PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 24-1828

IN RE: GARDASIL PRODUCTS LIABILITY LITIGATION.

TESSA NEEDHAM,

Plaintiff – Appellant,

and

PAYTON BERGIN; KAMERON HILTON; JESSICA RAYMER; KRISTA LANDERS; TANJA WAGNER, on behalf of S.W.; SCOTT WAGNER, on behalf of S.W.; JASMYNE GRAMZA; ADRIANA MERINO; ALLEN VELA, on behalf of J.V.; EDNA BARBA, on behalf of J.V.; MAESON DERR; CORINN MCELERNEY; RUBY SILVER; ELIZABETH LANDERS, on behalf of I.L.; JULIA BALASCO; ASHLEY DALTON; SAHARA WALKER; ASHLEY MULLER; MARK THOMAS, on behalf of Z.T.; JEFFREY K. HODDICK; COOPER HUMPHRIES; MADELYN LIPSCOMB; SAVANNAH FLORES; MICHAEL COLBATH; NALON A. SOILEAU; EMMA SULLIVAN; DARBY HENDRIX; CARISSA FETTERS, as lawful guardian ad litem of Minor Child S.F.; EDUARDO ATJIAN, II; SKYLEE BUTLER; MADELYN MALLOY; JULIETTE LEVY, as lawful guardian ad litem of Minor Child J.L.; AVERY ESHELMAN; SARAH LUKAS; MACKENZIE PENNELL; ETHAN HARTLE; CHRISTINA L. PRUDDEN; MEGAN MARIE ROEDER; AUDREY HINOJOSA HERNANDEZ SARNI; AINA RIZVI; CHERYL ROLF, on behalf of M.R.; SHANNON CANITZ; MADISON IVEY; ARIANNA REDDICKS; KRISTA O'BRIEN, Individually and on behalf of M.O., Individually and; TRISTEN J. HORTON; MADELINE A. COUNTS; KORRINE HERLTH; PAIGE GRAVES, Individually and on behalf of D.G.; ISABELLA NEVES; CAMILLE NYBOER; ALEXANDRA NUNEZ; LAKIA BRAYBOY; KELLI S. FOLEY, individually and as Administratrix of the Estate of Noah Tate Foley; CLIFTON K. FOLEY, individually and as Administrator of the Estate of Noah Tate Foley; DANA HILDEN; CATHERINE BOSS; ASHLEY AMERICA; KAITLYN KING; FAHTIMA ISAAC; LJUBITZA GHIARDI; COURTNEY KUNYSZ; ASHLYN BANCROFT; MARY ELLOUISE BOND;

EMILY CAFARELLA; SEAN C. SICARD; ERIKA N. SNELL; JAYDEN SUMRALL; JENCY MCCLAIN, as lawful guardian ad litem of Minor Child M.M.; CHAUNNA M. LANE; ALYSSA M. WILFONG; HANNAH FOSTER; CLARA J. NICKELS; GEORGIA T. WALL; KRISTEN LINTON, as lawful guardian ad litem of Minor Child C.K.; LAURENCIA AMPEDU, as lawful guardian ad litem of Minor Child J.A.; CARLY ZIMMERMAN; LOGAN T. DUNN; JADEN I. MCTIGHE; ANNA PUNSWICK; HANNAH E. DAVIS; WHITNEY ALEXANDER; OLIVIA TILLEY; CAROLINE GRACE CANTERA; RYAN SUGHRUE; SAMANTHA N. BRADY; MICHELE DAMIANO; AUSTIN L. DEGRANGE; SORIELY FLORES; HAILEY SCHMACHT; ELAINA BOUW; ARTURO VASQUEZ, II; KATHERINE SHOWALTER; AUTUMN ORM; REBECCA SULLIVAN, as lawful guardian ad litem of Minor Child A.S.; IMANI CORBETT; GRACE DRUMMOND; CHASE A. CLARKE; MARY WHITE, as lawful guardian ad litem of Minor Child M.A.; KATHERINE E. MILLER; JODIE E. JOHNSON; YOUN HEE LEE; CIENA WESTRICH; GIANNA N. DINARDO; GWENDOLYN KIEFT; ANN MARIE INDORF, as lawful guardian ad litem of Minor Child K.I.; BRIANNA HEISEY; TAYLOR ARCHIBALD-ROMERO; EMILY HASS; MAIAH FAAPOULI; KYLEE A. CARLESON; MEGAN ROGERS; LINDSEY PEPPERS; KATIE R. NEHRING; REBECCA GRAEME; SHERRY BURD, as lawful guardian ad litem of Minor Child E.B.; ELIZABETH LAYNE; TAREK H. MAKKI; BRAELYN CATES; MARYAH N. BETHEL; AARON MILLER; HALEY PHILLIPPI; ADRIAN MONTANO; KAITLYN WILSON; JUNIOUS NIELSEN; JOSEPH MEIER; CHRISTY ALLEN, on behalf of Her Minor Child E.A.; LESLIE M. MARTINEZ; SUZANNE TANNER, as lawful guardian ad litem of Minor Child L.T.; SHILOH WILLIAMS; ANDREA LEATHERS; CRISTAL BELLO; ALEXIS HOBACK; TEAGAN GRABISH; KRISTEN MCCAFFERTY; MADISON AGUILERA; ALEXIS NOWAKOWSKI; MACKENZIE GARDETT; MELANIE HOARD, as lawful guardian ad litem of Minor Child R. H.; HARMONY L. CALHOUN; VALERIE BETANCOURT; TORRI KIDDER; HALEY PETZ; STEPHANIE M. MCCOY; ASHLEY B. JOHNS; CHARLEIGH GADD; LAUREN JOHNSON; JACOB DRAKE; HANNAH M. HUIE; AARON FORD; CLARISSA D. OLIVE; PHAEDRA MCLAUGHLIN; HUNTER MILLER; SYLVIA KLINE, on behalf of B.H.; MADELINE DANIEL; TRICIA UNRATH, on behalf of A.U.; LAUREN HOOVER; KRISTILEE MAIELLA; T.J.B., as lawful guardian ad litem of Minor Child C.A.B.; D.B., as lawful guardian ad litem of Minor Child C.A.B.; NICHOLAS POLITANO; JADA BRISBOIS; MARY E. HARNOCZ; LYNDZEE WEISS; KRISTINE ZUGGI, Individually and as Administrator of the Estate of Isabella L. Zuggi; LYNNE GUZMAN, Individually and as Administrator of the Estate of Sydney M. Figueroa; LAUREN ARGIRI; DAVID HAMMETT, on behalf of minor child E.H.; JUDY HAMMETT, on behalf of minor child E.H.; WILLIAM D. ESKEW; PARKER G. ESKEW; JESSICA A. FISCHER; MATTHEW LAURENZI; EMILY MERCER; JESSICA N. BROWN; ANNALISE N. GRATOVICH; CRYSTAL MOREFIELD, as lawful guardian ad litem of Minor

Child A.J.; ERIN FERGUSON as Administrator of the Estate of Haley N. Ferguson; NADIA NOEL; AVA WILSON; CASSANDRA L. SURACI; SHAREE BARBER, as lawful guardian ad litem of Minor Child A.B.; ASHLEY LANGELIER; SHAREE BARBER, as lawful guardian ad litem of Minor Child A.B.; DENISE BERNHANG, as lawful guardian ad litem of Minor Child B.B.; SHANIE D. ROMAN; JORDAN AGUILAR; ALEXA FLORES; ELIZABETH MILLER; ALYSSA ROBINSON; SAMANTHA SEAGER; MIKAYLA J. VACHER; ALEXANDRA CANTALUPO; CHRIS STRICKLAND, individually and as next friend of K.S.; AMANDA FLORES, as guardian ad litem of J.F.; CARLEY L. KUNYSZ; SHEA GILLSTRAP, as lawful guardian ad litem of Minor Child A.N.; MELISSA MALLOY; WILLOW WREN; ANGELA M. WALKER; ELLA BURROUGHS; ANNA KRUPP; MATTHEW IROKU; MORGAN KIRBY; KARESSA HINSON-SHERWOOD; SHYLA SMITH; REBECCA J. BARGER; CHLOE LEMAY-ASSH; HALYN DUTCHER; AMY TURNER; ZACHARIA FARAG; KRISTEN EDWARDS DEMPSEY; ANDREA MAE WARREN,

Plaintiffs,

v.

MERCK & COMPANY, INC.; MERCK SHARP & DOHME LLC,

Defendants – Appellees,

and

WATCHUNG PEDIATRICS, a Partnership; VINEETHA A. ALIAS, D.O.; SUSAN P. KORB, APN; DOES 1 THROUGH 50, inclusive,

Defendants.

No. 24-1831

IN RE: GARDASIL PRODUCTS LIABILITY LITIGATION.

ANGELA M. WALKER,

Plaintiff – Appellant,

and

PAYTON BERGIN; KAMERON HILTON; JESSICA RAYMER; KRISTA LANDERS; TANJA WAGNER, on behalf of S.W.; SCOTT WAGNER, on behalf of S.W.; JASMYNE GRAMZA; ADRIANA MERINO; ALLEN VELA, on behalf of J.V.; EDNA BARBA, on behalf of J.V.; MAESON DERR; CORINN MCELERNEY; RUBY SILVER; ELIZABETH LANDERS, on behalf of I.L.; JULIA BALASCO; ASHLEY DALTON; SAHARA WALKER; ASHLEY MULLER; MARK THOMAS, on behalf of Z.T.; JEFFREY K. HODDICK; COOPER HUMPHRIES; MADELYN LIPSCOMB; SAVANNAH FLORES; MICHAEL COLBATH; NALON A. SOILEAU; EMMA SULLIVAN; DARBY HENDRIX; CARISSA FETTERS, as lawful guardian ad litem of Minor Child S.F.; EDUARDO ATJIAN, II; SKYLEE BUTLER; MADELYN MALLOY; JULIETTE LEVY, as lawful guardian ad litem of Minor Child J.L.; AVERY ESHELMAN; SARAH LUKAS; MACKENZIE PENNELL; ETHAN HARTLE; CHRISTINA L. PRUDDEN; MEGAN MARIE ROEDER; AUDREY HINOJOSA HERNANDEZ SARNI; AINA RIZVI; CHERYL ROLF, on behalf of M.R.; SHANNON CANITZ; MADISON IVEY; ARIANNA REDDICKS; KRISTA O'BRIEN, Individually and on behalf of M.O., Individually and; TRISTEN J. HORTON; MADELINE A. COUNTS; KORRINE HERLTH; PAIGE GRAVES, Individually and on behalf of D.G.; ISABELLA NEVES; CAMILLE NYBOER; ALEXANDRA NUNEZ; LAKIA BRAYBOY; KELLI S. FOLEY, individually and as Administratrix of the Estate of Noah Tate Foley; CLIFTON K. FOLEY, individually and as Administrator of the Estate of Noah Tate Foley; DANA HILDEN; CATHERINE BOSS; ASHLEY AMERICA; KAITLYN KING; FAHTIMA ISAAC; LJUBITZA GHIARDI; COURTNEY KUNYSZ; ASHLYN BANCROFT; MARY ELLOUISE BOND; EMILY CAFARELLA; SEAN C. SICARD; ERIKA N. SNELL; JAYDEN SUMRALL; JENCY MCCLAIN, as lawful guardian ad litem of Minor Child M.M.; CHAUNNA M. LANE; ALYSSA M. WILFONG; HANNAH FOSTER; CLARA J. NICKELS; GEORGIA T. WALL; KRISTEN LINTON, as lawful guardian ad litem of Minor Child C.K.; LAURENCIA AMPEDU, as lawful guardian ad litem of Minor Child J.A.; CARLY ZIMMERMAN; LOGAN T. DUNN; JADEN I. MCTIGHE; ANNA PUNSWICK; HANNAH E. DAVIS; WHITNEY ALEXANDER; OLIVIA TILLEY; CAROLINE GRACE CANTERA; RYAN SUGHRUE; SAMANTHA N. BRADY; MICHELE DAMIANO; AUSTIN L. DEGRANGE; SORIELY FLORES; HAILEY SCHMACHT; ELAINA BOUW; ARTURO VASQUEZ, II; KATHERINE SHOWALTER; AUTUMN ORM; REBECCA SULLIVAN, as lawful guardian ad litem of Minor Child A.S.; IMANI CORBETT; GRACE DRUMMOND; CHASE A. CLARKE; MARY WHITE, as lawful guardian ad litem of Minor Child M.A.; KATHERINE E. MILLER; JODIE E. JOHNSON; YOUN HEE LEE; CIENA WESTRICH; GIANNA N. DINARDO; GWENDOLYN KIEFT; ANN MARIE INDORF, as lawful guardian ad litem of Minor Child K.I.; BRIANNA

HEISEY; TAYLOR ARCHIBALD-ROMERO; EMILY HASS; MAIAH FAAPOULI; KYLEE A. CARLESON; MEGAN ROGERS; LINDSEY PEPPERS; KATIE R. NEHRING; REBECCA GRAEME; SHERRY BURD, as lawful guardian ad litem of Minor Child E.B.; ELIZABETH LAYNE; TAREK H. MAKKI; BRAELYN CATES; MARYAH N. BETHEL; AARON MILLER; HALEY PHILLIPPI; ADRIAN MONTANO; KAITLYN WILSON; JUNIOUS NIELSEN; JOSEPH MEIER; CHRISTY ALLEN, on behalf of Her Minor Child E.A.; LESLIE M. MARTINEZ; SUZANNE TANNER, as lawful guardian ad litem of Minor Child L.T.; SHILOH WILLIAMS; ANDREA LEATHERS; CRISTAL BELLO; ALEXIS HOBACK; TEAGAN GRABISH; KRISTEN MCCAFFERTY; MADISON AGUILERA; ALEXIS NOWAKOWSKI; MACKENZIE GARDETT; MELANIE HOARD, as lawful guardian ad litem of Minor Child R. H.; HARMONY L. CALHOUN; VALERIE BETANCOURT; TORRI KIDDER; HALEY PETZ; STEPHANIE M. MCCOY; ASHLEY B. JOHNS; CHARLEIGH GADD; LAUREN JOHNSON; JACOB DRAKE; HANNAH M. HUIE; AARON FORD; CLARISSA D. OLIVE; PHAEDRA MCLAUGHLIN; HUNTER MILLER; SYLVIA KLINE, on behalf of B.H.; MADELINE DANIEL; TRICIA UNRATH, on behalf of A.U.; LAUREN HOOVER; KRISTILEE MAIELLA; T.J.B., as lawful guardian ad litem of Minor Child C.A.B.; D.B., as lawful guardian ad litem of Minor Child C.A.B.; NICHOLAS POLITANO; JADA BRISBOIS; MARY E. HARNOCZ; LYNDZEE WEISS; KRISTINE ZUGGI, Individually and as Administrator of the Estate of Isabella L. Zuggi; LYNNE GUZMAN, Individually and as Administrator of the Estate of Sydney M. Figueroa; LAUREN ARGIRI; DAVID HAMMETT, on behalf of minor child E.H.; JUDY HAMMETT, on behalf of minor child E.H.; WILLIAM D. ESKEW; PARKER G. ESKEW; JESSICA A. FISCHER; MATTHEW LAURENZI; EMILY MERCER; JESSICA N. BROWN; ANNALISE N. GRATOVICH; CRYSTAL MOREFIELD, as lawful guardian ad litem of Minor Child A.J.; ERIN FERGUSON as Administrator of the Estate of Haley N. Ferguson; NADIA NOEL; AVA WILSON; CASSANDRA L. SURACI; SHAREE BARBER, as lawful guardian ad litem of Minor Child A.B.; ASHLEY LANGELIER; SHAREE BARBER, as lawful guardian ad litem of Minor Child A.B.; DENISE BERNHANG, as lawful guardian ad litem of Minor Child B.B.; SHANIE D. ROMAN; JORDAN AGUILAR; ALEXA FLORES; ELIZABETH MILLER; TESSA NEEDHAM; ALYSSA ROBINSON; SAMANTHA SEAGER; MIKAYLA J. VACHER; ALEXANDRA CANTALUPO; CHRIS STRICKLAND, individually and as next friend of K.S.; AMANDA FLORES, as guardian ad litem of J.F.; CARLEY L. KUNYSZ; SHEA GILLSTRAP, as lawful guardian ad litem of Minor Child A.N.; MELISSA MALLOY; WILLOW WREN; ELLA BURROUGHS; ANNA KRUPP; MATTHEW IROKU; MORGAN KIRBY; KARESSA HINSON-SHERWOOD; SHYLA SMITH; REBECCA J. BARGER; CHLOE LEMAY-ASSH; HALYN DUTCHER; AMY TURNER; ZACHARIA FARAG; KRISTEN EDWARDS DEMPSEY; ANDREA MAE WARREN,

Plaintiffs,

v.

MERCK & COMPANY, INC.; MERCK SHARP & DOHME LLC,

Defendants – Appellees,

and

WATCHUNG PEDIATRICS, a Partnership; VINEETHA A. ALIAS, D.O.; SUSAN P. KORB, APN; DOES 1 THROUGH 50, inclusive,

Defendants.

No. 24-1832

IN RE: GARDASIL PRODUCTS LIABILITY LITIGATION.

SHANIE D. ROMAN,

Plaintiff – Appellant,

and

PAYTON BERGIN; KAMERON HILTON; JESSICA RAYMER; KRISTA LANDERS; TANJA WAGNER, on behalf of S.W.; SCOTT WAGNER, on behalf of S.W.; JASMYNE GRAMZA; ADRIANA MERINO; ALLEN VELA, on behalf of J.V.; EDNA BARBA, on behalf of J.V.; MAESON DERR; CORINN MCELERNEY; RUBY SILVER; ELIZABETH LANDERS, on behalf of I.L.; JULIA BALASCO; ASHLEY DALTON; SAHARA WALKER; ASHLEY MULLER; MARK THOMAS, on behalf of Z.T.; JEFFREY K. HODDICK; COOPER HUMPHRIES; MADELYN LIPSCOMB; SAVANNAH FLORES; MICHAEL COLBATH; NALON A. SOILEAU; EMMA SULLIVAN; DARBY HENDRIX; CARISSA FETTERS, as lawful guardian ad litem of Minor Child S.F.; EDUARDO ATJIAN, II; SKYLEE BUTLER; MADELYN MALLOY; JULIETTE LEVY, as lawful guardian ad litem of Minor Child J.L.; AVERY ESHELMAN; SARAH LUKAS; MACKENZIE PENNELL; ETHAN HARTLE; CHRISTINA L.

PRUDDEN; MEGAN MARIE ROEDER; AUDREY HINOJOSA HERNANDEZ SARNI; AINA RIZVI; CHERYL ROLF, on behalf of M.R.; SHANNON CANITZ; MADISON IVEY; ARIANNA REDDICKS; KRISTA O'BRIEN, Individually and on behalf of M.O., Individually and; TRISTEN J. HORTON; MADELINE A. COUNTS; KORRINE HERLTH; PAIGE GRAVES, Individually and on behalf of D.G.; ISABELLA NEVES; CAMILLE NYBOER; ALEXANDRA NUNEZ; LAKIA BRAYBOY; KELLI S. FOLEY, individually and as Administratrix of the Estate of Noah Tate Foley; CLIFTON K. FOLEY, individually and as Administrator of the Estate of Noah Tate Foley; DANA HILDEN; CATHERINE BOSS; ASHLEY AMERICA; KAITLYN KING; FAHTIMA ISAAC; LJUBITZA GHIARDI; COURTNEY KUNYSZ; ASHLYN BANCROFT; MARY ELLOUISE BOND; EMILY CAFARELLA; SEAN C. SICARD; ERIKA N. SNELL; JAYDEN SUMRALL; JENCY MCCLAIN, as lawful guardian ad litem of Minor Child M.M.; CHAUNNA M. LANE; ALYSSA M. WILFONG; HANNAH FOSTER; CLARA J. NICKELS; GEORGIA T. WALL; KRISTEN LINTON, as lawful guardian ad litem of Minor Child C.K.; LAURENCIA AMPEDU, as lawful guardian ad litem of Minor Child J.A.; CARLY ZIMMERMAN; LOGAN T. DUNN; JADEN I. MCTIGHE; ANNA PUNSWICK; HANNAH E. DAVIS; WHITNEY ALEXANDER; OLIVIA TILLEY; CAROLINE GRACE CANTERA; RYAN SUGHRUE; SAMANTHA N. BRADY; MICHELE DAMIANO; AUSTIN L. DEGRANGE; SORIELY FLORES; HAILEY SCHMACHT; ELAINA BOUW; ARTURO VASQUEZ, II; KATHERINE SHOWALTER; AUTUMN ORM; REBECCA SULLIVAN, as lawful guardian ad litem of Minor Child A.S.; IMANI CORBETT; GRACE DRUMMOND; CHASE A. CLARKE; MARY WHITE, as lawful guardian ad litem of Minor Child M.A.; KATHERINE E. MILLER; JODIE E. JOHNSON; YOUN HEE LEE; CIENA WESTRICH; GIANNA N. DINARDO; GWENDOLYN KIEFT; ANN MARIE INDORF, as lawful guardian ad litem of Minor Child K.I.; BRIANNA HEISEY; TAYLOR ARCHIBALD-ROMERO; EMILY HASS; MAIAH FAAPOULI; KYLEE A. CARLESON; MEGAN ROGERS; LINDSEY PEPPERS; KATIE R. NEHRING; REBECCA GRAEME; SHERRY BURD, as lawful guardian ad litem of Minor Child E.B.; ELIZABETH LAYNE; TAREK H. MAKKI; BRAELYN CATES; MARYAH N. BETHEL; AARON MILLER; HALEY PHILLIPPI; ADRIAN MONTANO; KAITLYN WILSON; JUNIOUS NIELSEN; JOSEPH MEIER; CHRISTY ALLEN, on behalf of Her Minor Child E.A.; LESLIE M. MARTINEZ; SUZANNE TANNER, as lawful guardian ad litem of Minor Child L.T.; SHILOH WILLIAMS; ANDREA LEATHERS; CRISTAL BELLO; ALEXIS HOBACK; TEAGAN GRABISH; KRISTEN MCCAFFERTY; MADISON AGUILERA; ALEXIS NOWAKOWSKI; MACKENZIE GARDETT; MELANIE HOARD, as lawful guardian ad litem of Minor Child R. H.; HARMONY L. CALHOUN; VALERIE BETANCOURT; TORRI KIDDER; HALEY PETZ; STEPHANIE M. MCCOY; ASHLEY B. JOHNS; CHARLEIGH GADD; LAUREN JOHNSON; JACOB DRAKE; HANNAH M. HUIE; AARON FORD; CLARISSA D. OLIVE; PHAEDRA MCLAUGHLIN; HUNTER MILLER; SYLVIA KLINE, on

behalf of B.H.; MADELINE DANIEL; TRICIA UNRATH, on behalf of A.U.; LAUREN HOOVER; KRISTILEE MAIELLA; T.J.B., as lawful guardian ad litem of Minor Child C.A.B.; D.B., as lawful guardian ad litem of Minor Child C.A.B.; NICHOLAS POLITANO; JADA BRISBOIS; MARY E. HARNOCZ; LYNDZEE WEISS; KRISTINE ZUGGI, Individually and as Administrator of the Estate of Isabella L. Zuggi; LYNNE GUZMAN, Individually and as Administrator of the Estate of Sydney M. Figueroa; LAUREN ARGIRI; DAVID HAMMETT, on behalf of minor child E.H.; JUDY HAMMETT, on behalf of minor child E.H.; WILLIAM D. ESKEW; PARKER G. ESKEW; JESSICA A. FISCHER; MATTHEW LAURENZI; EMILY MERCER; JESSICA N. BROWN; ANNALISE N. GRATOVICH; CRYSTAL MOREFIELD, as lawful guardian ad litem of Minor Child A.J.; ERIN FERGUSON as Administrator of the Estate of Haley N. Ferguson; NADIA NOEL; AVA WILSON; CASSANDRA L. SURACI; SHAREE BARBER, as lawful guardian ad litem of Minor Child A.B.; ASHLEY LANGELIER; SHAREE BARBER, as lawful guardian ad litem of Minor Child A.B.; DENISE BERNHANG, as lawful guardian ad litem of Minor Child B.B.; JORDAN AGUILAR; ALEXA FLORES; ELIZABETH MILLER; TESSA NEEDHAM; ALYSSA ROBINSON; SAMANTHA SEAGER; MIKAYLA J. VACHER; ALEXANDRA CANTALUPO; CHRIS STRICKLAND, individually and as next friend of K.S.; AMANDA FLORES, as guardian ad litem of J.F.; CARLEY L. KUNYSZ; SHEA GILLSTRAP, as lawful guardian ad litem of Minor Child A.N.; MELISSA MALLOY; WILLOW WREN; ANGELA M. WALKER; ELLA BURROUGHS; ANNA KRUPP; MATTHEW IROKU; MORGAN KIRBY; KARESSA HINSON-SHERWOOD; SHYLA SMITH; REBECCA J. BARGER; CHLOE LEMAY-ASSH; HALYN DUTCHER; AMY TURNER; ZACHARIA FARAG; KRISTEN EDWARDS DEMPSEY; ANDREA MAE WARREN,

Plaintiffs,

v.

MERCK & COMPANY, INC.; MERCK SHARP & DOHME LLC,

Defendants – Appellees,

and

WATCHUNG PEDIATRICS, a Partnership; VINEETHA A. ALIAS, D.O.; SUSAN P. KORB, APN; DOES 1 THROUGH 50, inclusive,

Defendants.

Appeals from the United States District Court for the Western District of North Carolina, at Charlotte. Kenneth D. Bell, District Judge. (3:22-md-03036-KDB; 3:24-cv-00291-KDB; 3:24-cv-00433-KDB; 3:24-cv-00278-KDB)

Argued: May 15, 2025 Decided: September 4, 2025

Before DIAZ, Chief Judge, and NIEMEYER and BERNER, Circuit Judges.

Affirmed by published opinion. Chief Judge Diaz wrote the opinion, in which Judge Niemeyer and Judge Berner joined.

ARGUED: Margery Sue Bronster, BRONSTER FUJICHAKU ROBBINS, Honolulu, Hawaii, for Appellants. Edward J. Dumoulin, GOLDMAN ISMAIL TOMASELLI BRENNAN AND BAUM LLP, Chicago, Illinois, for Appellees. **ON BRIEF:** Robert M. Hatch, BRONSTER FUJICHAKU ROBBINS, Honolulu, Hawaii, for Appellant Angela M. Walker. Bijan Esfandiari, WISNER BAUM, Los Angeles, California, for Appellant Shanie D. Roman. Allison Mullins, L. Cooper Harrell, TURNING POINT LITIGATION MULLINS DUNCAN HARRELL & RUSSELL PLLC, Greensboro, North Carolina, for Appellant Tessa Needham. Rami N. Fakhouri, Allyson M. Julien, Betsy Farrington, GOLDMAN ISMAIL TOMASELLI BRENNAN & BAUM LLP, Chicago, Illinois; David C. Wright III, Stephen D. Feldman, ROBINSON, BRADSHAW & HINSON, P.A., Charlotte, North Carolina, for Appellees.

DIAZ, Chief Judge:

Title XXI of the Public Health Service Act, often called the Vaccine Act, establishes a no-fault compensation program for vaccine-related injuries. Generally, a person claiming injury from certain vaccines must first pursue this statutory remedy before suing a vaccine manufacturer. 42 U.S.C. § 300aa-11(a)(2)(A). To do so, a claimant must file a petition in the Court of Federal Claims within 36 months of the onset of the first symptom of vaccine-related injury or the injury's "significant aggravation." *Id.* § 300aa-16(a)(2).

The three Plaintiffs here filed petitions in the Court of Federal Claims after receiving the Gardasil vaccine, which prevents strains of human papillomavirus.[1] Plaintiffs conceded that their petitions were untimely but sought to equitably toll the Vaccine Act's limitations period. The special master who adjudicated the petitions agreed that they were untimely and dismissed them.

Plaintiffs then sued Merck & Co. and its affiliate, Merck Sharp & Dohme LLC, (together, "Merck"), both of which manufacture Gardasil, in the Western District of North Carolina, the forum for multi-district litigation arising from alleged Gardasil-related injuries. The district court dismissed the complaints because Plaintiffs failed to file timely Vaccine Act petitions.

[1] Human papillomavirus is a family of viruses, some strains of which have been linked to cancer. *About HPV*, U.S. Centers for Disease Control and Prevention, https://www.cdc.gov/hpv/about/index.html [https://perma.cc/9F23-K74X].

Plaintiffs appeal that ruling, along with two others the district court made that apply to all cases within the multi-district litigation: a ruling on a motion for partial judgment on the pleadings and a ruling rejecting a constitutional challenge to the Vaccine Act.

We hold that the addition of Gardasil to the Vaccine Table via 42 U.S.C. § 300aa-14(e) didn't violate the constitution. We also hold that timely participation in the Vaccine Act compensation program is a prerequisite to bringing a tort suit; courts faced with vaccine-related tort suits may not consider whether a petition under the Act was timely once the Vaccine Act process yields a timeliness finding.

Accordingly, we affirm the district court's rulings.

I.

A.

Plaintiffs present materially identical allegations and procedural histories.

First, each received the Gardasil vaccine. *Needham v. Sec'y of Health & Hum. Servs.*, No. 23-630V, 2023 WL 9287882, at *1 (Fed. Cl. Dec. 20, 2023); *Walker v. Sec'y of Health & Hum. Servs.*, No. 23-1038V, 2024 WL 1281508, at *1 (Fed. Cl. Feb. 29, 2024); *Roman v. Sec'y of Health & Hum. Servs.*, No. 23-705V, 2024 WL 470570, at *1 (Fed. Cl. Jan. 5, 2024).[2]

[2] The district court took judicial notice of the special master's decisions, and we do the same, since they are "matters of public record" that "can be accurately and readily determined from sources whose accuracy cannot be questioned." *Goldfarb v. Mayor of Baltimore*, 791 F.3d 500, 508 (4th Cir. 2015) (quotation omitted); Fed. R. Evid. 201(b).

Second, each experienced adverse symptoms "[f]ollowing [the] Gardasil injections." J.A. 831 ¶ 350; J.A. 1079 ¶ 348; *see also* J.A. 733 ¶ 347. Each Plaintiff's symptoms manifested more than three years before she petitioned for compensation under the Vaccine Act. *Needham*, 2023 WL 9287882, at *1; *Walker*, 2024 WL 1281508, at *1; *Roman*, 2024 WL 470570, at *1.

Third, Plaintiffs "acknowledged" before the special master that their petitions were untimely but sought to benefit from equitable tolling. *Needham*, 2023 WL 9287882, at *3; *Walker*, 2024 WL 1281508, at *2; *Roman*, 2024 WL 470570, at *2. The special master found that Plaintiffs weren't entitled to equitable tolling, and so dismissed the petitions. *Needham*, 2023 WL 9287882, at *5; *Walker*, 2024 WL 1281508, at *4; *Roman*, 2024 WL 470570, at *4.

B.

Plaintiffs then sued Merck in the Western District of North Carolina, where their cases joined others that were consolidated for pretrial proceedings under 28 U.S.C. § 1407. *In re Gardasil Prods. Liab. Litig.*, 619 F. Supp. 3d 1356 (J.P.M.L. 2022).

Merck moved to dismiss the three cases under both Federal Rule of Civil Procedure 12(b)(1), for lack of subject-matter jurisdiction, and Rule 12(b)(6), for failure to state a claim. Merck argued that Plaintiffs failed to timely pursue their remedies under the Vaccine Act before filing suit, as the Act required.

The district court concluded that the proper forums for challenging the special master's timeliness rulings were the special master's reviewing courts—the Court of Federal Claims and the Federal Circuit. *In re Gardasil Prods. Liab. Litig.* ("Dismissal

Order"), 743 F. Supp. 3d 726, 734–35 (W.D.N.C. 2024). So the district court dismissed the complaints. The court declined to decide whether Rule 12(b)(1) or 12(b)(6) served as the basis for dismissal, since either supported the ruling "in accordance with" the Vaccine Act. *Id.* at 735 n.10.

The court alternatively concluded that, even if it was the proper forum to "determine the timeliness of a Vaccine [Act] petition . . ., it would find that these Plaintiffs' petitions were not timely filed," and that Plaintiffs were not entitled to equitable tolling. *Id.* at 735.

C.

Before the district court dismissed the cases before us, and to manage the many others in the multi-district litigation, the court permitted Merck to file "bellwether" motions in two other cases.[3] Merck moved for partial judgment on the pleadings under Federal Rule of Civil Procedure 12(c) as to those two cases.

The district court granted the motion in part, finding that many of the theories of liability the two bellwether plaintiffs pleaded were disguised design defect or failure to warn claims that the Vaccine Act preempts. As is typical of bellwethers, the court "appl[ied its ruling] to all substantially similar allegations/claims asserted in the cases subject to the [multi-district litigation]." *In re: Gardasil Prods. Liab. Litig.* ("Rule 12(c) Order"), 724 F.

[3] In a "bellwether" proceeding, "some members of a large group of claimants" have "common issues or claims" decided first to guide the rest of the group members' cases toward resolution. *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019 (5th Cir. 1997). The district court used bellwether motions to test the legal sufficiency of the complaints in the multi-district litigation.

Supp. 3d 474, 493 (W.D.N.C. 2024). But the court invited plaintiffs with "good cause" to move "to avoid the application of th[e] ruling to her or his claims." *Id.*

All non-bellwether plaintiffs filed a joint motion seeking relief from the Rule 12(c) Order. They argued that the Vaccine Act's procedure for adding to the list of vaccines it covers violates the Constitution's Presentment Clause, which requires all legislation to be passed by both Houses of Congress and signed by the President. *See* U.S. Const. art. I, § 7, cl. 2.

The Vaccine Act's original text included a list of covered vaccines. Plaintiffs argued that adding vaccines to the table, even under procedures Congress incorporated into the Act, was an unconstitutional modification of statutory text.

But the district court rejected the argument, concluding that "[t]he addition of new vaccines [including Gardasil] to the Vaccine Injury Table satisfies" the criteria used to determine whether the executive branch is legislating impermissibly. *In re Gardasil Prods. Liab. Litig.* ("Presentment Order"), No. 22-md-03036, 2024 WL 3240677, at *4 (W.D.N.C. June 27, 2024).

The court alternatively explained that Congress enacted, and the President signed, a bill providing for an excise tax on Gardasil vaccines that was necessary for Gardasil's addition to the table "to become an effective part of the Vaccine Act." *Id.* at *5. The court therefore found that Gardasil's addition didn't violate the separation of powers. *Id.*

D.

After the district court dismissed the complaints for failure to file timely Vaccine Act petitions, each Plaintiff appealed. "When the transferee court overseeing pretrial

proceedings in multidistrict litigation grants a defendant's dispositive motion on all issues in some transferred cases, those cases become immediately appealable." *Gelboim v. Bank of Am. Corp.*, 574 U.S. 405, 415 (2015) (cleaned up). That's what happened here, so we have jurisdiction under 28 U.S.C. § 1291.[4]

II.

Before addressing the issues before us, we lay out the Vaccine Act's framework.

A.

Following "a massive increase in vaccine-related tort litigation" that threatened vaccine availability, Congress moved "[t]o stabilize the vaccine market and facilitate compensation" to those alleging injury from a vaccine. *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 227–28 (2011). The Vaccine Act "establishes a no-fault compensation program 'designed to work faster and with greater ease than the civil tort system.'" *Id.* at 228 (quoting *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995)).

"Special masters in the Court of Federal Claims hear vaccine-related complaints, which they adjudicate informally, within strict time limits, subject to similarly expeditious review." *Shalala*, 514 U.S. at 270 (citations omitted). In those proceedings, "the only questions the special master addresses are those related to the fact of injury and causation,"

[4] Whether a district court dismisses a claim under Rule 12(b)(1) or 12(b)(6), we review the dismissal de novo. *Evans v. B.F. Perkins Co.*, 166 F.3d 642, 647 (4th Cir. 1999) (Rule 12(b)(1)); *Roberts v. Carter-Young, Inc.*, 131 F.4th 241, 249 n.3 (4th Cir. 2025) (Rule 12(b)(6)). We also review a Presentment Clause challenge de novo. *Viegas v. Holder*, 699 F.3d 798, 801 (4th Cir. 2012).

so, unlike tort suits, the proceedings don't resolve manufacturer "liability issues." *Milik v. Sec'y of Health & Hum. Servs.*, 822 F.3d 1367, 1378 (Fed. Cir. 2016). Instead, the claim is for compensation and is brought against the Secretary of Health and Human Services, not against vaccine manufacturers. Successful petitioners recover from a common fund that the Secretary administers. 42 U.S.C. § 300aa-15(f)(4)(A).

The Act bars anyone from bringing a tort suit seeking more than $1,000 in damages against the manufacturer of a covered vaccine "unless a petition has been filed, in accordance with [42 U.S.C. § 300aa-16], for compensation under the Program," and the petitioner either (1) rejects the outcome of the compensation process, or (2) withdraws the petition under a provision we explain below. 42 U.S.C. § 300aa-11(a)(2)(A).

Section 300aa-16, in turn, requires a petition to be filed within "36 months [of] the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of [the claimant's] injury." *Id.* § 300aa-16(a)(2). This limitations period is subject to equitable tolling. *Cloer v. Sec'y of Health & Hum. Servs.*, 654 F.3d 1322, 1337, 1340 (Fed Cir. 2011).

"If a civil action which is barred under [§ 300aa-11(a)(2)(A)] is filed in a State or Federal court, the court shall dismiss the action." 42 U.S.C. § 300aa-11(a)(2)(B).

B.

The Vaccine Act creates a "Vaccine Injury Table" listing vaccines, certain purported side effects of those vaccines, and time periods within which those side effects might manifest. 42 U.S.C. § 300aa-14(a).

The table serves two functions. First, it identifies the vaccines covered by the Act. *See id.* §§ 300aa-13(a), 300aa-11(c). Second, it expedites the special master's decision-making.

If a petitioner receives a covered vaccine and later develops one of the listed side effects within the defined onset period, the petitioner doesn't need to show actual causation to receive compensation. *Bruesewitz*, 562 U.S. at 228. But if a petitioner receives a covered vaccine and alleges an injury not listed on the table, or if a listed injury begins after the onset window set out in the table, then "a claimant may [still] establish prima facie entitlement to compensation by introducing proof of actual causation." *Shalala*, 514 U.S. at 270.

The Secretary may rebut the prima facie case by proving that the injury was caused by something other than the vaccine. Barring that, the claimant is entitled to compensation. *See* 42 U.S.C. § 300aa-13(a).

The special masters who adjudicate petitions must generally make findings of fact and conclusions of law "not later than 240 days" after a claimant files a petition for compensation. *Id.* § 300aa-12(d)(3)(A)(ii).

Either party can seek review of the special master's findings and conclusions in the Court of Federal Claims. *Id.* § 300aa-12(e)(1)–(2). That court can either uphold the special master's ruling, issue its own findings of fact and conclusions of law, or remand for additional proceedings. The court generally "shall complete" its review and enter judgment "within 120 days" after a response to a motion for review is filed. *Id.* § 300aa-12(e)(2).

A petitioner may accept the judgment of the Court of Federal Claims (whether entered after the special master's determination or review in the Court of Federal Claims). *Id.* § 300aa-21(a). Doing so bars the petitioner from suing "for the vaccine-related injury . . . for which the judgment was entered." *Id.*

Any party "aggrieved by the findings or conclusions of the [Court of Federal Claims] may obtain review of the judgment of the court in the . . . Federal Circuit." *Id.* § 300aa-12(f). An aggrieved petitioner needn't seek Federal Circuit review to pursue a lawsuit. A petitioner can elect, either after the Court of Federal Claims enters judgment or after the Federal Circuit's mandate issues (if appellate review is sought), to sue in lieu of accepting the compensation award. *Id.* § 300aa-21(a).

The Act also allows a petitioner to withdraw from the Vaccine Act remedy program and sue if the process takes too long, generally if the special master fails to decide a petition within 240 days of the petition's filing, or the Court of Federal Claims fails to enter judgment within 420 days of the same. *Id.* §§ 300aa-12(g), 300aa-21(b).

In a tort suit that follows the Vaccine Act process, "any finding of fact or conclusion of law" by the special master or Court of Federal Claims, and "the final judgment" of the Court of Federal Claims or Federal Circuit, "shall not be admissible." *Id.* § 300aa-23(e).

C.

The Vaccine Act only provides compensation for vaccine-related injuries, and it only requires injured parties to participate in the compensation program, if the allegedly harmful vaccine is listed on the vaccine injury table. The Act includes an "[i]nitial table"

that Congress enacted. *Id.* § 300aa-14(a). The initial table lists four vaccines that the Act has covered from its inception.

The table may be modified in two ways. First, the Secretary may "promulgate regulations to modify" the table by "add[ing] to, or delet[ing] from" the injuries and injury onset windows listed in the table Congress enacted. *Id.* § 300aa-14(c)(1), (3). Any such modification applies only prospectively. *Id.* § 300aa-14(c)(4). The Secretary's authority to modify the listed injuries and onset windows doesn't change the vaccines listed on the injury table.

Second, the Act requires the Secretary to "amend the Vaccine Injury Table" to add vaccines that the Centers for Disease Control and Prevention (CDC) recommends for routine administration to children. *Id.* § 300aa-14(e)(2). Such an amendment "shall take effect upon the effective date of a tax enacted" on administered doses of a vaccine for which the CDC makes such a recommendation. Revenue Reconciliation Act of 1993, Pub. L. 103-66, § 13632(a)(3), 107 Stat. 312, 646 (1993). To add a vaccine to the table, then, the CDC must recommend routine administration of the vaccine to children, and Congress must tax the vaccine.

The Secretary added vaccines against human papillomavirus (including Gardasil) to the table in 2007. National Vaccine Injury Compensation Program: Addition of Meningococcal and Human Papillomavirus (HPV) Vaccines to the Vaccine Injury Table, 72 Fed. Reg. 19937, 19938 (Apr. 20, 2007). The Secretary's announcement followed the CDC's recommendation that human papillomavirus vaccines "be routinely administered to females aged 11–12 years," *id.* at 19937, and the effective date of an excise tax on human

papillomavirus vaccines that was part of the Tax Relief and Health Care Act of 2006. *See* Pub. L. 109-132, § 408, 120 Stat. 2922, 2962–63 (enacted Dec. 20, 2006).

III.

We turn now to the issues on appeal.

A.

Plaintiffs only had to pursue their Vaccine Act remedies if the Secretary lawfully added Gardasil to the vaccine injury table. So we address that issue first.

Plaintiffs contend that the Vaccine Act violates the Presentment Clause because it allows the Secretary to modify the vaccine table. According to Plaintiffs, both the Secretary's ability to (1) change the injuries and onset windows Congress listed in the initial table under § 300aa-14(c), and (2) add vaccines to the table under § 300aa-14(e) violate the Clause.

But Plaintiffs didn't preserve the first argument, so it's forfeited. And the second lacks merit.

B.

The Constitution doesn't "authorize[] the President to enact, to amend, or to repeal statutes." *Clinton v. City of New York*, 524 U.S. 417, 438 (1998). Rather, the Presentment Clause requires every law to "have passed the House of Representatives and the Senate" and "be presented to the President of the United States" for signature. U.S. Const. art. I, § 7, cl. 2.

In *Clinton*, the Supreme Court struck down the Line Item Veto Act, which purported to give the President the authority to cancel portions of duly enacted laws. 524 U.S. at 438. The statute effectively enabled the President to craft "truncated versions of . . . bills that passed both Houses of Congress," rather than laws that were the "product[s] of the 'finely wrought' [legislative] procedure that the Framers designed." *Id.* at 440.

The Court identified three "critical" factors that suggest a constitutional problem: (1) the same conditions exist when Congress passes a statute and the executive takes the challenged act, (2) the executive's discretion is unconstrained with respect to the challenged act, and (3) the executive isn't "executing the policy that Congress" set in the statute when taking the challenged act. *Id.* at 443–44.

The Line Item Veto Act didn't pass constitutional muster because it failed each of these criteria. First, the President's use of the veto didn't turn on different on-the-ground facts than Congress's legislative judgment. Second, the President had unfettered discretion to veto portions of statutes. And third, the President could exercise the veto solely for his own policy aims without regard to Congress's. *Id.*

By contrast, the Court rejected a Presentment Clause challenge to the Tariff Act of 1890 in *Marshall Field & Co. v. Clark*, 143 U.S. 649 (1892). That statute exempted certain goods from import duties. But it also gave the President the authority to suspend exemptions for some of those goods "whenever and so often" as he determined that foreign countries imposed "reciprocally unequal and unreasonable" duties on American goods. *Clark*, 143 U.S. at 680.

In concluding that the President's suspension authority was constitutional, the Court explained that Congress directed the President to take an action (suspending exemptions) when "he ascertained the fact" of unreasonable duties on American goods (a future condition). *Id.* at 693. The President's suspension authority was valid because it was "a part of the law itself as it left the hands of Congress." *Id.* (cleaned up).

As we explain, the Vaccine Act's process for adding vaccines to the injury table is closer to *Clark* than *Clinton*.

1.

The Secretary added Gardasil to the vaccine injury table under 42 U.S.C. § 300aa-14(e)(2). That provision directs the Secretary to "amend the Vaccine Injury Table" to include "vaccines recommended [by the CDC] for routine administration to children" within two years of the recommendation. *Id.* For such additions to "take effect," however, Congress must have "enacted" a "tax" on doses of the vaccine proposed to be added to the table to fund the Vaccine Act's compensation system. Revenue Reconciliation Act of 1993, § 13632, 107 Stat. at 646.

We see no Presentment Clause issue with § 300aa-14(e). Adding a vaccine to the injury table doesn't modify the Act's text. Instead, it reflects the Secretary's recognition that the two conditions needed for a vaccine to be added have been satisfied: the CDC recommended the vaccine for routine administration to children, and Congress passed an excise tax on the vaccine to fund the compensation system. Just like the Tariff Act of 1890, the Vaccine Act directs the executive to take an action (add a vaccine to the injury table) when the conditions built into the statute are satisfied. *Clark*, 143 U.S. at 693.

Therefore, § 300aa-14(e) complies with the Presentment Clause.

2.

Perhaps recognizing the weakness of their argument as framed, Plaintiffs insist (for the first time on appeal) that a different section of the statute (§ 300aa-14(c)) violates the Presentment Clause.

Section 300aa-14(c) invites the Secretary to "add to, or delete from," the list of compensable injuries and their onset periods that Congress enacted in the initial vaccine injury table. 42 U.S.C. § 300aa-14(c)(3). As a result, even if the initial vaccine injury table remains on the books, a § 300aa-14(c) amendment means that part of the table might have no ongoing effect.

For example, if the Secretary removes a listed injury for the polio vaccine (one of the initially covered vaccines), then future claimants can only recover for that injury by showing actual causation—even though the Act's text says they don't need to. In Plaintiffs' view, this is a Presentment Clause problem.[5]

But § 300aa-14(c) has nothing to do with how the Secretary added Gardasil to the injury table. As is true for all vaccine additions, the Secretary did so through the process outlined in § 300aa-14(e).

[5] The Federal Circuit rejected this argument, explaining that the Secretary's § 300aa-14(c) authority "merely grants . . . the power to promulgate new regulations" that "appl[y] only prospectively," which leaves the initial injury table "codified and unaltered" with continuing application "to all petitions filed before the revision." *Terran ex rel. Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1312 (Fed. Cir. 1999). Since we conclude that Plaintiffs' challenge to § 300aa-14(c) isn't properly before us, we take no view on *Terran*.

Plaintiffs' argument therefore hinges on the Vaccine Act's non-severability clause, which states that if § 300aa-14 (among other provisions) "is held" unconstitutional, the entire Vaccine Act compensation scheme "shall be considered invalid."[6] National Childhood Vaccine Injury Prevention Act of 1986, Pub. L. 99-660, § 322, 100 Stat. 3755, 3783 (codified as amended at 42 U.S.C. § 300aa-1 note).

The problem for Plaintiffs is they didn't challenge § 300aa-14(c) in the district court, so they've forfeited that argument. *United States v. Olano*, 507 U.S. 725, 733 (1993) (forfeiture "is the failure to make the timely assertion of a right"); *see Jones v. Liberty* (*In re Wallace & Gale Co.*), 385 F.3d 820, 835 (4th Cir. 2004) (noting that a party's failure to "raise a certain interpretation" of a document before a lower court "results in a [forfeiture] of that argument on appeal absent exceptional circumstances").

In the district court, Plaintiffs asserted that "Gardasil is not covered by the Vaccine Act because it is not included in the Vaccine Injury Table created by Congress." J.A. 1004. From this, the district court understood that Plaintiffs challenged the Secretary's addition of Gardasil to the Vaccine Act, which occurred through § 300aa-14(e). But the court wasn't on notice that Plaintiffs also objected to the Secretary's ability to amend the initial vaccine table under § 300aa-14(c).

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[6] Without the non-severability clause, Plaintiffs would lack standing to challenge § 300aa-14(c). *See DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 353 (2006). And even that might not be enough. *California v. Texas*, 593 U.S. 659, 684 (2006) (Thomas, J., concurring) (noting that the Supreme Court "has not addressed standing-through-inseverability in any detail, largely relying on it through implication"). We needn't consider standing, though, since we conclude Plaintiffs forfeited their argument that § 300aa-14(c) is unconstitutional.

Because Plaintiffs forfeited reliance on § 300aa-14(c) and the non-severability provision in the district court, they're precluded from making arguments about them here. *Bell v. Brockett*, 922 F.3d 502, 513 (4th Cir. 2019) ("Appellants may not raise arguments on appeal that were not first presented below to the district court.").

IV.

Next, we address Plaintiffs' two-pronged argument that the district court erred in dismissing their cases for failing to file timely Vaccine Act petitions.

First, Plaintiffs insist that Congress designed the Vaccine Act program "to preserve tort claims with a *de novo* action," Appellants' Br. at 27, so the district court should have independently considered whether they complied with the Vaccine Act's requirements. Second, they press that they're entitled to establish equitable tolling in the district court.

We reject the first argument and do not reach the second.

A.

Plaintiffs' first ground is, at bottom, that the trial court in a tort suit may consider whether a Vaccine Act petition was timely filed notwithstanding a special master's finding of untimeliness. But that's not what Congress planned when it designed the Act's compensation program.

The Act requires a person injured by a covered vaccine to file a petition "in accordance with" 42 U.S.C. § 300aa-16 and compels the trial court to dismiss a tort suit

that doesn't adhere to that requirement.[7] 42 U.S.C. § 300aa-11(a)(2). Section 300aa-16 includes the Vaccine Act's statute of limitations, which requires petitions to be filed within 36 months of vaccine-related symptom onset or aggravation, subject to equitable tolling. *Id.* § 300aa-16(a)(2); *Cloer*, 654 F.3d at 1340–41.

So the Act requires a claimant to file a *timely* Vaccine Act petition to later be able to bring a tort suit. *See Shalala*, 514 U.S. at 270 ("A claimant . . . *must exhaust* the Act's procedures and refuse to accept the resulting judgment before filing any *de novo* civil action." (emphasis added)); *Bruesewitz*, 562 U.S. at 229 (noting that the "Act requires claimants to seek relief through the compensation program *before* filing suit" (emphasis added)); *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 3 (1st Cir. 1994) (Breyer, C.J.) ("The Act requires that a person injured directly by a vaccine *first* bring a Vaccine [Act] proceeding.").

Who then decides timeliness? The Act tells us: the special masters tasked with adjudicating petitions, along with their reviewing courts. The Act grants to these forums "jurisdiction over proceedings to determine if a petitioner under section 300aa-11[, which incorporates the Vaccine Act's limitations period,] . . . is entitled to compensation under the [Act]." 42 U.S.C. § 300aa-12(a).

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[7] The Vaccine Act's instruction that a "court shall dismiss [an] action" brought by a plaintiff who failed to adhere to the Act's compensation program, 42 U.S.C. § 300aa-11(a)(2)(B), likely creates a jurisdictional requirement rather than a mandatory claim-processing rule. *See Riley v. Bondi*, 145 S. Ct. 2190, 2202 (2025) (explaining that one of the hallmarks of a jurisdictional requirement is statutory language directed "to *courts*"). But since Merck promptly raised the issue whether Plaintiffs adhered to the Vaccine Act process, we needn't settle the question.

The Act also details how petitioners who lose before the special masters can press their claims: by moving for review in the Court of Federal Claims and petitioning for review in the Federal Circuit. *Id.* § 300aa-12(e), (f). The Act contemplates that those forums will review a special master's decision on a petition's timeliness, not another court in a later tort suit. *See id.* § 300aa-12(f) (making the "findings of fact and conclusions of law [from those forums] . . . on a petition [the] final determinations of the matters involved").

We conclude that the Vaccine Act grants to the special masters the authority to decide whether a petition was timely. If a special master finds a petition untimely, the claimant can only seek relief from that decision in the Court of Federal Claims and, subsequently, the Federal Circuit.

B.

Still, Plaintiffs argue that the special master's timeliness decision should have no force in a tort suit. They say instead that the civil case is supposed to be "*de novo*." Appellants' Br. at 27; *see also Shalala*, 514 U.S. at 270 (commenting that a tort suit is a "*de novo* civil action").

But they misread what it means for the tort suit to be "de novo." The trial court needn't shut its eyes to the result of the Vaccine Act proceedings. In fact, because trial courts facing vaccine-related tort claims are required to dismiss suits filed by plaintiffs who fail to follow the Vaccine Act's requirements, they can't wholly disregard the Vaccine Act proceedings. 42 U.S.C.§ 300aa-11(a)(2)(B).

The "de novo" nature of the tort suit means only that "findings of fact and conclusions of law" made in Vaccine Act proceedings aren't "admissible" at "any stage of a civil action." *Id.* § 300aa-23(e); *cf. Rohrbough v. Wyeth Labs., Inc.*, 916 F.2d 970, 976 n.12 (4th Cir. 1990) (noting that this provision "expressly renders" the vaccine injury table "inadmissible" to prove causation).

Subsection (e)'s reference to "any stage of a civil action" must be read against § 300aa-23's other subsections, which describe three "stage[s]" of civil actions: liability, general damages, and punitive damages. 42 U.S.C. § 300aa-23(b)–(d). Subsection (e)'s prohibition on admitting findings of fact and conclusions of law from Vaccine Act proceedings in "any stage of a civil action" refers to these three stages. But subsection (e) doesn't bar the findings of fact and conclusions of law of the special master or Court of Federal Claims from being considered for other purposes, like determining whether a petition was timely filed.

In short, subsection (e) preserves the ordinary burdens of production and persuasion a tort plaintiff must satisfy to succeed in the suit. But it doesn't require courts facing tort suits to disregard Vaccine Act proceedings.

C.

Although we conclude that the Vaccine Act alone leaves no role for trial courts to decide a petition's timeliness after a special master has ruled on the issue, Plaintiffs' attempt to relitigate timeliness runs headlong into another barrier—issue preclusion.

That doctrine instructs that "once an issue is actually and necessarily determined by a court of competent jurisdiction, that determination is conclusive in subsequent suits based

on a different cause of action involving a party to the prior litigation." *Montana v. United States*, 440 U.S. 147, 153 (1979). Issue preclusion applies to determinations made in many kinds of adversarial proceedings, not just traditional litigation in courts, and not just where the two proceedings involve the same "rights." *B&B Hardware, Inc. v. Hargis Indus., Inc.*, 575 U.S. 138, 148–49, 152 (2015).

Applying issue preclusion requires:

> (1) the issue or fact is identical to the one previously litigated; (2) the issue or fact was actually resolved in the prior proceeding; (3) the issue or fact was critical and necessary to the judgment in the prior proceeding; (4) the judgment in the prior proceeding is final and valid; and (5) the party to be foreclosed by the prior resolution of the issue or fact had a full and fair opportunity to litigate the issue or fact in the prior proceeding.

In re Microsoft Corp. Antitrust Litig., 355 F.3d 322, 326 (4th Cir. 2004). In every case where a special master dismisses a claim as untimely, each of these elements is met.

We see no reason to depart from ordinary issue preclusion principles here. The text, structure, and purpose of the Vaccine Act warrant applying the doctrine. We've already noted that the Act grants to special masters "jurisdiction" to decide a petition's timeliness. 42 U.S.C. § 300aa-12(a). That language is found in the statutory provision labeled "Jurisdiction" that explains in detail the process for resolving Vaccine Act petitions before the special masters, Court of Federal Claims, and Federal Circuit. These aspects of the statute signal Congress's intent that compliance with the Vaccine Act's procedures be decided in those forums.

What's more, Congress chose to channel claims for vaccine-related injuries into the Vaccine Act compensation program before a petitioner can bring a tort case. To pursue

vaccine-related tort claims, a petitioner must first bring a timely petition and either reject the outcome of the Vaccine Act proceedings or withdraw a petition that remains in limbo for too long. Otherwise, a person injured by a covered vaccine can't sue.

Plaintiffs assert that their ability to withdraw a stalled petition renders the Vaccine Act compensation program a mere box-checking exercise. Not so. Plaintiffs don't have an unfettered right to opt out of the program; they may do so only if a petition remains pending for too long. *Id.* § 300aa-21(b).

In designing the program, Congress wanted "[t]o stabilize the vaccine market and facilitate compensation." *Bruesewitz*, 562 U.S. at 228. Both aims can be accomplished only by generally requiring would-be tort plaintiffs to consider what they'd recover through the compensatory program before electing to sue. Plaintiffs' preferred reading would eviscerate Congress's intent.

We therefore conclude that whether a Vaccine Act petition was timely is a question for the special master, with any review or reconsideration of that decision taking place in the Court of Federal Claims and Federal Circuit. Once those forums have settled the question, their answer can't ordinarily be relitigated in a later tort suit.[8] *See* Restatement (Second) of Judgments §§ 28–29 (A.L.I. 1982).

[8] A petitioner's right to withdraw a petition that sits with the special master for more than 240 days might mean that a special master fails to decide timeliness before the petitioner brings a tort suit. In that case, the trial court may need to decide the issue. But that's not this case since the special master found Plaintiffs' petitions untimely within the 240-day window and Plaintiffs didn't withdraw their petitions.

The special master who decided Plaintiffs' Vaccine Act petitions concluded that their petitions were untimely. Plaintiffs didn't pursue review of that determination in the Court of Federal Claims and, therefore, that ruling stands. Thus, Plaintiffs can't sue Merck. It also means that Plaintiffs aren't entitled to discovery in this case to allow them to establish equitable tolling with respect to their petitions.[9]

V.

For these reasons, we affirm the district court's judgment.

AFFIRMED

[9] We take no view on the district court's alternative conclusion that Plaintiffs failed to show equitable tolling. And because we affirm the district court's dismissal on exhaustion grounds, we don't reach the merits of the Rule 12(c) Order.