein, including the clinical trial reports and peer review publications; (8) post approval commitments made to FDA pertaining to NuvaRing®; and (9) clinical, epidemiologic, and laboratory studies on NuvaRing®, including any new studies or data that become available.

Defendants amend their original disclosure as follows with respect to Dr. Mulders' expected testimony:

1. Dr. Mulders will testify that NuvaRing® is a safe and effective contraceptive, and an important contraceptive option. It is a reliable non-daily method of contraception which offers compliance advantages over birth control pills. When used in accordance with the label, the benefits of NuvaRing® exceed the risks.
2. Dr. Mulders will testify that NuvaRing® and the combination of hormones therein have been extensively researched. Relevant studies demonstrate, among other things, safety, efficacy, favorable haemostatic, pharmacokinetic, pharmacodynamic, and metabolic profiles, high patient satisfaction, and excellent cycle control. Dr. Mulders will testify about, among other things, relevant individual studies in the published literature, the research and development of NuvaRing® and 3d generation combined oral contraceptives, the decades of safety data and established reputation concerning 3d generation products, and the use of 3d generation products as comparators by regulatory authorities.
3. Dr. Mulders will testify that NuvaRing® and the vaginal route of administration have several advantages over oral contraceptives and the gastrointestinal route of absorption. These include, but are not limited to, lower dose, avoidance of the hepatic first pass, and compliance advantages.

4. Dr. Mulders will testify that the risk of VTE with combined hormonal contraceptives is related to the dose of estrogen. The risk of VTE is higher with higher doses of estrogen and lower with lower doses of estrogen.

\* \* \* \* \*

28. Dr. Mulders will testify about the formation, function, discussion, and decisions of the company's NuvaRing® Project Teat, or team by similar designations over time, including but not limited to the company's design and execution of the clinical trial program and product label discussions with the FDA.
29. Dr. Mulders will testify about the formation, function, discussion, and decisions of the company's Life Cycle Management Team, or team by similar designations over time, including but not limited to the company's considerations of the Temperature Stable Ring and NoDoFo Ring and the reasons therefor.

The Disclosure as to Dr. Mulders concludes:

Defendants do not regard Dr. Mulders' expected testimony as traditional expert testimony; but rather, as factual, historical and state of mind testimony regarding Defendants' involvement with NuvaRing® and hormonal contraceptives generally, but which necessarily involves scientific knowledge. Dr. Mulders' testimony will be based on her personal knowledge, education, and training, and company records. She has personal knowledge of many of the facts relevant to the Defendants' defense and this disclosure as to her areas of knowledge is not intended to restrict her testimony as to those facts to which she has personal knowledge. Dr. Mulders was designated by Defendants as knowledgeable on each of the above-referenced topics and numerous others in response to Plaintiffs' deposition notice served pursuant to Fed. R. Civ. Proc. 30(b)(6) and New Jersey Court Rule 4:14-2(c). Defendants incorporate those previous designations by reference as topics about which Dr. Mulders may testify. During the course of this litigation, Dr. Mulders has been deposed extensively on the categories for which she was designated. Dr. Mulders may also testify about any other areas raised during her prior testimony and/or respond to any topics

raised by Plaintiffs or their experts that fall within her areas of testimony.

(*Id.* at pp. 2-6).

The Amended Disclosures contain similar statements as to the testimony of Dr. Rekers and Mr. de Graaff. (*Id.* at pp. 6-16). The Amended Disclosures provide detailed itemized lists of 29, 13, and 51 (totaling 93) statements regarding the anticipated testimony of Dr. Mulders, Mr. de Graaff, and Dr. Rekers, respectively. (*Id.*)

Plaintiffs have deposed each of the three company employees identified in the Amended Disclosures on multiple occasions. After producing each of these three witnesses for a full day of depositions as an individual, in response to Plaintiffs' 30(b)(6) deposition notice, Defendants produced Dr. Mulders for an additional deposition in July 2010, Mr. de Graaff for two days in 2011, and Dr. Rekers in July 2010. In each instance, Defendants listed the 30(b)(6) topics on which these witnesses are expected to testify. Plaintiffs then requested further depositions of Drs. Rekers and Mulders. (*See* MDL Document No. 854, Winters Cert. Ex. D). Although Defendants opposed further depositions of these witnesses, they produced Drs. Rekers and Mulders for third and fourth days of depositions each, in April 2011, based on a list of agreed topics which plaintiffs claimed they needed further time to explore. (Winters Cert. Ex. E). Plaintiffs completed the supplemental depositions. In total, the depositions of these three witnesses have spanned ten (10) days with the shortest (Mr. de Graaff) consuming more than 440 pages of transcript, while Dr. Rekers' includes more than 1500 pages. Subsequently, on February 28, 2012, the MDL Court ordered Defendants to produce these three witnesses for another round of depositions – this time on the very topics listed in the Amended

Disclosures. (Winters Cert. Ex. F). These witnesses are currently scheduled to be deposed on June 26, 27 and 28, 2012.

Plaintiffs having asserted that Defendants' Amended Disclosures for these witnesses are insufficient to satisfy the requirements for "expert reports" under *New Jersey Court Rules*, Defendants now move this Court to enter a protective order relieving them of any obligation to provide formal expert reports for these company witnesses.<sup>3</sup>

### **DEFENDANTS' ARGUMENT**

Defendants argue that the company witnesses have knowledge and opinions acquired and developed *not* in anticipation of litigation or trial, but through their day-to-day responsibilities with regard to NuvaRing® over a period of many years, including the research and development and regulatory approval of the product. Thus, while these witnesses may be "experts" in their field, they are not "retained experts" for purposes of this litigation. Because these company witnesses should not be treated as "expert witnesses" governed by *Rule 4:10-2*, Defendants submit that they are not required to provide formal expert reports and, accordingly, a protective order should be entered.

Nevertheless, Defendants argue that, even if *Rule 4:10-2* applies to these witnesses, Defendants have already provided sufficient information as to each of the company witnesses to satisfy the requirements of *Rule 4:17-4(e)* in the form of Defendants' Amended Disclosures. These Amended Disclosures, according to Defendants, contain detailed statements of the company witnesses' qualifications,

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<sup>3</sup> At the Case Management Conference, the Court was informed that there may be a similar application filed before Judge Sipple in the MDL. This Court strives for consistency, cooperation and coordination among parallel state court and MDL proceedings, and towards that end has directed the parties to meet and confer in hopes that they might come to terms over defendants' submissions without the necessity of judicial intervention. However, though the parties may have reached agreement on this issue in the MDL, they have been unable to agree in this matter, due in large part to the substantive distinctions between *Fed. R. Civ. P. 26(a)(2)* and *New Jersey Court Rules 4:10-2 et seq.* and *4:17-4 et seq.*

expected testimony, the facts and data forming the basis for their testimony, as well as plaintiffs' 30(b)(6) topics and Defendants' responses thereto. Because the Amended Disclosures refer Plaintiffs to the various witnesses' depositions and spell out the testimony which each witness is expected to give, Defendants argue that their Amended Disclosures actually surpass the requirements of *Rule 4:17-4(e)*.

Defendants further argue that there is clearly no design to mislead Plaintiffs given the substantial detail contained in the Amended Disclosures. Nor can Plaintiffs claim surprise or prejudice given the extensive opportunities for discovery already provided with regard to the company witnesses, who were proffered for deposition and examined for ten days on the precise topics listed in the Amended Disclosures. The thousands of pages of deposition testimony as individuals and *Rule 30(b)(6)* witnesses, along with the Amended Disclosures are more than adequate to allow Plaintiffs' counsel another opportunity to prepare for further examinations of these witnesses on the same topics and to question them about any additional information in the Amended Disclosures that was not previously covered by prior depositions.

Given the extent of the previous discovery as to these witnesses, as well as the upcoming opportunities for further deposition questioning, Defendants submit that Plaintiffs' request for expert reports is mere gamesmanship which warrants entry of a protective order to prevent unnecessary expert reports.

### **PLAINTIFFS' ARGUMENT**

Plaintiffs argue that Defendants have failed to meet the good cause standard required for this Court to grant a protective order, as there is no evidence that serving

expert reports for these individual experts would in any way cause defendants annoyance, embarrassment, oppression, or undue burden or expense.

Further, Plaintiffs argue that the testimony of these company witnesses will “assuredly” go beyond simple first-hand knowledge and into expert testimony, and without a written report to hold them to its four corners, they will have free reign to testify not only to first-hand knowledge, but to areas that are clearly expert opinion.<sup>4</sup> As a result of Defendants’ failure to serve expert reports, Plaintiffs claim that they will be both surprised and prejudiced by the company witnesses’ testimony at trial.

Plaintiffs submit that Defendants’ Amended Disclosures are insufficient to meet the requirements of *Rule 4:17-4(e)*, as there is simply no permitted substitute for serving a written report from a proposed expert allowed under New Jersey law.<sup>5</sup> Similarly, Plaintiffs argue that New Jersey jurisprudence does not recognize any distinction in the obligation to serve reports of experts in a party’s regular employ versus those specifically retained to testify at trial. Rather, New Jersey’s Court Rules require that any testifying expert furnish a report upon due demand, without distinguishing between those specifically employed for litigation and those in a party’s regular employ.

### **DEFENDANTS’ REPLY**

Defendants respond that Plaintiffs mistakenly assert that *Rule 4:17-4(e)* applies here when, in fact, it does not. This is so, according to Defendants, because these witnesses are not “expert” witnesses as contemplated by *Rule 4:10-2* and there has been

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<sup>4</sup> As explained, *infra*, this objection is clearly premature and should be raised at trial if/when the witnesses’ testimony goes beyond first-hand knowledge and into the realm of expert opinion.

<sup>5</sup> Of course, this argument hinges upon the assumption that the company witnesses are being offered as “expert witnesses” and not as “fact witnesses.”

no interrogatory requesting the reports of these witnesses. Defendants submit that there is no basis under the New Jersey rules (or case law) to require these company witnesses to provide formal expert reports. Particularly under these circumstances, where the company witnesses' opinions and the factual basis for those opinions are already well-known, Plaintiffs' insistence that the witnesses provide formal expert reports amounts to mere harassment.

### **DECISION**

*Rule 4:10-2(d)* governs expert discovery. The *Rule* states, in relevant part: "Discovery of facts known and opinions held by experts, otherwise discoverable under the provisions of *R. 4:10-2(a)* and acquired or developed in anticipation of litigation or for trial, may be obtained ... through interrogatories ... to disclose the names and addresses of each person whom the other party expects to call at trial as an expert witness ... The Interrogatories may also require, as provided by *R. 4:17-4(a)*, the furnishing of a copy of that person's report."

*Rule 4:17-4(e)* requires that expert reports contain:

a complete statement of that person's opinions and the basis therefore; the facts and data considered in forming the opinions; the qualifications of the witness, including a list of all publications authored by the witness within the preceding ten years; and whether compensation has been paid or is to be paid for the report and testimony.

*Id.* The *Rule* further provides: "If an interrogatory requires a copy of the report of an expert witness or treating or examining physician as set forth in *R. 4:10-2(d)(1)*, the

answering party shall annex to the interrogatory an exact copy of the entire report or reports rendered by the expert of physician.” *Id.*<sup>6</sup>

Here, Defendants have requested that this Court enter a protective order relieving them of any obligation to provide formal expert reports for the company witnesses. The crux of Defendants’ argument is that the company witnesses are not “expert witnesses” as contemplated by *Rule* 4:10-2 and, even if *Rule* 4:10-2 applies to these witnesses, Defendants’ Amended Disclosures have provided Plaintiffs sufficient information as to each of these witnesses as to satisfy the requirements of *Rule* 4:17-4.

*Rule* 4:10-3 governs the issuance of protective orders seeking to limit or prohibit requested discovery. *Kerr v. Able Aantary and Environmental Services*, 295 N.J. Super. 147 (App. Div. 1996). The *Rule* provides, in relevant part: “Upon motion ... by the person from whom discovery is sought, and for good cause shown, the court may make any order which justice requires to protect [the] ...person from annoyance, embarrassment, oppression, or undue burden or expense...” *R.* 4:10-3; *see also Brady v. Dept. of Personnel*, 149 N.J. 244 (1997). The “good cause” standard in discovery applications is “flexible and its meaning is not fixed and definite. Each application for discovery ... must be evaluated upon the circumstances appearing from all of the pleadings and then determined in the sound discretion of the court.” *Tholander v. Tholander*, 34 N.J. Super. 150, 152-53 (Ch. Div. 1955); *Templeton Arms v. Feins*, 220 N.J. Super. 1, 21 (App. Div. 1987) (good cause takes “its shape from the particular facts

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<sup>6</sup> The *Rules* were amended in 2002 to further define the scope of expert reports. Under the amended *Rules*, oral summaries are no longer permitted. Rather an exact copy of the report must be furnished. The amendment also specifies the required contents of the report, namely, a complete statement of the opinion, the basis therefor, and the facts and data relied on together with any exhibits proposed to be used at trial; the expert's qualifications; and whether the expert is being compensated by the party retaining him. Thus, pursuant to our *Court Rules*, as amended, a summary of the expert’s opinion and expected testimony is no longer sufficient to satisfy the requirement of an “expert report.”

to which it is applied). While the “good cause” standard may be a malleable one, it is clear that the movant bears the burden of persuading the court that good cause exists for the issuance of a protective order. *Horan Holding Corp. v. McKenzie*, 341 N.J. Super. 117, 129 (App. Div. 2001); *D’Agostino v. Johnson & Johnson*, 242 N.J. super. 267, 281 (App. Div. 1990) (“[u]nder R. 4:10-3, the burden is clearly on the [moving party] to show that a protective order is necessary...”)

For the reasons that follow, and subject to the limitations described herein, the Court is of the opinion that good cause exists for issuance of a protective order relieving Defendants of the obligation to provide formal expert reports as to the company witnesses.

Defendants’ Amended Disclosures specifically note that the company witnesses’ expected testimony consists of “factual, historical and state of mind testimony regarding Defendants’ involvement with NuvaRing® and hormonal contraceptives generally.” (Winters Cert. Ex. A) Although these witnesses are undoubtedly “experts” in their respective fields, they have not been retained as experts and are more accurately characterized as fact witnesses. To the extent that the testimony of the company witnesses is, in fact, limited to facts and historical accounts, only, they need not furnish an expert report in order to testify in these matters.

However, the scope of the proposed testimony, as outlined in Defendants’ Amended Disclosures, clearly demonstrates Defendants’ intention to solicit expert opinions from the company witnesses. In the event that any expert opinion testimony is offered from these witnesses, the Court disagrees with Defendants’ analysis as to the necessity of an expert report: the *Rules* are clear that if expert opinions are being sought

or proffered a report is required, even if the witness is a company employee. *R. 4:10-2; 4:17-4*. Although the Court applauds Defendants' efforts to comply with the spirit of our *Court Rules* – namely, avoiding surprise and prejudice – the *Rules* require that any testifying expert furnish a report upon due demand, without distinguishing between those witnesses specifically employed for litigation and those in a party's regular employ. *Id.*<sup>7</sup>

Therefore, if Defendants intend to offer expert opinion testimony from these company witnesses they are required to prepare and serve expert reports, and it may nevertheless be wise to do so out of an “abundance of caution.” Supplying expert reports in advance of trial may obviate future motion practice and objections by plaintiffs as to these witnesses at relatively little expense to Defendants. If, however, Defendants chose

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<sup>7</sup> The Court is mindful of our Supreme Court's decision in *Stigliano v. Connaught Labs.*, 140 N.J. 305 (1995). However, the facts *sub judice* are clearly distinguishable. In *Stigliano*, a medical malpractice case, plaintiff brought suit alleging that a vaccine manufactured by respondent laboratory and administered to plaintiff by defendant-physician caused plaintiff to develop a seizure disorder. Thereafter, plaintiff consulted three physicians (“the treating doctors”) for diagnosis and treatment of the seizures, but opted not to call these treating doctors as witnesses at trial. On plaintiff's motion, the trial court entered an order precluding defendants from referring to the treating doctors' opinions on the cause of the disorder, and the causation testimony was to be redacted from the doctors' videotape depositions. The Appellate Division reversed and the Supreme Court affirmed. The Court held that by placing her medical condition in issue, plaintiff waived the physician-patient privilege, which was waived with regard to all knowledge of the physical condition asked about. The Court further held that Defendants need not have qualified the doctors as experts before the doctors could testify about causation because plaintiff consulted the doctors not for the purpose of obtaining expert testimony to support their cause of action but for treatment. The Court said: “Unlike an expert retained to testify at trial, the treating doctors gained no confidential information about plaintiffs' trial strategy. Although the treating doctors are doubtless ‘experts,’ in this case they are more accurately fact witnesses. Their testimony relates to their diagnosis and treatment of the [] plaintiff. In this context, moreover, the characterization of the treating doctors' testimony as ‘fact’ or ‘opinion’ creates an artificial distinction....As fact witnesses, the treating doctors may testify about their diagnosis and treatment of [plaintiff]'s disorder, including their determination of that disorder's cause. Their testimony about the likely causes of [plaintiff]'s seizure disorder is factual information, albeit in the form of opinion.” *Id.* at 314 (citing *N.J.R.E.* 701).

Although *Stigliano* provides guidance, the holding<sup>7</sup> of that case should be limited to the facts considered by the Court. Here, unlike in *Stigliano*, the company witnesses are not treating physicians. They have no first-hand knowledge of any individual plaintiff and, therefore, are not qualified to opine as to causation. However, the company witnesses do have first-knowledge of Defendants' involvement with NuvaRing® and hormonal contraceptives generally. These witnesses did not gain this information nor form their opinions in anticipation of litigation or in preparation of trial but as part of their day-to-day responsibilities with regard to NuvaRing® over a period of many years in Defendants' employ. This knowledge is certainly technical in nature and these witnesses are doubtless “experts” in their respective fields. Nevertheless, they may testify as fact witnesses and offer factual information, albeit in the form of opinion, about their personal involvement in the research and development of NuvaRing®.

not to serve expert reports for these company witnesses, they run the risk of having any improper testimony barred at trial.<sup>8</sup> See *N.J.R.E.* 403; *HSJ Properties, L.L.C. v. Secret Garden Landscaping*, 2011 WL 1118993 (App. Div. 2011) (finding trial court did not abuse its discretion in excluding expert opinion that had not been disclosed in report prior to trial); *Estok Corp. v. Bill Westervelt Paving, Inc.*, 2011 WL 1598845 (App. Div. 2011) (barring testimony of party employee/expert from whom no report had been furnished in violation of propounded discovery and court ordered disclosure).

### CONCLUSION

For the reasons stated herein, Defendants' Motions is GRANTED.

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<sup>8</sup> It should be noted that, even if a report is prepared and served, since Defendants have retained experts for this litigation much of the proposed testimony outlined in Defendants' Amended Disclosures may nevertheless be barred at trial as cumulative or irrelevant. See *N.J.R.E.* 403 ("Except as otherwise provided by these rules or other law, relevant evidence may be excluded if its probative value is substantially outweighed by the risk of (a) undue prejudice, confusion of issues, or misleading the jury or (b) undue delay, waste of time, or needless presentation of cumulative evidence."). However, it is premature to reach the merits of such an objection and the court declines to do so at this time. The Court will revisit the issue if and when it is raised at trial.