UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

SADIE MILLER	)	
	)	
	)	
Plaintiffs	)	**Civil Action No.: 4:14-cv-00652-SRB**
	)	
v.	)	
	)	
BAYER HEALTHCARE PHARMACEUTICALS INC., et al.	)	
	)	
	)	
Defendants.	)	
	)	

PLAINTIFF'S RESPONSE TO MOTION FOR SUMMARY JUDGMENT

Among the many exogenous agents associated with intracranial hypertension, the best evidence exists for the tetracyclines, vitamin A and retinoids, corticosteroid withdrawal, human growth hormone, nalidixic acid, leuprorelin acetate, chlordecone pesticide, **and levonorgestrel contraceptive system.**

See Bayer's Non-Testifying Expert Consulting Witness, Deborah I. Friedman, MD, *Idiopathic Intracranial Hypertension*, Current Pain and Headache Reports 11:62-68 at p. 67 (2007) (emphasis added), attached as Ex. 1.

In contrast to oral contraceptives, ***there is a well established relationship between PTC and levonorgestrel-releasing implants.***

See Bayer's Non-Testifying Expert Consulting Witness, Deborah I. Friedman, MD, *Medication-Induced Intracranial Hypertension*, Am. J. Clin. Dermatol 2005: 6(1)-29-37 at p. 35 (emphasis added), attached as Ex. 2.

Exposure to an LNG-IUS was significantly associated with the development of IIH (OR 7.7, 95% CI 3.2-16.4, p<0.001); the prevalence of IIH was 0.18% in the LNG-IUS population (8/4408, 95% CI 0.07-0.35) versus 0.02% in the non-LNG-IUS population (51/216555, 95% CI 0.01-0.03). … There were no significant differences between LNG-IUS users and non-users in terms of age, body mass index, recent weight gain, or presenting signs and symptoms.

Rai/Digre, et al., "The relationship between the levonorgestrel-releasing intrauterine system and idiopathic intracranial hypertension", *Invest. Ophthalmol. Vis. Sci.*. 2015; 56(7):2228 (emphasis added), attached as Ex. 3.

INTRODUCTION

Bayer admits in its "corporate causality statement" what it refuses to admit in this litigation, to the FDA, foreign regulatory authorities, and medical organizations or otherwise convey to patients and their healthcare providers: The "company considers CEREBRI PSEUDOTUMOR BEHIND EYE to be ***related to Mirena.***" *See e.g.* Collective Ex. 18, (case no. 2011-092783) (emphasis added); (case no. 2011-048838) (the "***company considers*** INTRACRANIAL HYPERTENSION ***to be related to Mirena***.") (emphasis added); (case no. 2011-059368) ("PSEUDOTUMOR CEREBRI is considered serious as medically important and is unlisted in the Company Core Data Sheet for Mirena event. With the apparent temporal association and the

absence of alternative explanation the ***causal relationship*** of the reported event to the treatment with Mirena assessed ***as related.”***) (emphasis added); (case no. 2011-110099) (“[A] causal relationship between pseudotumor cerebri and treatment with Mirena cannot be excluded since a temporal relationship is to consider. No proven alternative explanation was reported. ***The causality is assessed as related.”***) (emphasis added); (case no. 2012-048903) (“As temporal relationship between all events and Mirena use is positive, ***causality cannot be excluded***.” (emphasis added); (case no. 2012-06117) (“Due to a compatible temporal relationship ***benign intracranial hypertension is considered as related to Mirena***.”) (emphasis added); (case no. 2012-065106) (***“Based on temporal association and positive dechallenge, the association between Mirena use and the event cannot be excluded.”***) (emphasis added); (case no. 200831604NA) (“Although the use of oral contraceptives is thought to increase the risk of IIH, it is unknown if the use of Mirena increases the risk of IIH, or if the occurrence of this disorder may be related to other factors. ***Be that as it may, with a compatible temporal relationship, and no specific known alternative explanation, a causal relationship to Mirena cannot be excluded.”***); (case no. 201036696NA) (“Based on a compatible temporal relationship, ***causality cannot be excluded.***”) (emphasis added); (case no. 2011-074707) (“BMI of patient is normal … Based on the positive temporal relationship a ***causal association*** between Mirena and the event ***cannot be excluded.***”) (emphasis added)[1]

Defendants’ internal causation determination is not completely surprising. Medication-induced intracranial hypertension is well-established, generally accepted in the medical community, and even acknowledged by Bayer’s own experts.[2] So is levonorgestrel-related

[1] Despite Bayer’s vigorous denial that there is absolutely no connection between Mirena and this serious and rare condition, a group of the most prominent researchers in the field (none of whom are experts in these cases) reported that their epidemiological study demonstrated that “[e]xposure to an LNG-IUS was significantly associated with the development of IIH (OR 7.7, 95% CI 3.2-16.4, p<0.001)[.]” *See Rai/Digre Study* at Ex 3. In other words, a woman exposed to a Mirena is 7.7 times (or 770%) more likely to develop the condition. Moreover, the group concluded that the prevalence of the condition was 9 times higher in Mirena users versus non-Mirena users. *Id.*

[2] One of Bayer’s key experts, Dr. Nancy Newman, even testified in 2009 in favor of an obese plaintiff who

intracranial hypertension. Of those medications recognized by the medical community to be related to the development of PTC/IH, Bayer's non-testifying consulting expert, Dr. Deborah Friedman, concludes that levonorgestrel is among those for which "the best evidence exists." *See* Ex. 1.

While Bayer proudly touts Mirena as "safe and effective" and "well-tolerated by patients," Defendants fail to tell the full story. In fact, just since 2004, the FDA has received 76,840 adverse event reports related to the Mirena product. Moreover, of every single drug product on the market in the United States since January 1, 2004, Mirena is the number one drug associated with adverse event reports of ***benign intracranial hypertension*** (which is the FDA MedDRA preferred term used in the FDA's FAERS database).[3] This was true before this litigation began and it still proves

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developed PTC/IH from the use of minocycline, concluding:

> So if you ask me to a degree of medical probability, like over 50 percent, given that she's still obese, and that the pseudotumor has not come back, and she has someone watching to make sure there is no swelling of her optic nerves, the lumbar puncture would no longer be at play, the Diamox would no longer be at play, the only thing at play is that she had stopped the minocycline..

See Ex. 21, Deposition of Nancy J. Newman, M.D., *Weilbrenner v. Teva Pharms U.S.A., Inc.*, Case No.: 7:08-CV-23 (M.D. Ga.) (March 10, 2009). The Court in that case ultimately denied Defendant's motion for summary judgment. *See Weilbrenner v. Teva Pharms U.S.A., Inc.*, 696 F. Supp. 2d 1329 (M.D. Ga. 2010).

[3] Defendants' continued attempts to mislead various courts, including this Court, about "idiopathic" intracranial hypertension borders on outrageous.

> By definition, the term 'IIH' describes patients with isolated raised ICP that is not related to an intracranial disorder, a meningeal process, or cerebral venous thrombosis. However, patients who develop a syndrome of ***raised ICP triggered by certain medications*** or who are found to have cerebral transverse venous sinus stenosis, not thrombosis, ***are still conveniently classified as having IIH.*** Therefore, although imperfect, the term 'IIH' is currently the preferred designation for this disorder in the English literature, to the exclusion of 'pseudotumor cerebri' (often including patients with other causes of raised ICP such as cerebral venous thrombosis) and 'benign intracranial hypertension' (erroneously reassuring considering that a number of IIH patients irreversibly lose vision). This imperfect nomenclature will need to be revised as our understanding of the etiology and pathophysiology of IIH improves.

See V. Biousse, B. Bruce (Bayer Expert) and N. Newman (Bayer Expert), Update on Pathophysiology and Management of Idiopathic Intracranial Hypertension, *J Neurol Neurosurg Psychiatry,* 83:488-494 (2012) (emphasis added). As Dr. Newman testified in the *Weilbrenner* case, with respect to the terms "idiopathic intracranial hypertension" and "pseudotumor cerebri," the terms are used "interchangeably" and it just "depends on what you prefer." *See* Ex. 21 at p. 38-39.

Like Dr. Tang, despite the other alleged "significant know risk factors" Defendants describe in their brief (DN 68 at p. 2-4), Dr. Newman testified in *Weilbrenner* that "I do think that the minocycline tipped it over in her, but I don't think it was there already. I think it's what made it happen in a susceptible person." *Id.* at 132. Indeed, in this case as

to be true today. Indeed, from January 1, 2004 (the oldest data available from FDA) through March 31, 2016 (the most recent data available from FDA), there were 620 reports of benign intracranial hypertension associated with all drugs. Of those 620 reports, 108 (or 17.42%) were reported in association with Mirena. *See* Ex. 4 (utilizing data from www.researchae.com, which Bayer's expert, Dr. Feigal, used for his report). When the dates are restricted to cases reported prior to the first-filed PTC/IH case, Mirena retains the number one spot; there are 433 reports –of which 25 reports (or 5.77%) were associated with Mirena. *See id.* Thus, Mirena has occupied the number one spot both ***before*** and ***after*** this litigation began.

a. History of Norplant and Other Levonorgestrel-Releasing Products

This is not a new problem for the Defendants. They've been down this road before, so to speak, with their first venture into the levonorgestrel-releasing contraceptive business –the Norplant levonorgestrel-releasing system –a very similar product that releases the same synthetic hormone, from the same type of cylinder, albeit in the arm instead of the uterus. The evidence of a causal association between levonorgestrel and PTC/IH actually begins not with the scientific literature, but with an FDA label change for the levonorgestrel-releasing Norplant contraceptive in the early 1990's. Developed by an organization called the Population Council Inc., Norplant was manufactured by Leiras OY (now Bayer OY) but sold in the United States by Wyeth Pharmaceuticals –while Leiras OY (now Bayer OY) sold Norplant to the rest of the world. Likewise, Mirena was developed by the Population Council, Inc., manufactured by Leiras OY (now Bayer OY) and sold by Berlex Laboratories (now Bayer Healthcare Pharmaceuticals, Inc.) beginning in 2001, well after the Norplant label change.

Before any case reports, case series, or other data were published, Wyeth (the U.S. seller

well, there is a fact issue regarding whether the levonorgestrel "tipped it over" in a "susceptible person," like Plaintiff.

of Norplant) and the FDA began discussions to change the Norplant label to include a PTC/IH warning on the product labeling. According to the plain language of the warning which was ultimately adopted by FDA, the change was based solely upon spontaneous case reports. The warning was direct, specific and informative:

> 7. Idiopathic Intracranial Hypertension
>
> Idiopathic Intracranial Hypertension (pseudotumor cerebri, benign intracranial hypertension) is a disorder of unknown etiology which is seen most commonly in obese females of reproductive age. There have been reports of idiopathic intracranial hypertension in NORPLANT SYSTEM users. A cardinal sign of idiopathic intracranial hypertension is papilledema; early symptoms may include headache (associated with a change in frequency, pattern, severity, or persistence; of particular importance are those headaches that are unremitting in nature) and visual disturbances. Patients with these symptoms, particularly obese patients or those with recent weight gain, should be screened for papilledema and, if present, the patient should be referred to a neurologist for further diagnosis and care. NORPLANT SYSTEM should be removed from patients experiencing this disorder.[4]

See Norplant Label at p. 5, attached as Ex. 5.[5] Again, at the time of this label change in the United States, Leiras OY (now Bayer OY) was manufacturing Norplant for Wyeth and selling Norplant in the rest of the world under its own name. Presumably, the Defendants were not only involved in the U.S. label change discussions, but also changed their own Norplant label as they sold it to the rest of the world. However, we will never know for sure because the Defendants have refused to provide Norplant discovery because they claim it "is not relevant" –even going as far as redacting the word "Norplant" from documents specifically discussing Mirena and PTC/IH.

Moreover, as it relates to the injury at issue in this case, there is a completely safer

[4] Notably, if one merely replaces the word "Norplant System" with the word "Mirena" in the warning above, everything in that warning was true over 15 years ago and remains true today as it relates to Mirena.

[5] Bayer and its predecessors (as manufacturers) were involved in obtaining product approval for a product called Jadelle or Norplant-2. It was approved by FDA in 1996 (before Mirena was placed on the market) and updated in 2002 (after Mirena was placed on the market). Jadelle has a similar Benign Intracranial Hypertension/Pseudotumor Cerebri warning. *See* Jadelle Label, attached as Ex. 6. Bayer continues to sell this product today, with the PTC warning.

alternative, which is a nearly identical device. At the time the Mirena levonorgestrel-releasing IUD was originally marketed, and even today, the Mirena had a nearly identical competitor product (also designed by the Population Council, Inc.) that releases copper instead of a potent synthetic hormone. The Paragard (a T-shaped IUD similar in size and design to Mirena) has been on the market longer than Mirena, it is indicated for five years longer than the Mirena, and it is highly effective. As Paragard claims, it is "more than 99% effective in preventing pregnancy and has no hormones at all." *See* http://www.paragard.com/What-is-Paragard.aspx, attached as Ex. 20. Because it has no hormones, the Paragard has no hormonal systemic effects. Not only has the Paragard T-shaped IUD been marketed in the United States for over 30 years, but **not a single PTC case** has been reported in relation to its use.[6]

b. Federal Law Regarding Warnings

At the time Mirena was initially introduced to the market, until 2006, federal law provided that a product's label must be revised to include a warning "as soon as there is reasonable evidence of an association of a serious hazard with a drug; ***a causal relationship need not have been proved***." *See* Ex. 23, Dr. Ross Expert Report at 31. On January 24, 2006, as part of the Physician Labeling Rule ("PLR Format"), the FDA labeling regulations were amended. Even after the PLR Format was implemented, it provided that the standard for adding a warning was "reasonable evidence of a causal association." 21 CFR 201.57(c)(6).

Under the PLR Format, the "Adverse Reactions" section of the warning label provides an even lower bar for adding information to the warning label:

> (7) *Adverse reactions.* This section must describe the overall adverse reaction profile of the drug based on the entire safety database. ***For purposes of prescription drug labeling, an adverse reaction is an undesirable effect, reasonably associated***

[6] As Bayer's Global Safety Lead for Mirena testified, it would be "absurd" to think that Paragard could cause PTC because "it doesn't contain any medication or any drug, which also means that it hasn't got any systemic effect." *See*. Schoendorf Dep. at 118, Ex. 22.

> ***with use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence.*** This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is ***some basis to believe there is a causal relationship*** between the drug and the occurrence of the adverse event.

21 CFR 201.57(c)(7) (emphasis added). This includes even "adverse reactions that occur with the drug and with drugs in the ***same pharmacologically active and chemically related class*** … ." *Id.* at 21 CFR 201.57(c)(7)(i) (emphasis added). Moreover, the PLR Format provides for a Post-Marketing Experience section of the label:

> (B) *Postmarketing experience.* This section of the labeling ***must list the adverse reactions***, as defined in paragraph (c)(7) of this section, ***that are identified from domestic and foreign spontaneous reports.*** This listing must be separate from the listing of adverse reactions identified in clinical trials.

Id. at 21 CFR 201.57(c)(7)(ii)(B) (emphasis added). Nonetheless, even today, Mirena still does not contain any mention of PTC/IH in its label.

c. History of Mirena and PTC/IH

Even specifically related to Mirena (as opposed to levonorgestrel generally), the potential association with PTC/IH became apparent from the beginning. Before the Mirena was even approved in the United States, according to a February 2000 document, Defendants updated their Investigator's Brochure (a document used to provide study investigator's with all of the product information and its full listing of risks) to include: "Benign intracranial hypertension" and "Retrobulbar pain and migraine-like defective vision" among other things. *See* MIR_INDA_00294078, attached as Ex. 7; *see also* Suspect Adverse Reaction Report, MIR_KJEU_00000938-941, attached as Ex. 8; Compare MIR_JR_00020508-517 at 509, attached as Ex. 9 (in discussing draft labeling noting "In this document we cannot miss anything important i.e. all relevant AEs should be mentioned even if they are rare ….") This update reflected serious adverse event ("SAE") reports that the company had received from foreign sources during the

period of 9/28/99 to 2/8/2000. *Id.* These are classic cases of PTC/IH.

In 2001, the New Zealand Health Authority (MEDSAFE) wrote to Schering (a Bayer predecessor):

> The WHO database holds 85 reports of intracranial hypertension and 45 of papilloedama with Mirena. Two cases have been reported in the literature of intracranial hypertension with Norplant, which is an implanted subdermal device also releasing levonorgestrel. The MARC [Medicines Adverse Reactions Committee] wondered whether there was a causal association between Mirena and benign intracranial hypertension.

See MIR_KJEU_00000923, attached as Ex. 10.

In May of 2005, according to a Bayer internal document, a United States physician called the company to ask if "pseudo-tumor cerebrii [sic] [is] a contraindication and why?" *See* MIR_AC_00399139 and MIR_AC_00056064, attached as Ex. 11. The response from Anthony Costales, the U.S. Medical Director for Mirena: "Spoke with Dr. Polanski: --emphasized that Berlex has not studied th [sic] use of Mirena in women with pseudotumor cerebri. –Although Mirena's mechanism of action are generally local, **Mirena does produce significant levels of LNG in the serum.** In especially sensitive women this may be associated with some form of edema, bloating or water retention – which may exacerbate the elevated intracranial pressure in pseudotumor cerebri ACC." *Id.* (emphasis added). Contrast Dr. Costales' admission with a May 4, 2006 e-mail, when Bayer's United States pharmacovigilance head said (about discussing a case of PTC/IH with a doctor): "Paul and I have slightly differing opinions on how much information to convey to the physician and whether to suggest that the physician should consider removing the IUS. The 'standard' response from Leiras, in my opinion, has more information than we would normally convey to a physician in the US." *See* MIR_CW_00416118, attached as Ex. 12; *see also* MIR_CW_00416114-17, attached as Ex. 13; MIR_AC_00357784, attached as Ex. 14. Not surprisingly, it was frowned upon by upper management to discuss such safety issues over the

email. *See* MIR_PK_00049632-633 ("Dear Tim and Tony, I [sic] please avoid any communications regarding safety issues by email."), attached as Ex. 15.

In 2008, the United Kingdom's Medicines and Healthcare Products Regulatory Agency ("MHRA") wrote to Bayer about 24 cases for "Mirena (levonorgestrel implant) & Benign Intracranial Hypertension (BIH)." *See* MIR_PKEU_00254948, attached as Ex. 16. According to the letter, ***Bayer*** reviewed the 24 cases and reported that ***Bayer*** "found no conclusive temporal patterns and no unambiguous cases of positive dechallenge." *Id.* Additionally, ***Bayer*** conducted a "literature review" that Bayer reported that it "did not find supporting evidence." *Id.* Further, ***Bayer*** concluded that the "current available data for Mirena do not indicate an associated risk for development of BIH." *Id.* While the MHRA "accept[ed] [Bayer's] conclusion," it requested that Bayer closely monitor the issue and expedite new information to the agency. *Id.* Importantly, Bayer never shared with the MHRA that its own internal company causality statements indicated otherwise.

As discussed in the *Daubert* responses, the company has engaged in at least five different internal safety signal investigations throughout the years –all relying upon largely the same materials and reaching the same result (i.e., the "standard response"). What Bayer did not do, and has not done, is take the initiative to study this serious issue itself. Nor has it ever placed a PTC/IH warning on its product labeling or in the Patient Information Booklet its provides to each and every patient. Given the causal association between levonorgestrel and PTC/IH, as discussed in the *Daubert* response briefs, Bayer should be held to answer before a jury for its conduct.

d. <u>Hormones/Hormonal Adverse Effects Misrepresentations</u>

Contraception is a choice. Not only whether to use it, but the kind of contraceptive a woman uses is also a choice. There are many, many contraceptive choices –even within the same

pharmacological classes. Whether a woman wants to use a progestin, an estrogen, or no hormone at all. Whether a woman wants to take something every day by mouth, get a shot, use a patch, have it inserted or implanted in the arm or in the uterus. There are many choices. And these are the things that women consider when making that choice. Bayer realizes this. It spends many millions of dollars per year advertising directly to prospective customers (or patients) in the form of television advertising, website advertising, pay-per-clicks, text messaging, podcasts, sponsorships, in-home seminars, YouTube videos, direct mail, etc.

Mirena was approved in the United States in December 2000 and was first marketed in 2001. Bayer suggests that the device releases such a low dose of hormone that it could not cause hormonal systemic adverse effects. This is simply not true. The measureable level of levonorgestrel is far from a trace amount. Bayer's marketing of this product and its defense in this case, has centered upon such a false theory. Indeed, Bayer has used the following terms to market its product to both consumers and the medical community alike: "tiny amounts of hormone in the body," "Mirena works by slowly releasing tiny amounts of levonorgestrel into the uterus," "mainly local progestogenic effects," "slowly releases small amounts of the hormone," "very small amount," "acts locally and only where it is needed," "releases small amounts of hormone directly to the womb" "[i]t has minimal hormonal adverse effects as it contains much smaller doses of progestogen (hormone) than the mini-pill (progestogen-only pill)," "keeps hormone levels steadier," "releases tiny amounts of local progestin," "[b]ecause of the low drug levels in plasma, the systemic effects of the progestogen are minimized," "IUDs have no systemic effects," "[a]s a local hormonal method, MIRENA releases only tiny amounts of levonorgestrel, and therefore adverse effects are rare and tend to diminish with time," "Mirena may be a good option for women who are sensitive to hormones," "only small amounts of this hormone enter your blood,"

"essentially no systemic effects," and "side effects are rarely … expect[ed] due to the low systemic effects of Mirena." *See e.g.* Ex. 24.

However, Bayer's "low hormone" theory is undermined by the admissions of its own employees, like Dr. Costales (i.e. "**Mirena does produce significant levels of LNG in the serum")**, as well as its creation of the much lower dose Skyla/Jaydess (also known as the mini-Mirena) and its efforts to develop a "New Progestin" for the very purpose of eliminating the hormonal adverse effects associated with Mirena. *See* Masterplan Project Description, New Progestins IUS at Ex. 25 (noting that "Undesired effects of Mirena concern systemic effects" that "are due to the systemic availability of Levonorgestrel" and the company's goal to produce a new progestin that has a "37-fold lower exposure" than Mirena "due to its high clearance compared to Levonorgestrel.")

Moreover, despite its own Medical Director's admission that Mirena "produces significant levels of LNG in the serum" (meaning "systemically" not "locally") which can cause systemic effects that "may exacerbate the elevated intracranial pressure in pseudotumor cerebri," Defendants built their marketing campaign around the exact opposite conclusion, one that has defrauded physicians and patients alike. For example, the company published an advertisement in Body + Soul magazine, directed at hormone averse/sensitive women states:

> Love your body, and it'll love you back! That's why you exercise and pay more attention to what you eat and drink. **You read product labels.** Avoid the bad stuff. **When it comes to contraception, you like the Pill, but you go as low-dose as you can. And wouldn't it be nice if you could go even lower.**
>
> You can! Mirena is a tiny, flexible, intrauterine contraceptive that **applies a tiny amount of hormone directly to the uterus**,[7] and contains no estrogen.
>
> So with Mirena, you're not only taking care of your body, but you're taking care of your contraceptive needs simply and completely.

[7] Actually, the local endometrial levels are more than 100 times higher than users of an LNG pill.

See MIR_AC_00391502, attached as Ex. 26 (emphasis added). In light of Dr. Costales' admission, such an ad campaign is fraudulent, misleading, and indeed dangerous.

Even Bayer's Patient Information Booklet (which is presented before the patient receives the Mirena and requires her to sign a consent form) recognizes that it is the *patient's choice* whether or not to use the Mirena: "Read this Patient Information carefully before ***you decide if Mirena is right for you.*** … You should also learn about other birth control methods to ***choose the one that is best for you.***" *See* Mirena Patient Information Booklet, attached as Ex. 19. The booklet advises that: **"**Only small amounts of the hormone enter your blood." *Id.* That's what Bayer tells patients –which is completely contrary to what Mr. Costales told a physician over ten years ago. Likewise, the Patient Information Booklet fails to mention PTC/IH as a potential side effect.

e. Ghostwriting: Creating Science

Perhaps even more unconscionable than its clearly misleading ad campaign directed at consumers and healthcare providers alike, Plaintiff has recently discovered hundreds of documents that evidence a coordinated effort by Defendants to use third party ghostwriters to write scientific manuscripts touting Mirena's safety, tolerability, and even off-label promotion of "benefits" not approved by FDA and then solicit prominent physicians to attach theirs names to the manuscripts with minimal involvement by the alleged authors. Defendants used companies such as Helix Medical Communications, Cerner, Wolters Kluwer and others. For insight into how this process played out, Defendants' publication plan, the cost of the ghostwriting, the stage at which the authors become involved, and the control that Defendants exercised over the substance, see the attached collective Exhibit 27. This is apparently how science is made, at least by the Defendants.

f. Ms. Miller's Diagnosis

Ms. Miller received a Mirena IUD for contraception on January 25, 2013. Ex. 17A, at

SMiller-PPR-0001821. After experiencing bleeding and pelvic pain, the device was found to be in the wrong position and was replaced on May 24, 2013. *Id*. at SMiller-PPR-000196. Just three months after her second Mirena insertion, Ms. Miller began experiencing bleeding; chest pains; lightheadedness; pain in the arm, neck, and back of the head; and severe headaches associated with tinnitus and blurry vision in both eyes. *Id.* at SMiller-PPR-000210, SMiller-PPR-000228 (record dated 08/11/2013, headache and associated symptoms "onset/duration: 2wk"). On August 1, 2013, Ms. Miller "requested removal of the IUD because of adverse effects related to the device." *Id.* at SMiller-PPR-000210.

After diagnosis of papilledema and associated symptoms, Ms. Miller was referred to neurology and underwent imaging, lumbar puncture, and cerebrospinal fluid (CSF) studies. *Id.* at SMiller-PPR-000027. Ms. Miller was diagnosed with "Atypical pseudotumor cerebri" as she did not fit the classic risk factors for the disease, and "her symptoms [were] quite precipitous and perhaps associated with the Mirena IUD." *Id.* at SMiller-PPR-000030. Unfortunately, Ms. Miller continued to experience symptoms including headaches, whooshing noises, and fluctuating visual acuity, despite removal of Mirena, medication therapy and weight loss attempts. However, continued improvement and eventual resolution was noted in her visual fields and imaging of the optic nerves. *See* Ex. 17B at SMiller-UKansasMC-MD-000086.

Two of Ms. Miller's treating providers told her that they thought the Mirena was the cause of her injuries. *See* Ex. 28, Miller Dep. 242:25 to 244:1-7. Dr. Thomas Whitaker wrote in his records" "The patient is not terribly obese, her symptoms quite precipitous perhaps associated with the Mirena IUD, so I am concerned this is not typical idiopathic intracranial hypertension." *See* Ex. 29, Thomas J. Whittaker, M.D. Dep. 95:24 to 95:1-5 (Of course, like many physicians who don't want to be involved in a lawsuit, Dr. Whittaker hedged on

this point at his deposition) *Id.* 95:6-24)[8]. Likewise, Dr. Rosa Tang, one of Plaintiff's experts, opined that Ms. Miller experienced "Mirena-induced intracranial hypertension" as discussed more thoroughly in the *Daubert* responses.

DISPUTED ISSUES OF MATERIAL FACT[9]

1. Have Plaintiff's experts presented admissible evidence that Mirena *can* cause PTC/IH and that Mirena *did* cause Plaintiff's PTC/IH?

2. Did Defendants provide an adequate warning to Plaintiff and her healthcare providers about the association between PTC/IH and Mirena/levonorgestrel?

3. Did the failure to provide any warning at all render the Mirena to be in a defective and unreasonably dangerous condition?

ARGUMENT

I. DEFENDANTS FAIL TO CARRY THEIR BURDEN TO SHOW THAT PLAINTIFF'S STRICT LIABILITY CLAIMS FAIL.

Missouri has adopted the rule of strict liability of tort as stated in Restatement (Second) of Torts § 402A. *Keener v. Dayton Elec. Mfg. Co.*, 445 S.W.2d 362, 364 (Mo. 1969). A product liability claim can arise from a design defect, manufacturing defect, or a failure to warn of danger. *Magnuson by Mabe v. Kelsey-Hayes Co.*, 844 S.W.2d 448, 455 (Mo. Ct. App. 1992). Negligence is not an element of a product liability case. *Welkener v. Kirkwood Drug Store, Co.*, 734 S.W.2d 233, 241 (Mo. Ct. App. 1987). "To succeed on a strict liability-product defect claim, a plaintiff must prove that a product was being sold in the course of a defendant's business, that the product was in a defective and unreasonably dangerous condition at the time of sale, that the product was

[8] Dr. Whittaker did agree that "female hormones" and "hormonal birth control" are both associated with PTC/IH. *Id.* 105:18-24 to 106:1-24.

[9] Defendants offer a "Statement of Uncontroverted Facts" in their brief. However, as indicated from Plaintiff's discussion above, many of such "facts" are far from uncontroverted.

being used in a reasonably anticipated manner, and that the defective condition was the cause of the plaintiff's damages." *Id.* (citing Mo. Rev. Stat. § 537.760 (2012); *Blevins v. Cushman Motors,* 551 S.W.2d 602, 607 (Mo. banc 1977)). Essentially, Mo. Rev. Stat. § 537.760 provides for three separate theories of liability under the general umbrella of products liability: (1) design defect, (2) manufacturing defect, and (3) failure to warn. Thus, one who sells a "product in a defective condition unreasonably dangerous to the user or consumer … is subject to liability" for injury to the user or the user's property caused by the defect. *Keener v. Dayton Elec. Mfg. Co*., 445 S.W.2d 362, 364 (Mo. 1969).

The term "unreasonably dangerous" does not need "judicial definition" and is instead "to be treated as an ultimate issue for the jury."[10] *Rodriguez v. Suzuki Motor Corp.*, 996 S.W.2d 47, 65 (Mo. 1999) (en banc) (citing to *Nesselrode v. Executive Beechcraft, Inc.*, 707 S.W.2d 371, 378 (Mo. 1986) (en banc), while declining to define "defect" and "unreasonably dangerous" for a strict liability claim); *accord* Moore v. Ford Motor Co. 332 S.W.3d 749, 756 (Mo. 2011) (en banc) (acknowledging, in a strict liability failure to warn case, that "'the concept of unreasonable danger . . . is presented to the jury as an ultimate issue without further definition'") (quoting *Nesselrode*, 707 S.W.2d at 378)). Moreover, existence of a defect may be inferred from circumstantial evidence and common experience; expert testimony is not required. *Williams v. Deere & Co.*, 598 S.W.2d 609, 612 (Mo. 1980).

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[10] The Missouri Supreme Court has declined to adopt both the risk-utility test and the consumer expectation test. *Rodriguez v. Suzuki Motor Corp.*, 996 S.W.2d 47, 65 (Mo. banc 1999)(citing *Nesselrode*, 707 S.W.2d at 377-78). Whether a product is "unreasonably dangerous" is an ultimate issue for the jury. *Id.* (citation omitted). The jury is permitted to give the concept of unreasonable danger content "by applying their collective intelligence and experience to the broad evidentiary spectrum of facts and circumstances presented by the parties. *Id.* (citations omitted). The litigants are allowed "to argue that the utility of a design outweighs its risks, or that that the consumer expectations were violated, or any other theory of unreasonable dangerousness supported by the evidence." *Id.* (citation omitted).

A plaintiff may join a negligence claim and a warranty claim with a strict liability design defect claim. *Peters v. General Motors Corp.*, 200 S.W.3d 1, 17 (Mo. Ct. App. 2006). However, a negligence claim differs from a strict liability claim in that the focus in a negligence claim is on the defendant's conduct, while the focus in a strict liability claim is on the product itself. *Blevins v. Cushman Motors*, 551 S.W.2d 602, 606-08 (Mo. 1977). More specifically, the difference between negligence and strict liability in tort in defective design cases,

> … is in strict liability we are talking about the condition (dangerousness) of a [product] which is designed in a particular way, while in negligence we are talking about the reasonableness of the manufacturer's actions in designing and selling the [product] as [the manufacturer] did. The [product] can have a degree of dangerousness which the law of strict liability will not tolerate even though the actions of the designer were entirely reasonable in view of what he knew at the time he planned and sold the manufactured [product].

Id. at 608 (quoting *Phillips v. Kimwood Mach. Co.*, 269 Ore. 485, 525 P.2d 1033, 1037 (Or. 1974) (en banc)). Although distinct from a strict liability theory, a negligence theory may rely on the same operative facts to support recovery except that, unlike a strict liability claim, the defendant's conduct is the focus in a negligence action. *Dorman v. Bridgestone/Firestone, Inc.*, 992 S.W.2d 231, 239 (Mo. Ct. App. 1999). If the design defect is such that "a reasonably prudent seller should have discovered it before selling the product to the consumer, [then] the seller may be held liable for the injuries caused by the defect." *Id.*

While it is true that causation is an element of Plaintiff's claims, and Plaintiff cannot rely upon speculation and conjecture, a plaintiff is not required either to exclude all possibility of another cause for his injuries or to present undisputed evidence of causation. *Wood v. Robert Bosch Tool Corp.*, 2015 U.S. Dist. LEXIS 128180, *15 (E.D. Mo. Sept. 24, 2015) (citing *Kircher v. Purina Mills, Inc.*, 775 S.W.2d 115, 117 (Mo. 1989) (en banc); *Daniel v. Indiana Mills & Mfg., Inc.*, 103 S.W.3d 302, 310 (Mo. Ct. App. 2003)). "'It is sufficient if the facts and circumstances in

evidence fairly warrant the conclusion that the defect claimed by plaintiff was the cause of the injury [the plaintiff] sustained.'" *Id.* (quoting *Daniel*, 103 S.W.3d at 310); *see also Kircher*, 775 S.W.2d at 117 (to demonstrate causation, a plaintiff need only present "substantial evidence that a particular cause for which [the] defendant is liable is responsible for [the] plaintiff's injuries or damages")). "If the jury is persuaded a defect exists at the time of purchase, a plaintiff is not obliged to pinpoint the cause." *Rauscher v. Gen. Motors Corp.*, 905 S.W.2d 158, 161 (Mo. Ct. App. 1995) (citations omitted). In this case, Plaintiff's claims rest upon design and failure to warn defects.

There is no dispute that the product does not contain a PTC/IH warning. In light of the information that has been available since the 1990's, beginning with the Norplant label change and continuing with Jadelle label, the failure to include a PTC/IH warning rendered the Mirena defective and unreasonably dangerous at the time it left the Defendants' hands.

Likewise, as it relates to the design of the product,[11] at the time the Mirena levonorgestrel-releasing IUD was originally marketed, and even today, the Mirena has a nearly identical competitor product (also designed by the Population Council, Inc.) that releases copper instead of a potent synthetic hormone. The Paragard (a T-shaped IUD similar in size and design to Mirena) has been on the market longer than Mirena, it is indicated for five years longer than the Mirena, and it is highly effective. As Paragard claims, it is "more than 99% effective in preventing pregnancy and has no hormones at all." *See* http://www.paragard.com/What-is-Paragard.aspx, attached as Ex. 20. Because it has no hormones, the Paragard has no hormonal systemic effects. Not only has the Paragard T-shaped IUD been marketed in the U.S. for over 30 years, but **not a**

[11] Plaintiff's design defect claims, which are different than her warning claims, are not pre-empted. *See Bates v. Dow Agrosciences LLC*, 544 U. S. 431, 443-444 (2005) (holding that a Texas state-law design-defect claim not to be pre-empted because the design-defect claim in question was not a "requirement 'for labeling or packaging' " and thus fell outside the class of claims covered by the express pre-emption provision at issue in that case.)

single PTC case has been reported in relation to its use.[12] Compared to Paragard, Bayer's hormonal releasing IUD is defective in design. Accordingly, the motion should be denied.

II. DEFENDANTS FAIL TO CARRY THEIR BURDEN TO SHOW THAT PLAINTIFF'S NEGLIGENCE CLAIMS FAIL.

"To prevail on a claim of negligence in Missouri, a plaintiff must prove the existence of a duty, the defendant's breach of the duty, and damages proximately caused by the defendant's breach." *Riley v. Willo Prods. Co.*, 2013 U.S. Dist. LEXIS 13887, *5-6, CCH Prod. Liab. Rep. P19,025 (E.D. Mo. Feb. 1, 2013) (citing *Morrison v. Kubota Tractor Corp.,* 891 S.W.2d 422, 425 (Mo. Ct. App. 1994) (citing *Commercial Distrib. Ctr., Inc. v. St. Regis Paper Co.,* 689 S.W.2d 664, 671 (Mo. App. 1985)). Missouri law has "long recognized that a manufacturer has the duty to warn ultimate users of its products or articles which are inherently dangerous or are dangerous because of the use to which they are put." *Thompson v. Brown & Williamson Tobacco Corp.*, 207 S.W.3d 76, 98 (Mo. Ct. App. 2006) (citation and quotation omitted). Moreover, as discussed above, Federal law provides that the Defendants change their product labeling under certain circumstances when an association becomes known or when the Defendants' post-marketing experience reveals previously unlabeled adverse reactions. "Whether a defendant's conduct falls short of the standard of care is a question of fact for the jury." *Id.* (citing *Harris v. Niehaus*, 857 S.W.2d 222, 225 (Mo. banc 1993)).[13]

As discussed above, Bayer knew ***before*** the Mirena was ever approved in the United States that the use of levonorgestrel had been associated with the development of PTC/IH; yet, Bayer

[12] As Bayer's Global Safety Lead for Mirena testified, it would be "absurd" to think that Paragard could cause PTC because "it doesn't contain any medication or any drug, which also means that it hasn't got any systemic effect." *See* Ex. 22, Schoendorf Depo. at 118.

[13] There is no dispute that the Mirena does not, and never has, included a warning for PTC/IH. Nor does Bayer claim that it does. Thus, if Bayer's "duty to warn" is implicated by the facts of this case as discussed above, then it breached that duty.

failed to include such information in the Mirena product label provided to physicians or the Patient Information Booklet provided directly to patients like Plaintiff. Its company causality statements also make clear that it knew of the association long before Plaintiff ever agreed to use the Mirena product. Moreover, Despite holding the number one spot in the FDA FAERS database for the number of PTC/IH reports, and despite the results of the Rai/Digre study, Bayer continues to stick to its "standard response" that there is no "confirmed evidence" (whatever that means) of a causal association between Mirena/Levonorgestrel and PTC/IH. There was no PTC/IH warning at the time Plaintiff received the product and the product remains without a warning to this day. The warning label does not even list the condition as something Bayer has seen in its "post-marketing experience" despite an enormous number of cases. As a result, Defendants' failure to warn the ultimate users about the association is a breach of Bayer's duty to warn.

Plaintiff's PTC/IH was caused or substantially contributed to causing by the Mirena levonorgestrel-releasing IUD. Dr. Whittaker's records show that he believed there was an association at the time of treatment. Moreover, Plaintiff claims that another doctor, besides Dr. Whitaker, also indicated that her PTC/IH was related to Mirena. This is consistent with Dr. Tang's opinion that Ms. Miller experienced Mirena-induced intracranial hypertension. The sum and substance of Bayer's argument is that her experts'[14] opinions cannot survive Bayer's *Daubert* challenge and thus her claims "fail in their entirety." (claiming that Plaintiff can produce no "reliable" evidence of general or specific causation). However, as discussed in detail in Plaintiff's responses to the *Daubert* motions (which are specifically incorporated herein by reference), Plaintiff strongly disagrees. Defendants' paid expert opinions disagreeing with such a conclusion are not sufficient basis to deny Plaintiff of her right to seek justice. Accordingly, the motion should

[14] While not even relevant to these motions, Plaintiff vigorously disputes Defendants' misleading characterization that her "lead causation expert" has withdrawn from this case.

be denied.

III. THE LEARNED INTERMEDIARY DOCTRINE DOES NOT BAR PLAINTIFF'S CLAIMS

Bayer's reliance on "learned intermediary doctrine" is inapposite to this case. First, and dispositive of Bayer's argument, the doctrine is properly asserted only when a manufacturer has *fulfilled* its duty to warn *through* a learned intermediary. *See e.g., In re Yasmin & Yaz (Drospirenone) Mktg. Sales Practices & Prods. Liab. Litig.,* No. 3:09-md-02100-DRH-PMF, 2011 U.S. Dist. LEXIS 145592, at *38-40 (S.D. Ill. Dec. 16, 2011) ("However, the learned intermediary doctrine only applies where the manufacturer has adequately warned the prescribing physician. [. . .] [d]octors who have not been *sufficiently* warned of the harmful effects of a drug cannot be considered 'learned intermediaries' and the adequacy of warnings is a question of fact, not law, for the jury to determine") (internal citation and quotation omitted). "Missouri courts adhere to the learned intermediary doctrine . . . and [hold] that in cases involving manufacturers of prescription drugs, the manufacturer has a duty to properly warn the doctor of the dangers involved and it is incumbent upon the manufacturer to bring the warning home to the doctor." *See Doe v. Miles, Inc.*, 2000 Mo. App. LEXIS 770, *42, (Mo. Ct. App. 2000) (citations and quotations omitted). In this case, Mirena's PTC/IH warning is not simply inadequate, it is nonexistent, so it definitely could not be said to "bring the warning home to the doctor."[15] Bayer cannot seriously argue the application of learned intermediary doctrine here.

Moreover, the learned intermediary doctrine is simply not applicable in contraceptive cases where, like here, Defendants spent millions of dollars advertising directly to users and directly

[15] If a warning would have been included by the manufacturer, the inserting provider would have had a legal duty to warn Plaintiff about the PTC/IH risk. To speculate about whether or not the inserting provider would have violated his/her legal duty is just that, rank speculation. Moreover, as Defendants acknowledge, several Missouri cases stand for the proposition that there is a presumption that an adequate warning would be heeded.

provided them with written materials (like the Patient Information Booklet) detailing the alleged risks and benefits of their product.[16] Contraception is a choice. Not only whether to use it, but the kind of contraceptive a woman uses is also a choice. There are many, many contraceptive choices –even within the same pharmacological classes. Whether a woman wants to use a progestin, an estrogen, or no hormone at all. Whether a woman wants to take something every day by mouth, get a shot, use a patch, have it inserted or implanted in the arm or in the uterus. There are many choices. And these are the things that women consider when making that choice. Bayer realizes this and spends many millions of dollars per year advertising not only to the prescribing physicians but directly to prospective customers (or patients) in the form of television advertising, website advertising, pay-per-clicks, text messaging, sponsorships, in-home seminars, YouTube videos, direct mail, etc.

Also, Bayer's Patient Information Booklet (which is presented before the patient receives the Mirena and requires her to sign a consent form) recognizes that it is the *patient's choice* whether or not to use the Mirena: "Read this Patient Information carefully before ***you decide if Mirena is right for you.*** … You should also learn about other birth control methods to ***choose the one that is best for you.***" *See* Mirena Patient Information Booklet, attached as Ex. 19. The booklet advises that: **"**Only small amounts of the hormone enter your blood." *Id.* That's what Bayer tells patients –which is completely contrary to what Dr. Costales told a physician over ten years ago.

Likewise, nowhere in the Patient Information Booklet does Bayer mention PTC/IH as a

[16] *See* Restatement 3d of Torts: Products Liability §6 at cmt. e; *see also Perez v. Wyeth Lab*., 734 A.2d 1245 (N.J. 1999); *Rimbert v. Eli Lilly*, 577 F.Supp. 2d 1174, 1214 (D.N.M. 2008) (The Court believes that the Supreme Court of New Mexico, given the opportunity in 2008, would not adopt the learned-intermediary doctrine, because of the erosion of the justifications for adoption of the doctrine, given the changing dynamics between doctors and patients, patients' self-diagnosis, and DTC advertising by drug manufacturers.)

potential side effect.[17] Incredibly, Bayer fails to mention any hormonal related side effects in the "What are the possible side effects of using Mirena?" section, despite the fact that hormonal-related side effects were one of the main causes of product discontinuation during the pre-market approval studies. *Id.* Bayer voluntarily (or perhaps at the direction of FDA) undertook a duty to provide information to patients like Plaintiff –in the form of the Patient Information Booklet— about the nature of the Mirena product, how it works and, importantly, the risks and dangers associated with the product. It is undisputed that there is no warning for PTC/IH within the Patient Information Booklet. Given Bayer's knowledge of the association between PTC/IH and levonorgestrel (going back to at least the early 1990's), Bayer did not exercise due care in conveying such information to Plaintiff. Even more egregious, however, is that Bayer concealed the information about PTC/IH from both patients and physicians alike and even misrepresented the amount of hormone that would flow through their bodies. Nonetheless, Bayer's voluntary assumption of this duty by producing a Patient Information Booklet for patients, takes this case outside the learned intermediary rule. Based upon the facts of this case, the learned intermediary rule does not bar Plaintiff's claims. Accordingly, Bayer's motion should be denied.

IV. PLAINTIFF'S FRAUD, MISREPRESENTATION AND WARRANTY CLAIMS SHOULD SURVIVE SUMMARY JUDGMENT.

Defendants' arguments regarding Plaintiff's fraud, misrepresentation and warranty claims hinge upon two cherry-picked deposition citations. *See* DN 82 at p. 29 (citing Miller Dep. 180:24-181:1; 192:21-195:22). That's it.

But Bayer's first citation (180:24-181:1) is clearly disingenuous. Because both the question

[17] Interestingly, in its *Daubert* motions, Defendants seek to hold Plaintiff to something close to "scientific certainty" in proving the connection between LNG and PTC/IH. However, Bayer has never even been held to such a high standard itself. Even Bayer admits "[i]t is not known exactly how Mirena works." *See* Mirena Patient Information, attached as Ex. 19. Bayer then offers several theories and concludes, "[m]ost likely, these actions work together to prevent pregnancy." *Id.*

and the answer ***relate to an entirely different product!*** *See* Miller Dep. 180:19-181:1 ("Q. Do you recall ever seeing any advertising or promotions about the ***patch***? A. Yes. Q. What do you recall seeing? A. Brochures in the office. Q. Okay. Do you recall anything about what they said? A. No.) (emphasis added). There is no dispute that the "patch" is an entirely different product than the Mirena.

Not quite as disingenuous, but still misleading, Bayer's other citation (192:21-195:22), indeed its money shot of a deposition quote, actually relates to ***television advertisements*** –not brochures, pamphlets and other information conveyed from her doctor:

> Q. And you think you saw some Mirena advertisements -- ***a Mirena advertisement on TV***; is that right?
> A. Yes.
> Q. Do you recall anything about ***the advertisement that you think you saw***?
> A. No.
> Q. So you don't recall in any of the advertisements that you believe that you were exposed to anything about risks that were discussed; is that correct?
> A. Correct.
> Q. And you don't recall anything that was discussed about benefits that were discussed; is that correct?
> A. On the advertisements?
> Q. Yes.
> A. I can't recall on the advertisements.
> Q. Do you recall anything about whether there were people in the advertisements or anything about what they looked like?
> A. No. I don't remember their advertisements.
> Q. Okay. ***Did the advertisements play any role*** in your decision to use Mirena?
> A. No. Because I -- the first time I'd ever really discussed it was when I was going to get it done. I mean, she talked about it the same day that I'm pretty sure I had it placed. So, no. My doctor's the only one that talked to me about getting it done, and that's what kind of swayed me into it.

See Miller Dep. 194:16-195:22 (emphasis added). For these reasons alone, Bayer's motion should fail.

Nonetheless, it is clear that Ms. Miller was in fact counseled by her doctor (with the false and incomplete information Bayer passed on to physicians) and relied on her doctor's advice

(212:14-17), reviewed brochures in her doctor's office (192:9-17, 194:7-15) and signed a consent form indicating that she reviewed the Patient Information Booklet (203:9-25, 204:1-23 ,224:21-25, 225:1-25, 226:1-4). Because Plaintiff reviewed and relied upon the fraudulent misrepresentations, the motion should be denied.

V. PLAINTIFF IS ENTITLED TO PRESENT EVIDENCE AT TRIAL IN SUPPORT OF HER CLAIM FOR PUNITIVE DAMAGES.

Knowledge is key. Defendants knew that levonorgestrel was associated with the development and/or worsening of PTC/IH at the time they introduced Mirena to the U.S. market. Defendants have known about the causal association for years, but did nothing more than offer a "standard response" denying an association to those who inquired. Even in light of a study showing a 770% increased risk of developing PTC/IH while using Mirena, the Defendants have still done nothing. At the same time, from the very beginning, Defendants marketed the Mirena as a product that released a small amount of hormone into the user's system and caused low to no hormonal systemic adverse effects. But internally, people like Dr. Costales, knew the truth: "**Mirena does produce significant levels of LNG in the serum."** The entire marketing campaign for this product burns to the ground if the medical community and the public ever learn that the Mirena produces significant levels of levonorgestrel that circulate in a user's blood serum.

Ignoring the Norplant label. Ignoring the Jadelle label. Ignoring the literature about Norplant. Ignoring the literature by its own experts. Hiding information from patients and physicians. Minimizing the hormonal levels. Minimizing or denying the systemic effects. Paying ghostwriters to create favorable scientific papers. Exercising substantive control over those papers. Lying to regulatory agencies. Lying to doctors. Lying to patients. It all adds up to a reckless disregard for the health and safety of patients across the country. It is outrageous and it

needs to be punished.

It's so simple. All Defendants had to do was tell the truth. All Defendants needed to do was add a warning like the warning on Norplant or the warning on Jadelle. This would have been enough. Defendants would have satisfied their duties under the law. But, instead, Defendants did not want to taint their blockbuster seller (Mirena) with the scarlet letters: PTC/IH. And because of that, many women like Plaintiff, have been injured. Punitive damages are necessary and appropriate in this case. The motion should be denied.

CONCLUSION

For the foregoing reasons, the motion should be denied in its entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that that the undersigned has served all counsel of record via the Court's ECF/CM system on November 17, 2016:

/s/ Lawrence L. Jones II
Lawrence L. Jones II