

# Exhibit 19

## Affidavit of Dr. Mahyar Etminan

PROVINCE OF BRITISH COLUMBIA

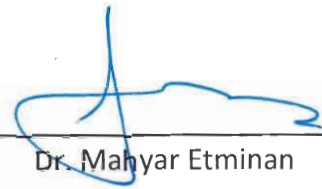
CITY OF VANCOUVER

On this date Dr. Mahyar Etminan personally appeared before me, the undersigned who is authorized by the law of Canada to administer oaths, and after being duly sworn on his oath under penalty of perjury, deposed and stated as follows:

1. My name is Dr. Mahyar Etminan. I am over 21 years of age and am competent to make this Affidavit. I have personal knowledge of the facts stated in this Affidavit, and these facts are true and correct. I make the statements contained in this Affidavit under no duress, coercion, promise of reward or gain, or undue influence after consulting with my attorney, Mr. Michael Peerless.
2. I am the lead author on the article titled, "Risk of intracranial hypertension with intrauterine levonorgestrel," published in 2015 in the journal *Therapeutic Advances in Drug Safety*.
3. The article reports the results of two different analyses concerning Mirena and intracranial hypertension. The first analysis used the U.S. Food and Drug Administration's Adverse Events Reporting System (FAERS) database to calculate reporting odds ratios (RORs). This type of analysis is sometimes referred to as a disproportionality analysis (DPA). The second analysis used information from IMS LifeLink, a large health claims database, to calculate risk ratios for Mirena versus two combination oral contraceptive (COC) pills. This analysis was a retrospective cohort study.
4. The FAERS DPA published in the article calculated RORs for Mirena versus all other products in the FAERS database; the comparator group was not limited to oral contraceptive pills or any other specific product.
5. I relied on an analyst to extract the data from the FAERS database used for the published FAERS DPA.
6. To the best of my knowledge, the analyst did not limit the groups compared in the FAERS DPA to reproductive age females. Because the background incidence of intracranial hypertension is higher in reproductive age females than in other demographic groups, failing to limit the comparator group to reproductive age females can artificially inflate the ROR for Mirena, as almost all Mirena users are reproductive age females. Therefore, a proper analysis would be limited to women of reproductive age.
7. I do not know if my analyst used unique cases, or instead used unique reports, for the FAERS DPA. Because the same individual case can have multiple unique reports filed in the FAERS database, using unique reports can result in individual cases being counted more than once in the analysis. The proper analysis should use unique cases, not unique reports.

8. I have no basis to say that the results of the FAERS DPA would have been statistically significant, or that the point estimate would have been greater than 2.0, had the control group been properly limited to reproductive age females and had the analysis properly used unique cases rather than unique reports. Indeed, re-running DPA analyses of the FAERS data using OpenVigil 2.1 software and properly limiting it to unique cases and women of reproductive age results in no elevated ROR for Mirena, suggesting that intracranial hypertension and Mirena use are “likely not related.”
9. The retrospective cohort analysis published in the article found no statistically significant difference in risk between Mirena and either of the COC comparators.
10. For neither the FAERS DPA nor the retrospective cohort analysis did I have weight data (BMI or recent weight gain) that would have allowed me to control for weight as a potential confounding variable as the FAERS data do not generally provide BMI information for every case
11. Based on the above, as the lead author of this article, I acknowledge that neither of the analyses in the article provide evidence that Mirena use increases the risk for intracranial hypertension. Therefore, there is no basis to say, based on these analyses, that the risk of intracranial hypertension with Mirena use outweighs the risks of unplanned pregnancies.
12. At the time I conducted these analyses and submitted them for publication, I was being paid by lawyers suing Bayer in cases alleging that Mirena caused users to develop idiopathic intracranial hypertension (IIH). I did not disclose that relationship when I submitted the manuscript for publication, nor in the published article itself.
13. In response to a letter to the editor regarding my article, I published an author reply in 2016, again in *Therapeutic Advances in Drug Safety*.
14. In my author reply, I reported that I had used the program OpenVigil 2.1 to calculate, using the FAERS database, a ROR of 3.4 (95% CI: 2.59-4.45) for “benign intracranial hypertension” (another name for IIH) when comparing female Mirena users to female users of all other products in the FAERS database.
15. That statement was in error. As I was not very familiar working with OpenVigil 2.1, when calculating the ROR of 3.4, I failed to limit the groups to reproductive age women, which introduced a bias against the Mirena group. I also inadvertently searched unique reports, rather than unique cases. As a result, some Mirena cases were included more than once.
16. When that analysis is properly limited to reproductive age females and unique cases, the resulting ROR for Mirena is 0.91 (95% CI: 0.57-1.45). This result is not statistically significant, the point estimate is below one, and it does not support the claim that Mirena use increases the risk for IIH.
17. On April 15, 2016, I provided sworn testimony on these and other related topics in my capacity as a paid expert witness for lawyers suing Bayer. I subsequently withdrew as an expert in those cases. I hereby adopt that sworn testimony in my capacity as a fact witness in the same litigation.

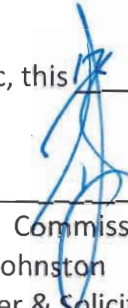
Further Affiant sayeth not.



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Dr. Mahyar Etminan

Subscribed and sworn to before me, a notary public, this 17 day of December, 2016.



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Commissioner for Oaths

Brent Johnston  
Barrister & Solicitor  
Three Bentall Centre – Suite 3013  
595 Burrard Street, P.O. Box 49043  
Vancouver, B.C., V7X 1C4

My Commission Expires:

N/A.