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February 27, 2018

VIA ECF

Honorable Paul A. Engelmayer United States District Judge Southern District of New York Thurgood Marshall United States Courthouse 40 Foley Square New York, NY 10007

Re: In re Mirena IUS Levonorgestrel-Related Products Liability Litigation (No. II), 17-MD-2767 (PAE), and 17-MC-2767 (PAE)

Dear Judges Engelmayer and Cott:

The parties received the Court's order dated February 20, 2018. The Court directed counsel to meet and confer on "the manner in which the Science Day primer is to be conducted" at the April 9 hearing "in the hope of developing jointly a plan to present a neutral primer on the relevant points." Feb. 20, 2018 Order (Dkt. #126). The parties have met and conferred and would like to request the Court's guidance on the format of the April 9 hearing. The parties' respective recommendations are set forth below.

Plaintiffs' Position

The Plaintiffs believe that Science Day should be an overview by counsel of the published literature, scientific data, and scientific methods at issue in the *Daubert* briefing. The purpose is to provide a clear scientific framework, unclouded by objections to specific experts, for the *Daubert* hearing that follows. The parties can freely present on these issues as they choose, so long as they do not go into the specifics of experts, which will be the subject of the *Daubert* hearing itself. The structure of the hearing is of course flexible. Plaintiffs propose a two-hour presentation by Plaintiffs, a two-hour presentation by Defendants, a 30-minute response by Plaintiffs, a 30-minute response by Defendants, and then whatever additional discussion the Court finds appropriate.

The Defendants have proposed using expert presentations for Science Day. There are circumstances in which an expert-led tutorial can be of use, but, as the *Manual for Complex Litigation* (*Fourth*) notes, expert tutorials typically involve "neutral court-appointed advisors" or "court-appointed experts." MCL, § 23.32, p. 498. The *Manual* cautions that "[t]he utility of outside advisors or experts

February 27, 2018

In re Mirena IUS Levonorgestrel-Related Products Liability Litigation (NO. II), 17-MD-2767 (PAE)

Page 2

depends on their ability to maintain objectivity and neutrality in their presentation." *Id.* At this stage of the case, the parties' experts have been deposed, and so the experts' presentations would either be redundant (because the same information is in their report or deposition) or be prejudicial to the other side (because the same information is *not* in their report or deposition). Worse, by the time of the presentation, *Daubert* briefs will have already been filed against these same experts. It would be only natural for the experts to use their presentations to defend their methods and to advocate for their opinions, particularly given that the opposing lawyers will not be able to cross-examine them. Plaintiffs thus submit that the use of expert presentations at this stage runs too high a risk of becoming a festival of objections rather than an informative session for the Court.

Defendants' Position

Defendants believe presentations from doctors who research and treat the condition at issue here and apply epidemiology in their own research would be most useful to the Court. To that end, Defendants propose lecture-style presentations by one or more experts for each party (allotting approximately two hours total per side), with questioning only by the Court. While the Court's February 20 Order states that the Court intends to limit the *Daubert* hearing on April 10-11 to oral argument, the Order does not specify whether the Court desires live presentations on April 9. Defendants' proposal is guided by the Court's comments from the June 13, 2017 conference, where Defendants proposed a Science Day format with presentations by experts for each side, and the Court commented that "hearing it from the expert and not through a litigator is far preferable" because the Court would be able to ask questions of the scientists. 6/13/16 Conference Tr. at 104:21-106:9. This format is also commonly used in similar MDLs. *See*, *e.g.*, Xarelto Order (Ex. A); Fluoroquinolones Order (Ex. B); Nuvaring Order (Ex. C).¹

These presentations will not be redundant; while the experts' reports contain background information, live presentations will provide the Court an opportunity to ask questions. If there is any risk of redundancy it is with lawyer presentations, given that the *Daubert* hearing will consist solely of lawyer argument. Similarly, the risk of advocacy is far greater with lawyers who have a duty to advance their clients' interests than with doctors who present on these same topics in their professional work outside of the courtroom. If the experts' presentations are appropriately focused on the relevant science, we think such an approach would best respond to the Court's request for a neutral primer without devolving into advocacy about competing methodologies or approaches. And if the experts do venture in an unhelpful direction, the Court would be able to refocus the presentation.

* * *

Ultimately, the Parties defer to the Court's preference and look forward to receiving guidance from the Court on this issue.

¹ The Manual section Plaintiffs reference is about a situation inapplicable here, where a Court decides to appoint a Special Master or independent expert to help meet its *Daubert* gatekeeping obligations.

February 27, 2018

In re Mirena IUS Levonorgestrel-Related Products Liability Litigation (NO. II), 17-MD-2767 (PAE)

Page 3

Respectfully submitted,

/s/ Martin D. Crump

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Jones Ward PLC
Co-Lead Counsel for Plaintiffs

Maxwell S. Kennerly Kennerly Loutey, LLC Liaison Counsel for Plaintiffs

CC (via ECF): All Counsel registered via ECF /s/ Shayna S. Cook

Shayna S. Cook Goldman Ismail Tomaselli Brennan & Baum LLP Co-Lead Counsel for Defendants

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E. James Shepherd Shook, Hardy & Bacon L.L.P. Counsel for Defendants

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF LOUISIANA

IN RE: XARELTO (RIVAROXABAN) PRODUCTS LIABILITY LITIGATION MDL NO. 2592

* *

SECTION L

JUDGE ELDON E. FALLON

MAG. JUDGE NORTH

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER NO. 18 **Science Day**

On June 11, 2015, the Court will hold "Science Day" to provide the Court with an overview of the medical and scientific issues associated with the medicine Xarelto® in an objective format without advocacy. Given the early stage of the litigation and discovery and to avoid duplication in presentation, the parties have agreed to the following ground rules to educate the Court on the basic issues in a non-adversarial manner and govern Science Day:

- 1. The parties have agreed that the topics to be discussed at Science Day include: a background on atrial fibrillation, a background on coagulation and anticoagulation therapy, anti-coagulation therapy before the Novel Oral Anti-Coagulants or NOACs, the approved indications and mechanism of action of Xarelto, clinical practice with Xarelto, adverse events with Xarelto, clinical trials pertaining to Xarelto, the use of blood test based dosing with Xarelto, and Xarelto pharmacology.
- 2. The Science Day presentations will be "off the record" without a court reporter and shall not be used or admissible for any purpose in the litigation other than for

the Court's benefit to gather informal knowledge at Science Day. The Parties

shall provide the Court with copies of the presentations on or before June 5, 2015

but will not share the presentations with each other.

3. The presentations shall be made by physicians and scientists. The presenters will

not be questioned by each other or opposing counsel. The Court will have the

opportunity to ask questions of the experts as the Court deems appropriate.

4. The format will be lecture-style presentations that incorporate the use of

PowerPoint presentations or other demonstrative visuals. The Parties will be

allowed to lead the experts through a modified direct format to focus the lecture

presentation.

5. The total length of time that will be allotted to Science Day shall be

approximately three and a half hours, as broken down by the following schedule:

a. Science Day will commence at 9:00am;

b. Defendants will proceed on all topics from 9:00am to 10:45am;

c. Plaintiffs will proceed on all topics from 11:00am to 12:15pm;

d. Final questions from the Court -12:15 to end

NEW ORLEANS, LOUISIANA this 20th day of May, 2015

UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

In re: FLUOROQUINOLONE PRODUCTS LIABILITY LITIGATION	MDL No. 15-2642 (JRT)
This Document Relates to All Actions	PRETRIAL ORDER NO. 11 SCIENCE DAY

On January 17, 2017, the Court will hold "Science Day" to provide the Court with an overview of the medical and scientific issues associated with the use of the fluoroquinolone medications Levaquin[®], Cipro[®], and Avelox[®] and peripheral neuropathy in an objective format without advocacy. Given the early stage of the litigation and discovery and to avoid duplication in presentation, the parties have agreed to the following ground rules to educate the Court on the basic issues in a non-adversarial manner and govern Science Day:

- 1. The parties have agreed that the topics to be discussed at Science Day include: a background on fluoroquinolone medications, including their uses and indications, risks and benefits, mechanism of action, and alternative treatments; and a background on peripheral neuropathy, including its diagnosis and treatment, risk factors and causes.
- 2. The Science Day presentations will be "off the record." A transcript will be prepared by a court reporter, but will be accessible only to the Court; the transcript may not be ordered by, and will not be made available to,

- the public or the parties. Presentations at Science Day are solely for the Court's benefit to gather informal knowledge and shall not be used to question or impeach any witness, and are not admissible for any purpose in the litigation.
- 3. The Parties shall provide the Court with copies of their presentations on or before **January 10, 2017**, but will not share the presentations with each other and will not file the presentations on the Court's docket.
- 4. Presentations shall be made by physicians and scientists. The presenters will not be sworn in, and will not be questioned by each other or opposing counsel. The Court will have the opportunity to ask questions of the experts as the Court deems appropriate.
- 5. The format will be lecture-style presentations that incorporate the use of PowerPoint presentations or other demonstrative visuals. The Parties will be allowed to lead their own experts through a modified direct format in order to focus the lecture presentation.
- 6. Each side shall have two (2) hours to present their experts. The schedule for Science Day shall be:
 - a. Plaintiffs will proceed on all topics from 10:00 am to 12:00 pm;
 - b. Lunch break: 12:00 pm 1:30 pm;
 - c. Defendants will proceed on all topics from 1:30 pm to 3:30 pm;
 - d. Final questions from the Court -3:30 pm to end.

DATED: October 26, 2016 at Minneapolis, Minnesota

s/John R. Tunheim

JOHN R. TUNHEIM

Chief Judge

United States District Court

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MISSOURI

IN RE NUVARING® PRODUCTS	 :	4:08 MDL 1964 RWS
LIABILITY LITIGATION	:	
	:	ALL CASES
	:	
	:	Honorable Rodney W. Sippel
	:	•

STIPULATED ORDER GRANTING DEFENDANTS' MOTION FOR A NUVARING® "SCIENCE DAY"

AND NOW, this day of ______, 2009, it is hereby ORDERED that Defendants' Motion for a NuvaRing® Science Day is GRANTED. The parties shall make their respective presentations to the Court on the _____ day of December_, 2009, in accordance with the following terms:

- 1. The focus of the presentations shall be solely on education, not argument. The subject matter will be limited to discussions of the NuvaRing®, the types of injuries claimed in this litigation, the terminology used to discuss the NuvaRing® and the injuries alleged, what if any effect the combination of hormones in NuvaRing® has when administered vaginally and whether the use of NuvaRing® increases the propensity of blood clot formations leading to potential Deep Vein Thrombosis and/or Pulmonary Embolism.
- 2. Lead counsel for Plaintiffs and counsel for Defendants shall each be entitled to identify at least one attorney and experts who will make a presentation. The length of each party's presentation shall not exceed two hours. Plaintiffs and Defendants may record their live presentations and provide the Court with a videotape or DVD of the presentation for the Court's future reference or may elect to submit their presentation already recorded on videotape or DVD.

- 3. The Science Day presenters will not be placed under oath. Counsel may not cross-examine the opposing party's experts. Neither the statements of the presenters nor their presentations will be transcribed by a court reporter or considered evidence. The presentations shall not include any testimony from or information about specific Plaintiffs or cases, and individuals who are not parties to this litigation shall not be present.
- 4. If a Science Day presenter later becomes a witness in the litigation, the presentation may not be used to cross-examine or impeach the presenter. The presentations are intended solely to educate the court about the scientific issues in the litigation and may not be used at any other time or for any purpose, except by the Court as it deems appropriate. The presentations are deemed confidential and subject to the Agreed Protective Order in place in this MDL.

BY THE COURT:

HONORABLE RODNEY W. SIPPEL, V.S.D.J

/s/ Paul D. Rheingold
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