

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS**

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IN RE YASMIN AND YAZ (DROSPIRENONE) 3:09-md-02100-DRH-PMF
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION MDL No. 2100

This Document Relates to: Judge David R. Herndon

ALL CASES

CASE MANAGEMENT ORDER NUMBER 41

Preservation of Highly Confidential Designation of Certain Materials

Herndon, Chief Judge

This matter is before the Court on Defendants Bayer HealthCare Pharmaceuticals Inc. and Bayer Pharma AG (collectively, “Bayer”) motion, pursuant to Case Management Order 7, to preserve the “highly confidential” designation currently protecting Case Summaries contained in the appendix to a German research study.¹ These documents were designated as “highly

¹ The European Active Surveillance (“EURAS”) study characterized and compared the short- and long-term risks of adverse events associated with the use of oral contraceptives. The study was conducted by the ZEG research group, and Bayer received certain interim and final reports. Over a five year period, more than 50,000 European women participated in the study. Each study participant received an informed consent and information form which assured her that no “individual data that could possibly reveal [her] identity” would be shared. *See* Doc. 1912-1. The Case Summaries reflect the private medical data of 522 study participants, including age, diagnosis, cardiovascular risk factors, medical (including gynecological) history, number of pregnancies and miscarriages, number of abortions, history of oral contraceptive use,

confidential” because they contain private medical data from identifiable persons that is protected under German data protection law. Bayer agreed to remove the confidentiality designation from the study report itself and most supporting materials. Plaintiffs are now requesting that Bayer remove the confidentiality designation from the Case Summaries as well. Bayer contends that doing so would place Bayer at risk of violating German law and would expose Bayer to civil and administrative penalties.

The plaintiffs and the plaintiffs’ experts have access to the Case Summaries for purposes of this litigation. Nonetheless, the plaintiffs are asking the Court to remove the confidentiality designation from these Case Summaries to allow for publication of the information contained therein. Plaintiffs have failed to convince this court that the confidentiality designation can be removed from these Case Summaries without directly violating German law – even with the elimination of case numbers or through the use of redaction. It is clear that the individuals who participated in this study did so believing that their information would remain private. Absent a compelling reasoning (which the plaintiffs have not shown) and absent a showing that the confidentiality designation can be removed without violating German law and the privacy rights of the study participants (which the plaintiffs also have not shown) the Court will not remove the confidentiality designation of these materials.

detailed symptoms and treatment. Doc. 1912. The Case Summaries do not contain individual names of study participants, but, Bayer contends, identification is nevertheless possible. *Id.*

Accordingly, Bayer's motion to maintain the confidentiality designation of these materials is **GRANTED**.

SO ORDERED

David R. Herndon



David R. Herndon

2011.09.14

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**Chief Judge
United States District Court**

Date: September 14, 2011