

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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IN RE:	:	
	:	17-MD-2767 (PAE)
MIRENA IUS LEVONORGESTREL-RELATED	:	17-MC-2767 (PAE)
PRODUCTS LIABILITY LITIGATION (NO. II)	:	
	:	<u>ORDER</u>
<i>This Document Relates to All Actions</i>	:	
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PAUL A. ENGELMAYER, District Judge:

On April 9, 2018, the Court will hold “Science Day” to provide the Court with an overview of the medical, scientific, and epidemiological issues associated with the Mirena® intrauterine device and intracranial hypertension in an objective format without advocacy. As previously reviewed with counsel, the Court intends Science Day to proceed in the following manner:

1. The parties have agreed that the topics to be discussed at Science Day include: (1) under the subtopic the female reproductive system, contraception, and Mirena: (a) the relevant anatomy and physiology, (b) the types of contraceptives available for use in the U.S., and (c) what Mirena is and how it is used; (2) under the subtopic the brain, intracranial hypertension, and IIH/PTC: (a) the relevant anatomy, (b) what intracranial hypertension is and how it presents, (c) what IIH/PTC is, how it is diagnosed and treated, and the typical disease course, and (d) the incidence rates of IIH/PTC in various populations; and (3) under the subtopic epidemiology: (a) the difference between association and causation, generally, (b) the different types of scientific evidence, (c) evaluating epidemiologic studies, design, confounding variables, and bias, and (d) statistics 101, including risk ratios, odds ratios, p values, confidence intervals, and statistical significance.

2. The parties have agreed that the following topics are off limits: comments about the disclosed experts or their opinions, general causation, levels of LNG, its variability, and its effects outside of the uterus, demographics of Mirena users and whether there is preferential prescribing to certain women, comparative LNG levels in various contraceptives, the potential relationship between non-Mirena contraceptives and IHH, the benefits of Mirena beyond indication, and Bradford Hill.
3. The Science Day presentations will be “off the record.” However a court reporter will be present to make a transcript of the proceedings. The transcript will be used solely by the Court to refresh its recollection of Science Day. It will not be used or admissible for any purpose in the litigation.
4. The presentations shall be made by physicians and scientists. The presenters may be questioned by counsel, but solely as a means of moving the presentation along smoothly. There will be no opportunity for cross examination. The Court will have the opportunity to ask questions of the experts as the Court deems appropriate. As a reminder, Science Day is not an opportunity for advocacy. Its purpose is solely educational.
5. The Court has allotted the full day of April 9, 2018 for Science Day. Proceedings will begin at 9 a.m. and will include an hour-long break for lunch, and comfort breaks in the mid-morning and mid-afternoon. Court will adjourn by 5 p.m. For the parties’ planning purposes, each side is allocated at least two hours in which to present. Plaintiffs will present first, and defendants will present second.

SO ORDERED.



Paul A. Engelmayer
United States District Judge

Dated: March 30, 2018
New York, New York