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UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

IN RE:

13-MD-2434 (CS)

MIRENA IUD PRODUCTS LIABILITY LITIGATION

This Document Relates To All Actions

DEFENDANT BAYER HEALTHCARE PHARMACEUTICALS INC.'S PRELIMINARY POSITION STATEMENT

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Pursuant to this Court's Order No. 1, Bayer HealthCare Pharmaceuticals Inc. ("Bayer") respectfully submits the following Preliminary Position Statement.

Factual Background

Mirena is a Safe and Effective FDA-Approved Contraceptive

First approved as safe and effective by the FDA in 2000 and still on the market today, Mirena is an intrauterine device ("IUD") manufactured by Bayer that is small (1.26 inches long), T-shaped, and made of soft, flexible plastic.

Mirena requires a doctor's prescription and must be inserted in a doctor's office. Once placed in the uterine cavity, Mirena continuously releases a small dose of levonorgestrel, a progestin hormone used in a variety of contraceptive products. Mirena provides contraceptive protection for up to 5 years.

Studies demonstrate that Mirena is over 99% effective in preventing pregnancy. The American College of Obstetrics and Gynecology encourages doctors to use IUDs in their patients because they are one of the most effective forms of reversible female contraception available to women and have been shown to be safe in appropriate patients. In 2009, the FDA also approved Mirena as safe and effective for the treatment of heavy menstrual bleeding for women who choose to use an IUD for contraception.

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A doctor removes Mirena during an office visit using two threads that extend from the IUD into the vagina. These threads also allow patients and doctors to check that the IUD remains in its proper position during use, as encouraged in the FDA-approved labeling. Upon removal of Mirena, women experience a rapid return to fertility.

Like all medicines, Mirena is not 100% risk-free and carries potential side effects common to all IUDs, including perforation of and migration out of the uterine wall. But Mirena does not carry the same risk of serious side effects like blood clots and strokes as birth control pills. When compared to alternative birth control options, Mirena is a safe and highly effective option for women.

Bayer Warned of the Risks of Perforation and Migration with Mirena

Bayer has warned of the risks of uterine perforation and migration with Mirena since the FDA first approved it in 2000. Every Mirena package includes a copy of the FDA-approved label for the prescribing doctor and an FDA-approved patient information booklet, both of which describe the potential risks of Mirena.

Perforation of the uterine wall is a rare but well-known risk of all IUDs. A number of studies published in peer-reviewed journals have found that about 1 out of every 1,000 IUDs inserted (Mirena or others) results in a perforation. Doctors learn about this risk beginning in medical school and throughout their training. When a perforation occurs, Mirena or any IUD may be placed or migrate outside of the uterus, requiring laparoscopic surgery to remove it.

Bayer's current FDA-approved label for Mirena includes the following warning of the risk of perforation¹ and migration and associated injuries:

¹ The FDA-approved label for Mircha also warns of the risk of embedment of Mirchain the myometrium (the muscular layer of the uterine wall), which is sometimes referred to as partial perforation.

5.7 Perforation

Perforation or penetration of the uterine wall or cervix may occur during insertion although the perforation may not be detected until some time later. If perforation occurs, pregnancy may result *[see Warnings and Precoutions (5,1 and 5.2)]*. Mirena must be located and removed; surgery may be required. Delayed detection of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses and crosion of adjacent viscera.

To mitigate the risk of perforation, Bayer provides step-by-step insertion instructions in

the FDA-approved label, as well as diagrams showing how to use the insertion tube that comes

with each Mirena. The label cautions doctors not to force the inserter into the cervix and to

gently guide Mirena into the uterine cavity until the doctor feels resistance.

The FDA-approved patient information booklet also warns patients of the potential risks

of perforation with Mirena and the consequences thereof:

• *Perforation.* Mirena may go through the uterus. This is called perforation. If your uterus is perforated, Mirena may no longer prevent pregnancy. It may move outside the uterus and can cause internal scarring, infection, or damage to other organs, and you may need surgery to have Mirena removed. The risk of perforation is increased in breastfeeding women.

Because of the risk of perforation, the FDA-approved label instructs doctors and patients to check to make sure Mirena is still in the right place. The label recommends that doctors examine their patients 4 to 12 weeks after Mirena insertion to ensure that it is still properly placed, and annually after that. The patient information booklet also instructs patients to check the threads periodically to make sure Mirena is in the proper position.

Critical Legal Issues in This MDL

Bayer believes that many of the legal issues surrounding these claims should be resolved through summary judgment and/or *Daubert* motions. Plaintiffs' primary claim is that Bayer failed to adequately warn of the risk of perforation or migration. Yet, Bayer did warn doctors and patients of those very risks. As plaintiffs' cases face significant legal hurdles, Bayer has already successfully disposed of multiple Mirena suits through motion practice.

Bayer's Warnings Were Adequate

Since Bayer first sold the product in the U.S. in 2001, every Mirena label clearly and conspicuously warned of perforation-related risks and cautioned doctors and patients to monitor the Mirena threads to make sure they remained in place. This warning adequately conveyed the potential risk of the injuries for which plaintiffs now seek to recover damages. Further, under some states' laws, an FDA-approved warning is presumptively adequate.

Bayer's Alleged Failure to Warn Did Not Proximately Cause Plaintiffs' Injuries

Under the learned intermediary doctrine applicable in most states, Bayer's duty to warn of known risks runs only to prescribing doctors, not patients. Doctors learn about the potential risks of perforation and migration that accompany all IUDs in their basic medical training. They weigh these potential risks against the proven contraceptive benefits of Mirena when making the decision to prescribe Mirena. Bayer believes that, in the majority of cases, plaintiffs will not be able to show that Bayer's alleged failure to give the warning they propose impacted the doctor's prescribing decision, because the doctor was well aware of the risk of perforation-related injuries and decided to prescribe Mirena despite these potential risks.

Plaintiffs' Claims Are Preempted

FDA carefully considered and edited the warning language concerning perforation in the label before approving Mirena in 2000. In 2008, FDA again rejected Bayer's proposed perforation warning language before approving a revised label for Mirena. Under *Wyeth v. Levine*, state law challenges based on failure to warn are preempted when there is "clear evidence" that FDA would not have approved a change to the drug's label. 555 U.S. 555, 571 (2009). The FDA's careful and continued scrutiny and rejection of certain perforation warnings

provides "clear evidence" that it would not have approved the label changes plaintiffs claim Bayer should have made.

Many Plaintiffs' Claims Are Time-Barred

Many of the plaintiffs' complaints, on their face, are time-barred under the applicable state statute of limitations. Limited discovery of plaintiffs' medical histories will likely confirm that many additional cases are untimely as well.

Various Causes of Action Lack Factual Support

Some plaintiffs have asserted generic claims for design defect, manufacturing defect, breach of express warranty, and fraud without pleading facts in support of these claims. As such, these claims should universally be dismissed under *Twomblyllqbal*.

List of Pending Cases

A complete list of related cases pending in state or federal court, together with their current status, including any discovery taken to date and pending motions, is Attachment A to this statement.

Dated: May 10, 2013

Respectfully submitted,

/s/ Shayna S. Cook Shayna S. Cook Andrew L. Goldman Tarek Ismail Brian P. O'Donoghue Jennifer L. Greenblatt GOLDMAN ISMAIL TOMASELLI BRENNAN & BAUM LLP 564 West Randolph Street – Suite 400 Chicago, IL 60661 Tel: (312) 681-6000 Fax: (312) 881-5191 scook@goldmanismail.com agoldman@goldmanismail.com

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Attorneys for Defendant Bayer HealthCare Pharmaceuticals Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 10th day of May, 2013, a copy of Bayer Healthcarc Pharmaceuticals Inc.'s Preliminary Position Statement was served by email on all counsel of record listed below as indicated:

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Attorneys for Plaintiffs

By:___/s/ Shayna S. Cook

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Attachment A

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Peliding Federal Court Cases					
CASE CAPTION	COURT	STATUS	DISCOVERY TAKEN	PENDING MOTIONS	
Caruthers, Jessica R. v. Bayer Corp., et al.	D. Kan.	Stayed	None	None	
Dudley, Jerilyn v. Bayer HealthCare Pharmaceuticals Inc., et al.	N.D. Cal.	Stayed	None	None	
Fowler, Stacy v. Bayer HealthCare Pharmaceuticals Inc.	D. Minn.	Active	None	None	
Gomez, Rosy, et al. v. Bayer HealthCare Pharmaceuticals Inc.	C.D. Cal.	Active	None	Joint Motion to Stay	
Harmon, Sandra, et al. v. Bayer HealthCare Pharmaceuticals Inc.	E.D. Ky.	Active	None	None	
Jennings, Tenisha v. Bayer HealthCare Pharmaceuticals Inc.	D. Md.	Active	None	None	
Jones, Melissa v. Bayer HealthCare Pharmaceuticals Inc.	E.D. La.	Active	None	None	
Kelly, Jaquayla v. Auliman Physician Cir, OB/GYN, et al.	N.D. Ohio	Active	None	None	
Kimbrough, Chassity R. v. Bayer HealthCare Pharmaceuticals Inc.	S.D. [1].	Stayed	None	None	
Krncevic, Margarita S., et al. v. Bayer HealthCare Pharmaceuticals Inc.	N.D. Ohio	Stayed	None	None	
Lopez, Maria, et al. v. Bayer HealthCare Pharmaceuticals Inc.	N.D. III.	Stayed	None	None	
Mehrer, Rebecca L. v. Bayer HealthCare Pharmaceuticals Inc.	N.D. [1].	Stayed	None	None	
Meyer, Heather v. Bayer HealthCare Pharmaceuticals Inc.	D. Minn.	Active	None	None	
Nordman, Laurie v. Bayer HealthCare Pharmaceuticals Inc.	C.D. Cal.	Active	None	None	
Scott, Brandy v. Bayer HealthCare Pharmaceuticals Inc.	W.D. Ky.	Active	None	None	
Solano, Cynthia v. Bayer Corporation, et al.	E.D. Pa.	Active	None	None	
Thompson, Amanda v. Bayer HealthCare Pharmaceuticals Inc.	D. Md.	Active	None	None	
Villarreal, Patricia v. Bayer HealthCare Pharmaceuticals Inc.	W.D. Tex.	Stayed	None	None	
Winston, Shelondia v. Bayer HealthCare Pharmaceuticals Inc.	C.D. 111.	Stayed	None	None	

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	Pending Sta	te Court C	ases	
Allen, Kiesha, et al. v. Bayer	Mo. Cir. Ct.	Active	None	Motion to
HealthCare Pharmaceuticals Inc.		Active	INOLIC	Sever/Transfer
Amos, Shanelle v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Anderson-Harris, Brianne v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Arrington, Rhonda v. Bayer HealthCare Pharmaceuticals, Inc.	NJ Super. Ct.	Activc	None	None
Ayissi, Ernestine v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Barnes, Adrienne v. Bayer Health <u>Care Pharmaceuticals Inc.</u>	N.J Super. Ct.	Active	None	None
Bassett, Shazta v. Bayer HealthCare Pharmaceuticals, Inc.	NJ Super. Ct.	Active	None	None
Bates, Yarnell v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Beaver, Tyra v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Bell, Jada v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Bennett, Cassandra v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Beseler, Heather v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Beyer, Cassie v. Bayer HealthCare Pharmaceuticals Inc.	N.I Super. Ct.	Active	None	None
Bloch, Shoshana v. Bayer HealthCare Pharmaceuticals Inc	NJ Super. Ct.	Active	None	None
Block, Megan v. Bayer HealthCare Pharmaceuticals Inc.	N.J Super. Ct.	Active	None	None
Blue, Sharon v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Bradley, Rochrata v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	Nonc	None
Brewington, Britney v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Brumley, Reyanne v. Bayer HealthCare Pharmaceuticals Inc	NJ Super, Ct.	Active	None	None
Bucher, Jayme v. Bayer HealthCar <u>e Pharmaceuticals Inc.</u>	NJ Super. Ct.	Active	None	None
Cantelli, Marie v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None

Castaneda, Ambrocia v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Cromer, Felicia, et al. v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Cundiff, Amber v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Daniels, Chasity v. Bayer HealthCare Pharmaceuticals Inc., et al.	Miss. Cir. Ct.	Active	None	None
DeLeon, Tammy v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Demastus, Samantha v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Denton, Kelsie v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Dodson, Tyanna v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Dotson, Nichola v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Duberry, Ariane v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Eagle, Rebecca v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Edmiston, Consenthia v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Elliott, Kimberly v. Bayer HealthCare Pharmaceuticals Inc.	N.I Super. Ct.	Active	None	None
Elmore, Marquisha v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Evans, Beth v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Fairbrass, Stephanie v. Bayer Corp., et al.	Mo. Cir. Ct.	Active	Plaint iff has responded to interrogatories and requests for production from Co-Defendants	None
Fattah, Reem v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Ferris, Mashell v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Fowler, Michele v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None

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Frano, Gina v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Gibson, Jacoby v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Gluck, Suzi v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	Nonc	None
Gomez, Lea v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Hall, Ashleigh v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Hamilton, Marlena v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Hammett, Jessica v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Hansen, Heather v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Harris, Autumn v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	Nonc
Henderson, Casey v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Herron, Katrina v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Holland, Kayla v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Holt, Joy v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Iniguez, Desiree, et al. v. Bayer HealthCare Pharmaceuticals Inc., et al.	Cal. Super. Ct.	Active	None	None
Jaramillo, Melissa v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	Nonc	None
Jaskiel, Samantha v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Jezioro, Claudia v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Jones, Jessica v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Kelly, Sarah v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	Nonc	Nonc
Kirkland, Carol v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Landers, Betsy v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None

Laurencin, Darlene v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Lee, Katelin v. Bayer HealthCare	NJ Super. Ct.	Active	None	None
Pharmaceuticals Inc. Lopez, Carmen v. Bayer				
HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Loyd, Amanda v. B e yer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Madden, Carrie v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Marquez, Esmeralda v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Mascaro, Dana v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None .	None
Mashala, Princess v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Mayhew, Sharon v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
McClain, Brittany v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
McGuire, Lillian v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Meekins, Dedra v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Melvin, Robin v. Bayer HealthCare Pharmaceuticals Inc.	N.J Super. Ct.	Active	None	None
Morian, Briana v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Munoz, Shi v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Nugent, Kala v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Oakley, Angela v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Olson, Kristy v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Orman, Kristine v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Ortiz, Alejandrina v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Parker, Yolanda v. Bayer HealthCare Pharmaceutical, Inc.	NJ Super. Ct.	Active	None	None
Perdue, Stephanie v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None

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NJ Super. Ct.	Active	Nonc	None
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Mo. Cir. Ct.	Active	None	None
NJ Super. Ct.	Active	None	None
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Thomas, Tarrin v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Thompson, Kimberly v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Tierncy, Erin v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super, Ct.	Active	None	None
Tillett, Brenda v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Toliver, Nicole et al. v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Toups, Elizabeth v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Valenciano, Carly v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Webster, Astin v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Wetzler, Gale v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Wilhite, Barbara v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	None
Winans, Celine v. Bayer HealthCare Pharmaceuticals Inc.	NY Supreme Ct.	Active	Written discovery exchanged; plaintiff deposed	Motion to Compel pending
Wright, Bryttany v. Bayer HealthCare Pharmaceuticals Inc.	NJ Super. Ct.	Active	None	Nonc

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GOLDMAN ISMAIL TOMASELLI BRENNAN & BAUM LLP

FACSIMILE TRANSMITTAL SHEET

TO: THE HON. CATHY SEIBEL U.S. DISTRICT JUDGE

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TOTAL NO. OF PAGES, INCLUDING COVER: 16

Re: In re: Mirena IUD Products Liability Litigation, 13-MD-2434 (CS) Preliminary Position Statement

Dear Judge Seibel:

Pursuant to Order No. 1, enclosed please find Bayer's Preliminary Position Statement for the above-named MDL as well a list of related cases pending in state and federal court.

Respectfully submitted,

Shayna Š. Cook Lead Counsel for Defendant Bayer HealthCare Pharmaceuticals Inc.

Enclosures

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