# UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

August Term 2020

(Argued: December 2, 2020 Decided: December 8, 2020)

Docket No. 19-2155

IN RE: MIRENA IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION (NO. II)

ABRA CONING, KAYLA TALLEY, TIFFANY HAUSNER, SHANE HAUSNER, SHELAIN COOPER, ALLISON SIMPSON, AMELIA HOLMAN MILES, JONATHAN MILES, JESSICA GUGLIELMO, MEGAN ROBINSON, KIMBERLY BLACK, CHAQUITA DUDLEY, KELLY RIEGEL-GREEN, DANISE HOFFMAN, JACQUELINE GOYENA, JANELLE PALLANSCH, BRITTANY GRECO, MISTY SOLOMON, DAPHNE HOUCK, HOLLY ALLEN, JENNIFER SANTIAGO, MELANIE HOWE, MISTY MCCANDLESS, ANGELA KLOPFENSTEIN, ADAM KLOPFENSTEIN, CATIE KESSLER, JACLYN SPETT, ABIGAIL MICHEL, CHERIE MCGEE, BRITTANY WILSON, BREANNA PIETERS, ELLEN BURNS, Individually, David Burns, Laura Burns, Whitney Walker, Jessica WATSON, KARNA LYNNE PETTLON, AMBERLY BUCKNER, CARLEY HAMILTON, DANIELLA PAVELKA, ANDREA JOHNSON, CHRISTINA STEPHANIE ALBERTSON, Abigail Thiesing, Amanda Massie, Amy Edwards, Sherricker Rodgers, Annalissa Sanchez, Nicole Vincent, Liana Erb, Sarah Marie Wessel, KATIE MYERS, LATOYA S. THOMPSON, ASHLEY BABICH-ZACHARIAS, BETHANY VINCENT, WHITNEY MANCHEL WASHINGTON, LAUREN HARDWICK, BRITTANY S. Smith, Elizabeth Heagy, Barbara Anderson, Shamara Von Lane, CRYSTAL VAZQUEZ, BRITTANY COLLINS, ASHLEY NOBLES-HOBBS, SHAKARA

CARTER, MIRANDA GLEDHILL, MELISSA TOLBERT, DEVON MAHLSTEDT, DANIELLE ADAMS, LAUREN CARMAN, ANNA CONLEY, STEPHANIE DAWSON, Andrea Gee, Victoria Lee, Lacey Langston Sanderlin, Ashley Amber COCKRELL, SHAWNA LOUISE COOPER, MARYSSA REESE, CARNESHIA CASON, KASEY GARRISON, ASHLEY STEED, STEFFANIE MICHELLE DENNIS, JESSICA MARIE PETERSON, KASEY JACKSON, LESLIE MARIE COAPMAN, LATRICIA ANDERSON JOHNSON, MARY MARGARET COTTINGHAM, SHAMEKA M. BRIDGES, PETERSON BRIDGES, LATONYA HOSKIN, KRISTEN DENISE BRYAN, SAMANTHA LIFORD, CHRISTI UTLEY, JESSICA STANLEY, MACEY BEELER, NOELLE HICKEY, CRYSTAL Taylor, Valerie Townsend, Andrea Vega, Amanda Evans, Breanna WILLIAMS, MANDY MITLYNG, LYSSA KIRK, MARSHA SAPP HANKINS, LEAH FACKRELL, TIARA MITCHELL, SIOBHAN SCHALL, KATHLEEN CHEEK, BILLY CHEEK, NICOLE HAMILL, KAREAMA PATTERSON, KYLARA BOOTH, DANIEL Parsons, Christa Diehl, Vanessa Bourgoin, Daniel Bourgoin, Kara STANLEY, TIFFANY SAWYER, CAITLYN ABOULBA, KEYSA ELLIS, MARIA AGUILAR, ELLEN BURNS, AS PERSONAL REPRESENTATIVE OR EXECUTRIX OR ADMINISTRATRIX OF THE ESTATE OF ANNE ALDEN BURNS, AMANDA CLARK, TAQUOYA KERYAWNA WILLIAMS, MARIA PITTS, HEATHER NICOLLE MCMULLAN, NICOLE LASSO, RANDI WHITE, HEATHER ONSUM STOOPS, JANEKA HAYNES, SHENEQUA PERDUE, RACHEL FREITAS, KATRINA EVERETT-CAREY, NAYELI JUAREZ-GARCIA, Melissa Frances Hall, Elizabeth Adams, Sylvia Greer, Ni'Matullah KING, MARIE SHIVER, SUSAN TOOMEY, MEGAN HARRIS, KATHRYN ASBEL, ASHLI GARNER, LISA VALLERY, BRITTANY NICOLE JAMES, SARA TESS SANBORN, ROBERT ZINN, KIMBERLY STIER, DEWAYNA DENILLE BROWN, LOIS MICHELLE PALMER, KELLI SALAZAR, JESSICA ROBERSON, STACY BRYAN, STEVEN BRYAN, REBECCA ELWOOD, AMBER HANSON, REBEKAH ROGERS, TESSA WATTS, SHEREE MITCHELL, LASHONDA ROBINS, MISTY REITZ, BERNESHA MEANS, SAMANTHA Davis, Tamatha Tucker-Whitaker, Misty Coleman-Woods, Sharon CAIN, SHANNON WALKER, STEPHANIE SCHLUETER, KATHARINE WELLS, CYNTHIA GUNN, JESSICA HIXSON ROBINSON, JESSICA GARDNER, CATHERINE DIANNE BEITEL, CHRISTY NICOLE MCGREGOR, AMBER DARLENE PROUT, Amanda Leeann Barber, Aleta Brek Richards, Erica Silva, John Silva, III, AMY HODGE, JOANNA LYNN LUCERO, KELSEY RAMM, KATIE REBECCA LAWRENCE, KELLI BOYT ROWLAND, CANDICE SMALL, JADE A. LUDWIKOWSKI,

SHAHIRA OSMAN, NAQUASHA RISER, LAUREN ELIZABETH SINGLETON, JETTA ALLEN, JULIANA CATARINA HERNANDEZ, TIRZAH MARIE ELLET, KAYLA SCOTT, TOMEKA WILLIAMS-JAMES, COURTNEY TRENNEPOHL, TIFFANY COLLINS, STACY Camino, Kathleen Fox, Chanthinia White, Brianna Peters, Devina WILLIAMS, CHAVON PLANGE, SADIE MILLER, STEPHANIE SELLERS, FREDDREKIA Bradley, Starla McCollum, Lacey Hubert, Anais Forcier, Jennifer Ure, RHONDA PEZZULLO, RACHAEL NIKL, ALECIA CONNER, KIMMI VESEY, DEANNA MOONEY, MARLENE MENDEZ, CIERA TURNER, TYSHEA MOTT, MELISSA POLOMSKY, HEATHER KURAMOTO, JESSICA BIHLER, LAMARA WALKER, CANDICE Bailey, Alyssa Johnson, Kristin Carrico, Gloribi Pastor, Chandra Brown, Julia Meachem, Shaquanda McMillion, Lakeyshia Tate, Ashley McLuckie, Katelynn Hammond, Doretha Smith, Lauren Hollobaugh, GEMBELLE HORLACHER, KIMBERLY BURKHART, KIMBERLY MACAULAY, Marisol Marcano, Ashlyn Hackworth-Williams, Nadine Kellam, JONEL EDWARDS, ELIZABETH MONTANARO, STEPHANIE BREWER, ANGELINE STANGER, JESSICA ROSELAND, JACOB ROSELAND, NICOLE ASKIN, CHRISTIE EPPERLY, TIFFANY MOSLEY, NICOLE CLARK, NAOMI WILSON, PORSCHE PATTERSON, NATASHKA MILLER, KAREN CREAR, STACIE HUFFER, LATOYA HUNT, LAUREN ROBERTS, BRITTANY THOMAS, AMBER HODA, CHRISTAL BAUGH, ARIN BOEHMER, JENNIFER DRAYTON, CHRISTINA HOLLAND, NIKIA BROWN, Alana Sirmans, Rosanna Knudsen, Michelle Morgan, Maureen GARRETT, NICOLE PARKER, CONSTANCE STEELE, AMANDA GOODLET, KIMBERLY HENAO, BRIANNA BLACKMAN, ANGELA NORRED, JESSIKA ALLEN, PATRICE Renee Frank, Christina Reid, Reva McDonald, Cassandra N. Johnson, FAITH LAW, JERALYN WILEY, JEFKIDA JOHNSON-STINSON, JALISA CRAPO, STEPHANIE GRADY, SIMIN KASHANI, IEACHA JACKSON, ALEXANDRA HAINES, HEIDI THOMAS, LATOYA KENDRIX, SARAH ANNE MCLAUGHLIN, TIERRA HALL, Jamisha Dyer, Amy Ammons, Stephanie Adams, Andrea Lucero, Jessica LYNN SIMMONS, KRISTEN CAMPBELL, LAURA BRYAN, AIDA LOZADA, TABITHA Lee, Amanda Pichla, Latoria Woodall, Brittany Watkins, Erendira CUEVAS, LINDSEY ROSS, CRYSTAL COVERT, CATHERINA ANDRADE, KENDRA WICKWARE, KELLY CICHETTI, ASIA SHAKESPEARE, SAMANTHA STAATS, HALEY HENN, JENNIFER LEGASSIE, DESHONDA KNIGHT, TABITHA SAYLOR, ELIZABETH K. Moore, Sierra Moore, Tamara Whalin, Brittany Harsch, Kristen N.

CHANDLER, BARBARA NAPIER, STEPHANIE BENNETT, JESSICA KILBOURNE, DONISHA BISHOP, MARGARET BENDER, CHELSEA M. SAWYER, GUADALUPE PINEDA, SHA. DEBRA COLLIER, VALERIE ARTHUR, CHRISTY S. MURPHY, JESSICA HUPMAN, JENNIFER SAND-SHEQUEN, DANA Y. COOPER, JENNIFER GUZDEK, TRICIA PONICKI, TRACY D. GOULD, CORTNIE SHORT, DAVID RODRIGUEZ, JESSICA NIESLAWSKI, KARLA M. DUELLEY, NATALEE WILLIAMS, STEPHANIE BURT, PAULA C. GARCIA, JULIE NELSON, HEATHER BAKER, DAPHNE FRANKLIN, Andrea Martinez, Eshia Davis, Juanita Figueroa, Dawn Breen, Kindra NELSON, AMBER R. DRYDEN, ASHLEY PEARSON, MELISSA S. HOPKINS, MARQUITA WILLIAMS, JESSICA CASH, ELIZABETH BRYCE, NICOLE PERKINS, MARY WALKER, MADISON FOWLER, ALAINA DICE, TONI STREETER, CHEETARR JACKSON, APRIL ROBERTSON, KELSEY HARRIS, SIERRA RADDEN, MARQUSEY Evans, Dalia Jasso, Kaitlyn Sklenar, Stephanie Pelletier, Sonya RAMSEY, CHEYLO COLLADO, DETRA FERGUSON, ALISON ASHCROFT, JEANIE LASCELLES, LORI ANNALORA, STEPHANIE STOCKMAN, TIERRA JACKSON, AMBER OSTERMILLER-FORD, AMANDA STEVENS, KATHERINE SOTELO, TONI IVY, ERICKA JONES-GEORGE, DONNA RAWDON, PAULENA WHITE, STEPHANIE CLARK, JESSICA CROUSE, KATI VALENTINE, ANALYCIA SANCHEZ, ERICA SMITH, Gabrielle Hoffman, Samantha Williams, Shaquetta Felder, Charmina LEWIS, TANIA KENT, MARQUISA JOHNSON, NICOLE JACKSON, EMILLIE HOPPER, Kristy Collins, Samantha Allen, Sara Washburn, Stephanie Treat, KIMBERLY MCKINNEY, TANIQUA BLETCHER, CRYSTAL RODGERS, SANDY TATUM, TIFFANY DEBUSK, AMANDA CRITES, ANISHA LONGMIRE, BETH BURTON, KAY PAGE, SHAVONTE JOHNSON, JULIA FERGUSON, DESIREE SAENZ, TRISTYN ARIYAN, DODIE ARNOLD, KIMBERLY MOULTON, JOAN REDFIELD, REBECCA DURDEN, CAROLYN SUTTON, TYMEIKA BASKIN, LILLIE BATTLE-EASON, RACHELLE LILLY, ANGELA HENDERSON, BRITTANY SHUMPERT, DANIELLE WEHRLEY, NICHOLE HITCHCOCK, JAMIE O'BRYAN, MEGAN DEAN, JOANNA MOMOKO CLINE, SHARI HERNANDEZ, KATHERINE JACOBSEN, LINDSAY MILLER, ANGELA ROSE PADILLA, JASMAN AL-SHWAIYAT, CHESSICA MAUS, CHRISTINE WILSON, JAIMER PELLER, ARLENE CORDERO, JULIE GONZALEZ, JENNIFER HULL, WENDY BROWN, AMANDA WAITE, TANAZIA MCCANTS, ALEXANDRIA ESTRADA, Alexis Walton, Kayla Owens, Corneisha Foster, Erika Nacke, Briana GARNER, ELIZABETH PAIGE, SHARLA BERNDT, KESHIA BARNETTE, DEVON

PINCKNEY, PORSCHE DAVIS, KHELEE SAWYER, DAFFNEY HICKS, ZEBERA LAUNIUS, CHARLA MYERS-PERKINS, WILMA F. MITCHELL, QUINEISHA JUDD, Mokeda Alexander, Kendra Hill, Valiencia Parker, Darnesia Finkley, MARY NORTON, ASHLEY MANDOLINE, JESSICA WATSON, COURTNEY SMITH, SARA SUTPHIN, KELLY HARRIGAN, JACQUELINE SHERLEY-DOUGLAS, NICOLE SWEITZER, TONJA ABIAKAM, JENNIFER DRAUGHN, HATTIE HANSEN, KHADIJAH ROBINSON, TONI E. COLEMAN, BRANDY FLETCHER, ANDREA ROBINSON, BRIANA STILLS, ALICIA THAMES, JESSICA GRABILL, VIVIAN DAIGLE, KELLY REIS, LESLIE MARTIN, ANGELA ROBINSON, GINGER KUCHLER, KARLENA JENKS, TESS MORSE, TAMMI MILLER, TINA WEBBER, AMANDA HARVEY, LAUREN DONALDSON, CATHERINE KING, BRANDI GEDDINGS, BRIGITTE COCKCROFT, ANN EVERETT, PEGGY POSPICHEL, SHONTON L. BURTON, SHANEEN THOMPSON, NICOLE AMARO, MICHELLE WHITTED, TERI CARMICHEAL, LAURA GABRIEL, BRIANA McCranie, Heather Hemberger, Tami Unroe, Charlene Gomez, Chelsea COULTER, ALIYA QUICK, ARIELLE CATRON, BRIDGET COBURN, ASHLEY ANTKOWIAK, KATIE LYNN ARABIE, JILL GENOVESI, STEPHANIE COEN, JULIE GARCIA, KAYLA FAULKNER, MELISSA SNOW, AISLYNN POUNDS, CORA CLEAR, KARRIE SHIELDS, CHRISTON FORE, KIMBERLY HAMILTON, SHUNIKA HEMINGWAY, CASSANDRA BECKER, DANYELL RUSSELL, ERICA OWENS, CATHERINE MARTINEZ, KIMBERLY GRANT, JACLYN HERALD, BROOKE BIRGE, TIFFANI DALTON, STACY BETH SWENTON, BRANDI CARROLL, ASHLEY RODRIGUEZ, KRISTIN ANDRICK, KERI RICE, STEFANIE THACKER, LAURA FRISBY, LINDSEY GRADY, BESS PATTERSON, ALYSTA ESPINAL, AISHA CUFFIE, EMILY COKRLIE, TAMMY SCHATZBERG, JAIME POWELL, SHELBY LUANN McCAIN, MELISSA FUSCO, JANELL DAVIS, ALICIA RUFFIN, ANGELA KOLEBUCK UTZ, JENNIFER BAXTER, AIMEE GALLOWAY, TINA PERSONETTE, HANNAH RUTLEDGE, KATIE ARABIE, TONINA BARTLES, CATHERINE JENSEN, BRIANNA SMITH, Shanekua Watkins, Desiree Lemaster, April Galloway, Quashunna MILLER, RACHEL MCINTYRE, SUNDRIA CARROLL, DENISE FORD, VICTORIA KYAKUWA, SHANTELLA BROWN SANDERS, GRACE DIXON, CHANELL WINN, ASHA' ANA THOMAS, LINDSEY CADWELL, ROBIN COLEMAN, AMANDA SAILORS, LAURA BOYCE, MICHELLE THOMAS, LISA KUEHL, JERRY JANE WYNNE, CHYNEICE OLIVER, CYNTHIA MAURO, DANIELLE HOLT, ANDREA NOVAK, MICHELLE KAPLAN, LYCIA SLEDGE, QUANTASHIA MOSLEY-MORRIS, LATOYA

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BODY, ALINKIE JOSEPH, JULIE LAVIGNE, EBONEE RICHARDSON, ELIZABETH DAMRON, NEDRA BELL, NATASHA MANNING, ANITRA WADE, LESLIE BERRY, CARRIE BREAUX, JESSICA JETT, TRICHELLE HARRISON ROBINSON, SCHAMEKA SANTA CRUZE, ANNE GUILLOT, PATRICE WEBSTER, FELITA DOOLEY, TRASULA CLARK, SHANTELL FIELDS, ANGELINA SHARIDAN, TERRAINE ZENO, SHARON TOUPS, ALISHA SCUDDER, KAYTLIN RAINES, LESLEE DIAZ, EBONY TAYLOR, JILL JOHNSON, SHERRIE LEWIS, SHARISH DAVIS, MELINDA JOSEPH, BRIGETTE MORRIS, Paula D'Amico, Leona Jimmerson, Jennifer Gibliant, Quintella Landry, RENEE PILCHER, DELILAH PEREZ, LESLIE FATZ, LEIGH RODERICK, JERRELDA SANDERS, HAILEY SHELTON, CINDY N. BEST, KATHLEEN RENATA SEEGERS, NICHOLE HILLER, JENNIFER SULLIVAN, KELSEY JACKSON, KEMISHA WILDER, ANNE WILSON, QUIANA BRYANT, KIMBERLY DAVIS, HEATHER GARCIA, JESSICA FULLER, LATONYA HILLIARD, AMANDA WILSON, AMBER FENNELL, NAOMI WILLIAMS, KELLY KENNEDY, MELISSA DILOSA, KIMBERLY JACKSON, SHAWN AUGUST, KAREN FRANCIS, BETTY WEMPE, HEATHER CRUVER, SEQUILLA GARRETT, SHAMIKKI SHIPP, KATRINA STEVENSON, KEIONNE THOMPSON, Donisha Butler, Shelia Spearman, Danielle Schmidt, Robin Guidry, Kia BARNES, AMBER BRUEGGERT, JASMINE BAYNHAM, MONIQUE DUNMILES, JOZZETTE RANDLE, ALEXIS GALLIEN, LISA CLANTON, JESSICA WHITE, INGRID Bustos, Rhonda Diamond, Jodie Swoffer, Chelsey Baudoin, Denise ANCAR, TANIKA BRUMFIELD, MARY SMITH, ANGELL NAVARRE, EVE SIMS, DANIELLE BUTLER, KYONDRA ALBERT, ANDREA BRUNO, KEYSHARA ARMSTEAD, BRIDGETTE BLUNT, KASSANDRA HALSTEAD, LINDSAY BOONE, JERESA MORGAN, JAMIE WHITELY, BRAYANNE FORD, ROSE RAINEY, NORMA THOMAS, KIMBERLY LANDRY, KIMBERLY STEWART, TONYA ALLEN, ARRIELLE HUGHES, HILLERY THOMPSON, CIERA LAMB, CHELSEA MARIE BRYANT, TEXAS BLUNDELL, FLORA JORDAN, JESSICA JEFFERSON, SHEENA CHENEAU, CAROLINA ROMERO, JASMINE LEFORT, DORIONNE HUNTINGTON, JASMINE SHORT, MARY DORAN, CAROL JACKSON, TONIA ROUEGE, TAMIKA HYDE, EBONI SHAW, BRIANNE TRIGGER, CHELSEA VAN WERT, TANERA DALE-NAPPER, NICOLE LOWRY, CIERRA DENISE GARNER, GINA BAKER, AMANDA WOLTERS, AMANDA GARCIA, CRYSTAL BARLOW, CHRISTOPHER BARLOW, NATALIE STEVANUS, KATRENA WARR, Brenda Yearout, Mylah Nwankwo, Clara Allen, Angela Schneider, JACQUELYN SEIFERT, TAMMIE WIRE, KEISHA CURRIE, DIANA LEONARD, CONICA

Winston, Amy Cholewinski, Carla Walcott, Victoria Honpy, Jami Olson, Danielle Korte, Brittney M. Gentry, Joshua Gentry, Krista Burke, Sarah Boettger, Carmen Morales, Sabrina Boisaubin, Nora Mata, Jenna True, Stephanie Baker, Katelyn Tower, Charlotte Stribling, Heidi Rosenow, Britney Murphy, Hope Garcia, Ashton Silvis, Emilie Sitzman, Rochell Myles, Anjanet Coleman, Samantha Darby, Kate Jensen, Ciera Cole, Denise Keiderling, Lisa Frazier, Ericka Turner, Jasmin Thurman, Katie Schubel, Kathleen Frizzell, Shakeema Moore, Jessica Wein, Jayde Seaford, Jena Cook, Holly Jones, Keisha Pierce, Melissa Love, DeShera Myers, Graceann Robinson, Sarah Ottmar, Nicole Nunery, Ashley Davis, Laura Dacus, Gloria Fields, April Johnson, Maria Rodriguez, Kathleena Hays, Lisa Settle, Tiffany Fitch, Nicole Mazzanti, Whitney Homer, Megan Isham, Danica Hendricks, Melinda Dobson, Charlotte Brown, Mary Burdette,

Plaintiffs-Appellants,

v.

BAYER PHARMA AG, BAYER OY, BAYER HEALTHCARE PHARMACEUTICALS INC.,

		De	fendants-Appellants.*
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			ISTRICT COURT
FOR TH	e Southern D	ISTRICT OF N	EW YORK
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Before:

SACK, CHIN, and LOHIER, Circuit Judges.

<sup>\*</sup> The Clerk of the Court is respectfully directed to amend the official caption to conform to the above.

Appeal from a judgment of the United States District Court for the Southern District of New York (Engelmayer, *J.*) granting summary judgment in favor of defendants-appellees dismissing plaintiffs-appellants' products liability claims after precluding, pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the opinions of plaintiffs-appellants' expert witnesses as to general causation.

AFFIRMED.

MAXWELL KENNERLY, Kennerly Loutey LLC, Elkins Park, Pennsylvania (Lawrence L. Jones II, Jones Ward PLC, Louisville, Kentucky, and Martin D. Crump, Davis & Crump, P.C., Gulfport, Mississippi, on the brief), for Plaintiffs-Appellants.

LISA S. BLATT (F. Lane Heard III, Matthew J. Greer, Kimberly Broecker, on the brief), Williams & Connolly LLP, Washington, D.C.; Paul W. Schmidt, Michael X. Imbroscio, Phyllis A. Jones, Covington & Burling LLP, New York, New York, and Washington, D.C.; Elmore James Shepherd, Shook, Hardy & Bacon, LLP, Houston, Texas; and Shayna S. Cook, Goldman Ismail Tomaselli Brennan & Baum LLP, Chicago, Illinois, for Defendants-Appellees.

## PER CURIAM:

Plaintiffs-appellants ("plaintiffs") appeal the district court's judgment entered June 21, 2019, in favor of defendant-appellee Bayer Pharmaceuticals Inc. ("Bayer") and dismissing all claims. By opinion and order entered October 24, 2018, the district court granted Bayer's motion pursuant to Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), to exclude the testimony of all of plaintiffs' experts. In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig., 341 F. Supp. 3d 213 (S.D.N.Y. 2018). By opinion and order entered June 11, 2019, the district court granted Bayer's motion for summary judgment on the ground that the remaining evidence was insufficient to establish general causation, or in other words, that plaintiffs failed to offer evidence to suggest that Bayer's product is capable of causing the type of injuries from which plaintiffs claim to suffer. In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig., 387 F. Supp. 3d 323 (S.D.N.Y. 2019).

On appeal, plaintiffs argue that the district court improperly excluded the opinions of their experts on general causation, erred in granting summary judgment for Bayer, and denied plaintiffs their right to obtain and produce evidence in discovery. We reject plaintiffs' arguments, and for

substantially the reasons set forth in the district court's thorough opinions, we affirm its judgment.

#### **BACKGROUND**

The Mirena Intrauterine System ("Mirena") is a plastic T-shaped intrauterine device ("IUD"), manufactured by Bayer, that releases a synthetic steroid hormone called levonorgestrel ("LNG") into the uterus to prevent pregnancy. Plaintiffs are women from across the country who allege that they developed idiopathic intracranial hypertension ("IIH") as a result of using Mirena. The Judicial Panel on Multidistrict Litigation ("JPML") consolidated plaintiffs' cases in the Southern District of New York for pretrial proceedings, where plaintiffs filed their consolidated amended complaint alleging negligence, manufacturing defect, design defect, failure to warn, breach of implied and express warranties, negligent misrepresentation, fraudulent misrepresentation, fraud, and state consumer fraud violations.

On June 21, 2017, the district court entered a scheduling order giving "priority" to the issue of "whether plaintiffs have admissible evidence sufficient

IIH is known by multiple names, including pseudotumor cerebri ("PTC") and benign intracranial hypertension ("BIH").

to establish general causation of the harms alleged." S. App'x at 212.

Accordingly, the district court scheduled a hearing pursuant to *Daubert*, "as to all expert evidence bearing on general causation." S. App'x at 214. The district court held its *Daubert* hearing April 9-11, 2018, at which plaintiffs and Bayer put forward seven and twelve expert witnesses, respectively, on the issue of general causation. Plaintiffs' experts were (1) Dr. Vincenzo Salpietro, (2) Dr. Conrad Johanson, (3) Dr. Philip Darney, (4) Dr. Lemuel Moyé, (5) Dr. James Wheeler, (6)

On October 24, 2018, the district court issued its 156-page opinion and order granting Bayer's *Daubert* motion as to all of plaintiffs' experts and denying as moot plaintiffs' motion to preclude Bayer's experts.

Dr. Frederick Fraunfelder, and (7) Dr. Laura Plunkett.

Bayer then moved for summary judgment, arguing that without expert witnesses, plaintiffs had insufficient evidence to establish general causation. On June 11, 2019, the district court granted Bayer's summary judgment motion, and on June 21, 2019, entered judgment and closed all of the cases in the MDL. This appeal followed.

## **DISCUSSION**

## I. Standard of Review

We review a "district court's decision to admit or exclude expert testimony under a highly deferential abuse of discretion standard." *Zuchowicz v. United States*, 140 F.3d 381, 386 (2d Cir. 1998) (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 141 (1997)). "A decision to admit or exclude expert scientific testimony is not an abuse of discretion unless it is manifestly erroneous." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 265 (2d Cir. 2002) (internal quotation marks omitted). "Significantly, the abuse of discretion standard 'applies as much to the trial court's decisions about *how to determine reliability* as to its ultimate conclusion." *Id.* (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). Thus, the trial judge has broad discretion in determining "what method is appropriate for evaluating reliability under the circumstances of each case." *Id.* 

We review a grant of summary judgment *de novo*, "construing the facts in the light most favorable to the non-moving party and drawing all reasonable inferences in that party's favor." *Burns v. Martuscello*, 890 F.3d 77, 83 (2d Cir. 2018).

#### II. Daubert

Under Federal Rule of Evidence 702, lower courts perform a "gatekeeping" function and are charged with "the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." Daubert, 509 U.S. at 597. But while "Rule 702 sets forth specific criteria for the district court's consideration, the *Daubert* inquiry is fluid and will necessarily vary from case to case." Amorgianos, 303 F.3d at 266. Similarly, while the Court in *Daubert* identified four factors bearing on reliability that district courts may consider -- (1) whether a theory or technique "can be (and has been) tested"; (2) "whether the theory or technique has been subjected to peer review and publication"; (3) a technique's "known or potential rate of error," and "the existence and maintenance of standards controlling the technique's operation"; and (4) whether a particular technique or theory has gained "general acceptance" in the relevant scientific community, *Daubert*, 509 U.S. at 593-94 -- the Court cautioned that "[t]hese factors do not constitute . . . a 'definitive checklist or test." Amorgianos, 303 F.3d at 266 (quoting Daubert, 509 U.S. at 593). So long as "an expert's analysis [is] reliable at every step," it is admissible. *Id.* at 267.

Plaintiffs argue that the district court abused its discretion by

(1) focusing on plaintiffs' experts' conclusions rather than their methodologies,

(2) requiring the experts to back their opinions with published studies that

definitively supported their conclusions, and (3) taking a "hard look" at the

experts' methodology. Appellant Br. at 14-15. Each argument is rejected.

We start with plaintiffs' third argument: that the district court erred by taking a "hard look" at each expert's methodology. This argument is central to plaintiffs' appeal, as they argue the district court's analysis of each expert was too searching. But as noted, an expert's methodology must be reliable at every step of the way, and "[i]n deciding whether a step in an expert's analysis is unreliable, the district court should undertake a *rigorous examination* of the facts on which the expert relies, the method by which the expert draws an opinion from those facts, and how the expert applies the facts and methods to the case at hand." *Amorgianos*, 303 F.3d at 267 (emphasis added). Accordingly, not only was it appropriate for the district court to take a hard look at plaintiffs' experts' reports, the court was required to do so to ensure reliability.

Plaintiffs' contention that the district court impermissibly focused on plaintiffs' experts' conclusions instead of their methodologies is similarly

unavailing. The district court provided in-depth analysis of whether the experts applied their methodologies reliably. S. App'x at 52 (discussing in detail how Moyé's analysis "is flawed by serious methodological deficiencies"), 70-71 (explaining the "number of methodological flaws" with Plunkett's analysis), 84 (Wheeler's methodology was "flawed in multiple respects"), 102 (discussing the "hallmarks of unreliability" throughout Fraunfelder's analysis), 119, 121 (noting that Darney's report suffers from a broad overarching lapse of methodology and two speculative leaps rendering it unreliable), 139 ("infirmities precluding a finding of reliability as to three of the four steps" of Johanson's method), 149 (Salpietro's opinion "does not meet any of the *Daubert* criteria for reliability"). Plaintiffs may (and do) challenge whether the reliability analysis was correct, but plaintiffs have no basis to argue that the district court did not engage in a detailed analysis of their experts' methodologies.

Next, plaintiffs argue that the district court erred by requiring the experts to back their opinions with studies definitively supporting their conclusions. Even assuming the district court did impose such a requirement, it did not err in doing so. We have held that "[w]here an expert otherwise reliably utilizes scientific methods to reach a conclusion, lack of textual support may go

to the weight, not the admissibility of the expert's testimony." Amorgianos, 303 F.3d at 267 (internal quotation marks and citations omitted). In other words, an expert need not back his or her opinion with published studies that support his or her conclusion if he or she has utilized reliable scientific methods to reach that conclusion. But here, because the district court found that plaintiffs' experts did not "otherwise reliably utilize[] scientific methods," and the conclusions were not supported by other studies, the experts' reports were properly excluded. *Id.*; see *Joiner*, 522 U.S. at 146. Further, the court was well within its discretion to consider whether plaintiffs' experts' conclusions were generally accepted by the scientific community. The "general acceptance" of an expert's conclusion is one of the four enumerated considerations in *Daubert*, 509 U.S. at 594, and while a court need not consider the Daubert factors, it does not abuse its discretion in doing so.

In sum, the district court appropriately undertook a rigorous review of each of plaintiffs' experts, and based on that review reasonably found that the experts' methods were not sufficiently reliable and that their conclusions were not otherwise supported by the scientific community. Accordingly, the district court did not abuse its discretion in precluding the experts' conclusions.

## III. Summary Judgment

We turn to whether the court correctly granted summary judgment in favor of Bayer. We conclude that it did, for we agree that no reasonable juror could find that it was more likely than not that general causation had been established based on plaintiffs' admissible evidence.

State law controls on the question of what evidence is necessary to prove an element of a state law claim, such as general causation. See Amorgianos, 303 F.3d at 268. The district court concluded that all fifty states "require some evidence of general causation in products liability cases involving complex products liability (or medical) issues." S. App'x at 175. This question was presented to us in a previous MDL regarding Mirena, and we affirmed the district court's holding to that effect there. See Mirena MDL Plaintiffs v. Bayer HealthCare Pharms. Inc. (In re Mirena IUD Prods. Liability Litig. I), 713 F. App'x 11, 15-16 (2d Cir. 2017) (summary order). Plaintiffs attack that conclusion from the previous Mirena IUD MDL case and the district court's holding below, but, as the district court noted and is still true now, plaintiffs have failed to point to any state that does not have a general causation requirement for the type of claims at issue here. Rather, plaintiffs argue that some states allow evidence on specific

causation before or in conjunction with the presentment of evidence on general causation, but that is a challenge to the way in which the district court managed the litigation -- which is discussed below -- not the substantive state law that the district court applied. Accordingly, we are not persuaded that the district court erred in holding that there is a general causation requirement across all states.

Alternatively, plaintiffs argue that even if they were required to satisfy a threshold general causation showing, their failure to do so was because the district court prevented them from obtaining and presenting such evidence. We also reject this argument.

"A district court has wide latitude to determine the scope of discovery, and we ordinarily defer to the discretion of district courts regarding discovery matters. A district court abuses its discretion only when the discovery is so limited as to affect a party's substantial rights." *Twinam v. Dow Chem. Co. (In re Agent Orange Prod. Liab. Litig.*), 517 F.3d 76, 103 (2d Cir. 2008) (internal quotation marks and alteration omitted). In other words, "[a] party must be afforded a meaningful opportunity to establish the facts necessary to support his claim." *Id.* 

Plaintiffs first argue that the district court erred in granting Bayer's summary judgment motion for lack of evidence of general causation because the district court excluded all of their experts' reports instead of just portions of them. Plaintiffs therefore are suggesting that the testimony that they believe should have been carved out as admissible would have been sufficient to establish general causation. But plaintiffs have not explained which portions of their experts' reports should have been carved out as admissible (assuming, as the plaintiffs ask us to on this issue, that the district court's *Daubert* analysis was correct but warranted exclusion of only portions of their experts' reports) nor do they explain how those portions would have established general causation. We cannot credit a nonmovant's merely speculative assertion that some evidence that they have not specifically identified could have created a genuine dispute regarding general causation. See DiStiso v. Cook, 691 F.3d 226, 229-30 (2d Cir. 2012).

Plaintiffs next argue that the district court erred in precluding differential-diagnosis evidence, which they argue would have established that Mirena may have been the likely cause of their IIH.<sup>2</sup> But whether Mirena

A differential diagnosis is "a patient-specific process of elimination that medical practitioners use to identify the 'most likely' cause of a set of signs and symptoms from

actually caused plaintiff's IIH is an issue of specific causation, not general causation, the latter of which concerns whether Mirena is even capable of causing IIH. See Amorgianos, 303 F.3d at 268. And while we have declined to adopt a bright-line rule that "a differential diagnosis may never provide a sufficient basis for an opinion as to general causation," we have explained that the "district judge has broad discretion in determining whether in a given case a differential diagnosis is enough by itself to support such an opinion." Ruggiero, 424 F.3d at 254. Here, plaintiffs failed to explain below or on appeal how "the rigor of differential diagnosis performed, the expert's training and experience, the type of illness or injury at issue, or some other case-specific circumstance" militates in favor of admitting that evidence to establish general causation. *Id.* Accordingly, the district court did not abuse its broad discretion in excluding differential-diagnosis evidence.

Plaintiffs also argue that the district court improperly precluded them from obtaining other general-causation discovery. But the district court did not abuse its broad discretion in managing discovery. After the parties notified the district court of numerous discovery disputes, the court issued rulings from

a list of possible causes." *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005).

the bench ordering Bayer to produce millions of documents from more than fifty custodians. Forty-one of those custodians had been identified in the previous Mirena IUD MDL, but the court allowed plaintiffs to obtain documents from eleven new custodians. Despite plaintiffs' arguments to the contrary, the district court considered relevance and proportionality when resolving the discovery disputes. We conclude that the district court's thorough and well-reasoned discovery orders throughout the litigation were well within its wide discretion.

#### **CONCLUSION**

For the foregoing reasons, the district court's judgment is **AFFIRMED**.