IN THE INTERMEDIATE COURT OF APPEALS OF WEST VIRGINIA

Fall 2024 Term

FILED

December 27, 2024

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ASHLEY N. DEEM, CHIEF DEPUTY CLERK INTERMEDIATE COURT OF APPEALS OF WEST VIRGINIA

Nos. 23-ICA-275, -276, -287, & -307

A.D.A., as next friend of L.R.A., a minor child under the age of 18, Plaintiff Below, Petitioner,

v.) No. 23-ICA-275

JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., NORAMCO, LLC, MCKINSEY & COMPANY, INC., U.S., and the WEST VIRGINIA BOARD OF PHARMACY, Defendants Below, Respondents.

AND

A.N.C., as next friend of J.J.S., a minor child under the age of 18, Plaintiff Below, Petitioner,

v.) No. 23-ICA-276

JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., NORAMCO, LLC, MCKESSON CORPORATION, CARDINAL HEALTH, INC., H.D. SMITH, LLC, H.D. SMITH HOLDINGS, LLC, H.D. SMITH HOLDING CO., AMERISOURCEBERGEN CORPORATION, AMERISOURCEBERGEN DRUG CORPORATION, ANDA, INC., TEVA PHARMACEUTICALS, USA, INC., ALLERGAN FINANCE, LLC, ALLERGAN SALES, LLC, ALLERGAN USA, INC., ABBVIE, INC., MCKINSEY & COMPANY, INC., MCKINSEY & COMPANY, INC., UNITED STATES, MCKINSEY, INC., WASHINGTON, D.C., and the WEST VIRGINIA BOARD OF PHARMACY, Defendants Below, Respondents.

AND

TRAVIS B., next friend and guardian of minor child Z.D.B., SCOTT O., next friend and guardian of minor child R.G.O., TAMMY B., next friend and guardian of minor children B.E.B. and S.F.B., TIMOTHY L., next friend and guardian of minor child L.C.M., STACEY H., next friend and guardian of minor child L.C.M., STACEY H., next friend and guardian of minor child N.M.B., CYNTHIA W., next friend and guardian of minor children E.G.W. and B.D.W., ANGELA W., next friend and guardian of minor children C.D.W. and C.G.W., FLORETTA A., next friend and guardian of minor child M.J.A., DIANNA B., next friend and guardian of minor children S.D.L. and H.G.L., STACEY A., next friend and guardian of minor children A.L.A. and T.L.A., THOMAS P., next friend and guardian of minor child Z.N.B., PATRICIA F., next friend and guardian of minor child A.J.F., DONNA J., next friend and guardian of minor children S.R.S., M.K.S., and J.A.S., STACY S., next friend and guardian of minor child T.K.L., and ROGER J., next friend and guardian of minor child T.K.L., and ROGER J., next friend and guardian of minor child S.A.J.,

Plaintiffs Below, Petitioners,

v.) No. 23-ICA-287

MCKESSON CORPORATION, CARDINAL HEALTH, INC., AMERISOURCEBERGEN CORPORATION, H.D. SMITH, LLC, H.D. SMITH HOLDINGS, LLC, H.D. SMITH HOLDING COMPANY, ANDA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICAL USA, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., SK CAPITAL, SK CAPITAL MANAGEMENT IV, QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC f/k/a ACTAVIS LLC, WATSON PHARMACEUTICALS, INC., n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS, LLC, ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC., AUROLIFE PHARMA, LLC, AUROBINDO PHARMA USE, INC., AUROBINDO PHARMA, RITE AID CORP, WAL-MART INC. f/k/a WALMART STORES, INC., PETERSTOWN PHARMACY, WEST VIRGINIA BOARD OF PHARMACY, BYPASS PHARMACY, INC., CVS PHARMACY, INC., CVS INDIANA LLC, CVS RX SERVICES, INC., CVS TN DISTRIBUTION LLC, WEST VIRGINIA CVS PHARMACY LLC, WALGREENS BOOTS ALLIANCE, WALGREEN EASTERN CO., WALGREEN CO., THE KROGER CO., WEST SIDE PHARMACY, INC., RIVERSIDE PHARMACY, INC., FOUR SEASONS PHARMACY, INC., BLACK DIAMOND PHARMACY, INC., BLUEWELLS FAMILY PHARMACY, INC., CRAB ORCHARD PHARMACY, INC., BECKLEY PHARMACY, INC., WELCH PHARMACY, INC. D/B/A CITIZENS DRUG STORE. WESTERN GREENBRIER PHARMACY, SUN PHARMACEUTICAL INDUSTRIES,

INC., SUN PHARMACEUTICAL INDUSTRIES, LTD., and RANBAXY LABORATORIES LTD,

Defendants Below, Respondents.

AND

TREY SPARKS, Plaintiff Below, Petitioner,

v.) No. 23-ICA-307

JOHNSON & JOHNSON, INC., JANSSEN PHARMACEUTICALS, INC., NORAMCO, MCKESSON CORPORATION, CARDINAL HEALTH, INC., H.D. SMITH, LLC, H.D. SMITH HOLDINGS, LLC, H.D. SMITH HOLDING CO., AMERISOURCEBERGEN CORPORATION, AMERISOURCEBERGEN DRUG CORPORATION, ANDA, INC., TEVA PHARMACEUTICALS USA, INC., ALLERGAN USA, INC., ALLERGAN SALES, LLC, ALLERGAN FINANCE, LLC, ABBVIE, INC., and the WEST VIRGINIA BOARD OF PHARMACY, Defendants Below, Respondents.

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Appeal from the Circuit Court of Kanawha County (Mass Litigation Panel)
Honorable Moats & Swope, Judges
Nos. 22-C-9000 NAS

AFFIRMED, IN PART, REVERSED, IN PART, VACATED, IN PART, AND REMANDED

Submitted: September 17, 2024 Filed: December 27, 2024

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CHIEF JUDGE SCARR delivered the Opinion of the Court.

SCARR, CHIEF JUDGE:

Petitioners A.D.A., A.N.C., Travis B., Scott O., Tammy B., Timothy L., Kelly M., Stacey H., Cynthia W., Debra W., Floretta A, Dianna B., Jacqueline A., Stacey A., Thomas P., Patricia F., Donna J., Brandy S., Stacy S., Roger J., and Trey Sparks (hereinafter, collectively, "Petitioners") appeal from the May 31, 2023, and June 27, 2023, orders of the Mass Litigation Panel ("MLP"), granting the collective Respondents' motions to dismiss the Petitioners' complaints for failure to state a claim under Rule 12(b)(6) of the West Virginia Rules of Civil Procedure.

Having reviewed the parties' arguments, the record on appeal, oral argument,³ and the controlling law, we affirm, in part, reverse, in part, vacate, in part, and remand these cases for further proceedings consistent with this decision. Specifically, we find that the MLP erred when it dismissed, with prejudice, Petitioners' claims against the

¹ To protect the confidentiality of the juveniles involved in this case, we refer to the parties' last names by the first initial. *See, e.g.*, W. Va. R. App. P. 40(e); *State v. Edward Charles L.*, 183 W. Va. 641, 645 n.1, 398 S.E.2d 123, 127 n.1 (1990). When these appeals were filed, some parties were named using only initials and those remain unchanged herein.

² The majority of Petitioners' individual complaints were dismissed by the MLP's May 31, 2023, order. The MLP's June 27, 2023, order addresses only the claims of Petitioner Trey Sparks.

³ This Court heard expanded Rule 20 oral argument on September 17, 2024, during ICA On Campus at Davis & Elkins College.

Pharmacy Respondents⁴ pursuant to the West Virginia Medical Professional Liability Act, W. Va. Code § 55-7B-1 to -12 (2015) ("MPLA"). Accordingly, we vacate that conclusion and remand those cases to the MLP for the entry of an order dismissing all claims against the Pharmacy Respondents without prejudice. Further, we find error in the MLP's May 31, 2023, order to the extent that it failed to meaningfully address the products liability claims brought by Petitioners and, accordingly, we reverse the MLP's dismissal of those claims. We also find error in the MLP's holding that the sole proximate cause of Petitioners' injuries was the ingestion of opioids by the birth mothers in all cases, and accordingly, vacate and remand that issue to the MLP for additional consideration, consistent with this opinion. Furthermore, we vacate the MLP's dismissal of Petitioners' claims for punitive

⁴ The Pharmacy Respondents named in one or more complaints are Rite Aid of West Virginia, Inc., Rite Aid of Maryland, Inc., CVS Indiana, LLC, CVS Rx Services, Inc., CVS TN Distribution, LLC, West Virginia CVS Pharmacy, LLC, Walgreens Boots Alliance, Inc., Walgreen Eastern Co., Walgreen Co., Wal-Mart, Inc. f/k/a Walmart Stores, Inc. ("Walmart Inc."), The Kroger Co., K-Mart Corporation, Trivillian's Pharmacy, LLC, Adkins Pharmacy, Alum Creek Pharmacy, Inc., Beckley Pharmacy, Inc., Black Diamond Pharmacy, Bluewells Family Pharmacy, Brown Bailey and Blankenship d/b/a Town Pharmacy Care, Bypass Pharmacy, Inc., Colony Drug, LLC, Crab Orchard Pharmacy, Inc., Cumberland Health Services, Inc. d/b/a Iaeger Pharmacy, Dennis' Pharmacy, Family Discount Pharmacy, Flat Iron Drug Store, Inc., Four Seasons Pharmacy, Inc., Good Family Pharmacy, Inc., Hickman's Pharmacy, Inc., Lincoln Primary Care Center Pharmacy, Loop Pharmacy, LLC, Peterstown Pharmacy, LLC, Professional Pharmacy, Inc. d/b/a Carriage Drive Pharmacy, Rhonda's Pharmacy, LLC, Riverside Pharmacy, Inc., Welch Pharmacy, Inc. d/b/a Citizen's Drug Store, Western Greenbrier Pharmacy, and Westside Pharmacy, Inc. d/b/a Renegade Pharmacy.

damages and medical monitoring and remand those issues for further consideration by the MLP consistent with this opinion. ⁵

We affirm the MLP's dismissal of Petitioners' claims relating to public nuisance, general negligence, fraud, civil conspiracy, and other intentional conduct against the Manufacturer Respondents⁶, the Distributor Respondents⁷, and the McKinsey

⁵ Although we find some error in the MLP's orders, we acknowledge the difficulty inherent in grappling with the complex legal issues presented by these twenty-one separate cases against multiple defendants, and the MLP's significant efforts in crafting detailed, substantive decisions comprised of a combined fifty-three pages.

⁶ The Manufacturer Respondents named in one or more complaints are Indivior, Inc., Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., Actavis Pharma, Inc., Actavis LLC, Johnson & Johnson, Janssen Pharmaceuticals, Inc., Noramco LLC incorrectly named as Noramco, Inc., SK Capital Partners LP, SK Capital Management IV, LP, Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., Qualitest Pharmaceuticals, Inc., Allergan Finance LLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.), Allergan USA, Inc., Allergan Sales, LLC, Hikma Pharmaceuticals, PLC, Hikma Pharmaceuticals USA Inc., KVK-Tech, Inc., Sun Pharmaceuticals Industries Limited, Sun Pharmaceutical Industries, Inc., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, LLC, Able Laboratories, Inc., Abbvie Inc., Ranbaxy Laboratories, Ltd., Ranbaxy Laboratories, Inc., Ranbaxy USA, Inc., Akorn Operating Company LLC, Akorn, Inc. n/k/a Akorn Operating Company LLC, Hi-Tech Pharmacal Co., LLC, Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC. Petitioners allege that the Manufacturer Respondents improperly marketed and misrepresented the risks and benefits of prescription opioids while also violating their legal obligations to prevent the diversion of the drugs into the stream of illicit drugs.

⁷ The Distributor Respondents named in one or more complaints are AmerisourceBergen Corporation, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., McKesson Corporation, Anda, Inc., H. D. Smith, LLC, H. D. Smith Holdings, LLC, and H. D. Smith Holding Company. Petitioners allege that the Distributor Respondents distributed massive quantities of prescription opioids in West Virginia while failing to

Respondents⁸ ("McKinsey"). Additionally, we affirm the dismissal of the West Virginia Board of Pharmacy ("BOP")⁹ and Indivior.¹⁰

I. FACTUAL AND PROCEDURAL BACKGROUND

Petitioners A.D.A., A.N.C., Travis B., Scott O., Tammy B., Timothy L., Kelly M., Stacey H., Cynthia W., Debra W., Floretta A, Dianna B., Jacqueline A., Stacey A., Thomas P., Patricia F., Donna J., Brandy S., Stacy S., and Roger J. are the parents/guardians of individual minors who allegedly suffer from the effects of Neonatal Abstinence Syndrome ("NAS") caused by exposure to opioids during their birth mothers' pregnancies. Petitioner Trey Sparks is an individual who allegedly suffers from the effects of NAS caused by exposure to opioids during his birth mother's pregnancy. Each of these Petitioners filed separate claims in the Circuit Court of Marshall County against multiple Respondents alleging various causes of action related to exposure to opioids during pregnancy, the dismissal of which forms the basis of this appeal.

adhere to their legal obligations intended to prevent the diversion of opioids into the stream of illicit drugs.

⁸ The McKinsey entities named in one or more complaints are McKinsey & Company, Inc., McKinsey & Company, Inc. United States, and McKinsey & Company, Inc. Washington D.C. Petitioners allege that McKinsey performed marketing consulting services for certain Manufacturing Respondents and contributed to the massive quantities of prescription opioids which were distributed in West Virginia.

⁹ Petitioners allege that the BOP failed to perform sufficient investigation and regulation to prevent the diversion of prescription opioids into the stream of illicit drugs.

¹⁰ Respondent Indivior is named as a Manufacturer Respondent in multiple underlying complaints.

A.D.A.

A.D.A. is the parent and legal guardian of L.R.A., born March 10, 2017. L.R.A. was born dependent on opioids due to prenatal exposure. The cord blood test administered at birth revealed that L.R.A.'s birth mother consumed oxycodone and other opioids during her pregnancy with L.R.A. It is alleged that her birth mother obtained oxycodone both legally through valid prescriptions written for her by a physician to treat migraines and back pain, and illegally, through prescriptions written for others. L.R.A. was diagnosed with NAS shortly after her birth. She spent the first weeks of her life receiving methadone treatment to control her opioid withdrawal symptoms. Petitioners contend that L.R.A. suffers permanent "developmental impacts" due to NAS and will require years of treatment and counseling to deal with the effects of prenatal exposure to opioid medications.

On December 27, 2021, A.D.A. filed the underlying complaint, alleging: (1) public nuisance; (2) negligence and recklessness (as to the Johnson & Johnson Respondents only); (3) negligence and recklessness (as to Respondent McKinsey only); (4) negligent and intentional misrepresentation (as to the Johnson & Johnson Respondents and Respondent McKinsey); (5) civil conspiracy (as to the Johnson & Johnson Respondents and Respondent McKinsey); and (6) malicious and intentional conduct (as to the BOP only).

¹¹ Civil Action No. 21-C-110 MSH.

A.<u>N.C.</u>

A.N.C. is the parent (birth mother) and legal guardian of J.J.S., born August 20, 2019, dependent on opioids from prenatal exposure. It is alleged that A.N.C. was consuming buprenorphine and other opioids during her pregnancy with J.J.S. A.N.C. allegedly obtained oxycodone both through legal prescriptions and illegally, through diversion of pills. J.J.S. was diagnosed with NAS shortly after his birth. He spent the first five days of his life in the hospital experiencing withdrawal symptoms as the doctors weaned him from opioid dependency. Petitioners contend that J.J.S. suffers permanent "developmental impacts," medical issues, and other problems requiring years of treatment and counseling as a result of opioid exposure in utero.

On August 26, 2022, A.N.C. filed her underlying complaint, ¹² alleging: (1) public nuisance; (2) negligence, gross negligence, and recklessness; (3) negligence and recklessness (as to Respondent McKinsey only); (4) negligent and intentional misrepresentation (as to Manufacturer Respondents and Respondent McKinsey); (5) civil conspiracy; (6) malicious and intentional conduct (as to Respondent BOP only); and (7) state law violations (as to Respondent BOP only).

¹² Civil Action No. 22-C-73 MSH.

Travis B.

Travis B. is the parent and legal guardian of Z.D.B., born May 29, 2017, dependent on opioids from prenatal exposure. Z.D.B.'s birth mother was allegedly prescribed opioids in 2005 and again in 2011 and became addicted prior to Z.D.B.'s gestation. It is alleged that she continued to consume opioids during the fourth month of pregnancy with Z.D.B., at which time she switched to methadone. Z.D.B. was born prematurely at thirty-four weeks gestation, diagnosed with NAS, and was admitted to the neonatal intensive care unit ("NICU") for detoxification and withdrawal, feeding issues, and respiratory distress. He remained on methadone treatment for the first month of life. It is alleged that Z.D.B. suffers from continued medical issues related to his in utero opioid exposure, including, but not limited to, severe cognitive and developmental delays, and recurring ear and upper respiratory infections.

On June 14, 2022, Travis B. filed his underlying complaint, ¹³ alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief for medical monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP only); and (7) punitive damages.

¹³ Civil Action No. 22-C-5 MSH.

Scott O.

Scott O. is the parent and legal guardian of minor child R.G.O., born February 20, 2019, dependent on opioids. It is alleged that R.G.O.'s birth mother was treated with opioids manufactured and distributed by one or more of the named Respondents for chronic back pain and became addicted prior to R.G.O.'s gestation. She continued to consume opioids until she was approximately four months pregnant with R.G.O. and switched to Subutex, which she used daily during pregnancy. R.G.O. was diagnosed with NAS and required care in the NICU for twenty-eight days for detoxification and withdrawal. She was later transferred to Lily's Place for long-term care beyond four weeks of life. She required methadone therapy and phenobarbital treatment and it is alleged that she suffers from medical issues due to in utero opioid exposure including, but not limited to, significant NAS symptoms, cognitive and developmental delays.

Scott O. filed his underlying complaint,¹⁴ alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief for medical monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP only); and (7) punitive damages.

¹⁴ Civil Action No. 22-C-20 MSH.

Tammy B.

Tammy B. is the grandparent and legal guardian of minor children B.E.B., born March 9, 2013, and S.F.B., born July 15, 2014, both of whom were born dependent on opioids and diagnosed with NAS. It is alleged that their birth mother was treated with prescribed opioids manufactured and distributed by one or more of the named Respondents for pain resulting from a vehicle collision in 2011. Her addiction allegedly began prior to B.E.B. and S.F.B.'s gestation and she continued to consume opioids during both pregnancies. S.F.B. required twenty-six days of inpatient care for withdrawal symptoms, feeding issues, respiratory distress, and administration of morphine. Both children suffered significant NAS symptoms at birth, recurring ear and upper respiratory infections, feeding problems, and tremors.

Tammy B. filed her underlying complaint,¹⁵ alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief for medical monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP only); and (7) punitive damages.

Timothy L.

Timothy L. is the parent and legal guardian of M.D.L., born December 21, 2010, and T.J.L., born October 3, 2003, both of whom were born dependent on opioids. It

¹⁵ Civil Action No. 22-C-21 MSH.

is alleged that their birth mother was treated with prescribed opioids manufactured and distributed by one or more of the named Respondents for pain resulting from an injury sustained in a motor vehicle collision in the early 2000's. Her addiction allegedly began prior to both babies' gestation and she continued to consume opioids throughout both pregnancies. Both babies were diagnosed with NAS and were delivered prematurely. T.J.L. required twenty-six days of inpatient methadone therapy. Petitioners contend that M.D.L. and T.J.L. suffered additional medical issues as a result of in utero opioid exposure, including, but not limited to, vision problems, learning disabilities, attention deficit hyperactivity disorder ("ADHD"), and a left elbow deformity.

Timothy L. filed his underlying complaint,¹⁶ alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief for medical monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP); and (7) punitive damages.

Kelly M.

Kelly M. is the parent (birth mother) and legal guardian of minor child L.C.M., born May 26, 2016, dependent on opioids. Kelly M. alleges she was treated with prescribed opioids manufactured and distributed by one or more of the named Respondents for pain resulting from a 2005 leg injury. Her addiction allegedly began prior to L.C.M.'s

¹⁶ Civil Action No. 22-C-22 MSH.

gestation and she continued to consume opioids throughout her pregnancy. She used buprenorphine daily during her last trimester. L.C.M. was diagnosed with NAS and required care in the NICU. It is alleged that L.C.M. suffers from ongoing medical issues as a result of his in utero opioid exposure including, but not limited to, jitteriness, recurring ear and upper respiratory infections, hearing loss, autism, and developmental delays which required an Individual Educational Plan ("IEP") for school.

Kelly M. filed her complaint,¹⁷ alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief for medical monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP); and (7) punitive damages.

Stacey H.

Stacey H. is the parent (birth mother) and legal guardian of minor child N.M.B., born May 6, 2016, dependent on opioids. Stacey H. alleges she was treated with prescribed opioids manufactured and distributed by one or more of the named Respondents for dental issues, Graves' Disease, and rheumatoid arthritis. Her addiction allegedly began prior to N.M.B.'s gestation and she continued use of buprenorphine daily during pregnancy. N.M.B. was delivered prematurely, then diagnosed with NAS, and required thirty-nine days of inpatient care in the NICU for detoxification and withdrawal and five

¹⁷ Civil Action No. 22-C-23 MSH.

weeks of methadone therapy. It is alleged that N.M.B. suffers from medical issues resulting from in utero exposure to opioids including, but not limited to, recurring ear and upper respiratory infections, feeding and swallowing issues, ADHD, and sensory issues requiring an IEP.

Stacey H. filed her underlying complaint, ¹⁸ alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief for medical monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP); and (7) punitive damages.

Cynthia W.

Cynthia W. is the parent (birth mother) and legal guardian of minor children E.G.W., born November 14, 2012, and B.D.W., born October 27, 2003, both of whom were born dependent on opioids. Cynthia W. alleges she was treated with prescribed opioids manufactured and distributed by one or more Respondents starting in 2003 for chronic pain resulting from her work as a paramedic. Her addiction allegedly began prior to the children's gestations, and she continued to consume opioids until her second month of pregnancy with E.G.W., when she allegedly switched to buprenorphine treatment. Both E.G.W. and B.D.W. were born prematurely and diagnosed with NAS. It is alleged that both children suffer from medical issues as a result of their in utero exposure to opioids

¹⁸ Civil Action No. 22-C-24 MSH.

including, but not limited to, low birth weight, feeding problems, acid reflux, poor weight gain, recurring ear and upper respiratory infections, heart murmur, developmental delays, and ADHD.

Cynthia W. filed her underlying complaint, ¹⁹ alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief for medical monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP only); and (7) punitive damages.

Debra W.

Debra W. is the grandparent and legal guardian of minor children C.D.W., born September 1, 2009, and C.G.W., born December 9, 2012, both of whom were born dependent on opioids. It is alleged that their birth mother was treated with prescribed opioids manufactured and distributed by one or more of the Respondents for sciatica in 2001. Her addiction allegedly began prior to both children's gestations, and she consumed opioids throughout both pregnancies. Both children were diagnosed with NAS and required care in the NICU for detoxification and withdrawal. C.D.W. required ten days of inpatient care and three months of phenobarbital treatment. C.G.W. required five days of inpatient care with morphine and two months of methadone treatment. It is alleged that both children suffer from health problems as a result of their in utero opioid exposure, including, but not

¹⁹ Civil Action No. 22-C-25 MSH.

limited to, developmental and cognitive delays, disruptive behavior disorder, depression, anxiety, ADHD, oppositional defiant disorder ("ODD"), IEP for education, hypertonia requiring leg braces before two years of age, eye alignment issues, and other vision issues.

Debra W. filed the underlying complaint,²⁰ alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief for medical monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP only); and (7) punitive damages.

Floretta A.

Floretta A. is the grandparent and legal guardian of minor child M.J.A., born June 12, 2004, dependent on opioids. It is alleged that M.J.A.'s birth mother was prescribed opioids manufactured and distributed by one or more of the named Respondents for pain resulting from an injury in 2003. Her addiction allegedly began prior to M.J.A.'s gestation. It is alleged that M.J.A. suffers from health problems as a result of the in utero exposure to opioids, including, but not limited to recurring ear infections, asthma, heart murmur, behavioral issues, anxiety disorder, ADHD, syncope, and personality disorder.

²⁰ Civil Action No. 22-C-26 MSH, which was filed by Debra W. However, for reasons not apparent to this Court, the MLP's May 31, 2023, order captions this case as "Angela W." as next friend and guardian of C.D.W. and C.G.W.

Floretta A. filed her underlying complaint²¹ alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief for medical monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP only); and (7) punitive damages.

Dianna B.

Dianna B. is the grandparent and legal guardian of minor child W.A.R., born April 22, 2012, dependent on opioids. It is alleged that his birth mother was prescribed Oxycodone for pain due to injuries sustained in a motor vehicle collision in 2011. Her addiction allegedly began prior to W.A.R.'s gestation and she continued to consume opioids throughout pregnancy. W.A.R. was diagnosed with NAS and required treatment in NICU for detoxification and withdrawal and two months of methadone treatment. He allegedly suffers from medical issues as a result of his in utero opioid exposure including, but not limited to, asthma, recurring ear and upper respiratory infections, adjustment disorder, anxiety disorder, and ADHD requiring an IEP for school.

Dianna B. filed her underlying complaint,²² alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief

²¹ Civil Action No. 22-C-27 MSH.

²² Civil Action No. 22-C-28 MSH.

for medical monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP only); and (7) punitive damages.

Jacqueline A.

Jacqueline A. is the grandparent and legal guardian of minor children S.D.L., born October 11, 2016, and H.G.L., born May 16, 2018, both of whom were born dependent on opioids. It is alleged that their birth mother was treated with prescribed opioids manufactured and distributed by one or more of the named Respondents for pain resulting from multiple dental procedures. Her addiction to opioids allegedly began prior to the children's gestations and she was allegedly prescribed Subutex upon discovering her pregnancies. Both S.D.L. and H.G.L. were diagnosed with NAS and required treatment in the NICU for detoxification and withdrawal. S.D.L. required nineteen days of inpatient care with morphine for weaning and H.G.L. required seventeen days of inpatient care with methadone therapy. It is alleged that both S.D.L. and H.G.L. suffer medical issues as a result of their in utero opioid exposure, including, but not limited to, insomnia, behavioral issues, and developmental delays.

Jacqueline A. filed her underlying complaint,²³ alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief

²³ Civil Action No. 22-C-29 MSH.

for medical monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP only); and (7) punitive damages.

Stacey A.

Stacey A. is the parent (birth mother) and legal guardian of minors A.L.A., born January 18, 2005, and T.L.A., born October 27, 2020, both of whom were born dependent on opioids. Stacey A. alleges that she was treated with prescribed opioids manufactured and distributed by one or more of the named Respondents for chronic thoracic back pain, migraines, and carpal tunnel syndrome, by her primary care physician. Her addiction allegedly began prior to the children's gestations and she continued to consume opioids throughout her pregnancies, including the use of methadone during A.L.A.'s gestation and buprenorphine during T.L.A.'s gestation. Both children were diagnosed with NAS and required care in the NICU for detoxification and withdrawal. It is alleged that A.L.A. and T.L.A. suffer medical issues as a result of their in utero opioid exposure, including, but not limited to, asthma, developmental and learning delays, cardiomegaly, astigmatism, and headaches.

Stacey A. filed her underlying complaint,²⁴ alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief for medical

²⁴ Civil Action No. 22-C-30 MSH.

monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP); and (7) punitive damages.

Thomas P.

Thomas P. is the grandparent and legal guardian of Z.N.B., born December 14, 2018, dependent on opioids. It is alleged that Z.N.B.'s birth mother was treated with prescribed opioids manufactured and distributed by one or more of the named Respondents for dental work in 2004. Her addiction allegedly began prior to Z.N.B.'s gestation and she continued to consume opioids throughout her pregnancy. Z.N.B. was diagnosed with NAS and required care in the NICU for detoxication and withdrawal, including morphine therapy and twenty-seven days of inpatient care. He allegedly suffers from medical problems as a result of his in utero opioid exposure, including, but not limited to, delayed maturation of left femoral head and tibial torsion causing limp, growth and developmental delay, speech delay resulting in the need for sign language, sleep disorder requiring medication, sensory disorder, behavioral issues, and ADHD.

Thomas P. filed his underlying complaint,²⁵ alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief for medical monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP only); and (7) punitive damages.

²⁵ Civil Action No. 22-C-31 MSH.

Patricia F.

Patricia F. is the grandparent and legal guardian of minor child A.J.F., born June 3, 2015, dependent on opioids and diagnosed with NAS. It is alleged that A.J.F.'s birth mother was treated with prescribed opioids manufactured and distributed by one or more of the named Respondents for chronic pain resulting from a motor vehicle collision in 2005. Her addiction allegedly started prior to A.J.F.'s gestation and she consumed buprenorphine throughout her pregnancy. A.J.F. was diagnosed with NAS and required care in the NICU and morphine therapy for detoxification and withdrawal. She allegedly suffers from medical issues as a result of her in utero exposure to opioids including, but not limited to, feeding problems and failure to thrive, recurring ear and upper respiratory infections, and behavioral and emotional disorders.

Patricia F. filed her underlying complaint,²⁶ alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief for medical monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP only); and (7) punitive damages.

Donna J.

Donna J. is the grandparent and legal guardian of minor L.M.J., born July 31, 2012, dependent on opioids. It is alleged that L.M.J.'s birth mother was treated with

²⁶ Civil Action No. 22-C-32 MSH.

prescribed opioids manufactured and distributed by one or more of the named Respondents for back injuries sustained in a motor vehicle collision in 2011. Her addiction allegedly began prior to gestation, and she continued to consume opioids throughout her pregnancy. L.M.J. was diagnosed with NAS and required care in the NICU for detoxification and withdrawal, including morphine and methadone therapies for the first six months of life. He allegedly suffers from medical problems as a result of his in utero opioid exposure including, but not limited to, allergies and skin rash, severe cognitive and developmental delays, ADHD, ODD, and autism.

Donna J. filed her underlying complaint,²⁷ alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief for medical monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP only); and (7) punitive damages.

Brandy S.

Brandy S. is the parent (birth mother) and legal guardian of minor children S.R.S., born April 5, 2007, M.K.S., born June 26, 2009, and J.A.S., born August 17, 2002, who were all born dependent on opioids. Brandy S. alleges she was first treated with prescribed opioids manufactured and distributed by one or more of the named Respondents for dental problems and procedures. Her addiction allegedly began prior to her gestation of

²⁷ Civil Action No. 22-C-33 MSH.

the three children, and she continued to consume prescribed opioids daily during her pregnancies. The children were all diagnosed with NAS. S.R.S. required forty-five days of inpatient care, methadone therapy, and outpatient physical therapy. M.K.S. required fifteen days of inpatient care and methadone therapy. It is alleged that S.R.S., M.K.S., and J.A.S. suffer from health problems as a result of their in utero opioid exposure including, but not limited to, vomiting, gastroesophageal reflux disease, behavioral problems, depression, learning delays, cognitive delays, speech delays, and vision issues.

Brandy S. filed her underlying complaint,²⁸ alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief for medical monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP only); and (7) punitive damages.

Stacy S.

Stacy S. is the parent (birth mother) and legal guardian of minor child T.K.L., born November 24, 2008, dependent on opioids. Stacy S. alleges she was treated with prescribed opioids manufactured and distributed by one or more of the named Respondents due to injuries sustained in an accident resulting in chronic pain in 2001. Her addiction allegedly began prior to T.K.L.'s gestation and she continued to consume opioids throughout her pregnancy. T.K.L. was diagnosed with NAS and required care in the NICU

²⁸ Civil Action No. 22-C-34 MSH.

for detoxification and withdrawal, including methadone therapy. It is alleged that he suffers from health problems as a result of his in utero opioid exposure, including, but not limited to, recurring skin rash, respiratory infections, sleep disturbances, ADHD, and ODD.

Stacy S. filed her underlying complaint,²⁹ alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief for medical monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP only); and (7) punitive damages.

Roger J.

Roger J. is the cousin and legal guardian of minor child S.A.J., born May 30, 2008, dependent on opioids. It is alleged that S.A.J.'s birth mother was treated with prescribed opioids manufactured and distributed by one or more of the named Respondents due to pain resulting from an accident. Her addiction allegedly began prior to S.A.J.'s gestation and she continued to consume opioids throughout her pregnancy. S.A.J. was diagnosed with NAS and required care in the NICU for detoxification and withdrawal. He allegedly suffers from medical issues as a result of his in utero opioid exposure, including, but not limited to developmental feeding disorder, recurring ear and upper respiratory infections, asthma, eczema, speech articulation disorder, and anxiety and panic disorder.

²⁹ Civil Action No. 22-C-35 MSH.

Roger J. filed his underlying complaint,³⁰ alleging: (1) fraud; (2) negligence and gross negligence; (3) civil conspiracy; (4) injunctive and equitable relief for medical monitoring and continuing treatment; (5) products liability; (6) state law violations (as to Respondent BOP only); and (7) punitive damages.

Trey Sparks

Trey Sparks is an individual who allegedly suffers from the effects of NAS caused by exposure to opioids during his birth mother's pregnancy. Mr. Sparks' birth mother allegedly used Oxycontin throughout her pregnancy and was using methadone at the time of his birth. Mr. Sparks' birth mother obtained oxycodone pills through both legal and illegal means. Mr. Sparks was diagnosed as suffering from NAS within hours after his birth and was immediately given methadone to attempt to ameliorate his suffering from opioid withdrawal. He continued to receive methadone treatment for the first months of his life to control the withdrawal symptoms. Throughout his life, Mr. Sparks has required multiple cardiac surgeries with complications that require daily medications. Now, as an adult, Mr. Sparks alleges that he suffers permanent learning and "developmental impacts" and will continue to require years of treatment and counseling to deal with the effects of prenatal opioid exposure.

³⁰ Civil Action No. 22-C-36 MSH.

On February 17, 2023, Mr. Sparks filed his underlying complaint,³¹ alleging: (1) public nuisance; (2) negligence, gross negligence, and recklessness; (3) negligent and intentional misrepresentation (as to the Manufacturer Respondents); (4) civil conspiracy; (5) malicious and intentional conduct (as to Respondent BOP only); and (6) state law violations (as to Respondent BOP only).

Procedural History

These twenty-one separate cases were transferred to the Mass Litigation Panel on August 9, 2022. Respondents filed motions to dismiss under Rule 12(b)(6) of the West Virginia Rules of Civil Procedure. The MLP entered a briefing schedule and held an omnibus hearing on the pending motions on March 24, 2023. On April 17, 2023, the MLP entered a preliminary order opining that all the pending cases should be summarily dismissed. On May 31, 2023, the MLP entered an order as to A.D.A., A.N.C., Travis B., Scott O., Tammy B., Timothy L., Kelly M., Stacey H., Cynthia W., Debra W., Floretta A., Dianna B., Jacqueline A., Stacey A., Thomas P., Patricia F., Donna J., Brandy S., Stacy S., and Roger J. which granted Respondents' motions to dismiss. On June 27, 2023, a similarly worded order was entered dismissing Mr. Sparks' complaint.

In the May 31, 2023, and June 27, 2023, orders, the MLP dismissed all of Petitioners' claims with prejudice, citing multiple rationales. First, the MLP concluded that

³¹ Civil Action No. 23-C-14 MSH.

Petitioners did not have standing to bring public nuisance claims. The MLP reasoned that, pursuant to West Virginia law, public nuisance actions are generally the duty of public officials to bring on behalf of the public, unless a private citizen can establish a "special injury" that cannot be fully compensated in an action at law. Thus, the MLP concluded that Petitioners, acting as private citizens, lacked standing to bring a public nuisance claim absent showing "an injury different from that inflicted upon the public in general, not only in degree, but in character[,]" a standard that Petitioners did not meet. Further, the MLP noted that public nuisance claims related to NAS had already been pursued by the State of West Virginia and various West Virginia cities and counties, and those claims were resolved by settlement. The approved settlement provided funds for the treatment and medical monitoring of children born with NAS.

Next, the MLP found that Petitioners A.D.A., A.N.C., Travis B., Scott O., Tammy B., Timothy L., Kelly M., Stacey H., Cynthia W., Debra W., Floretta A., Dianna B., Jacqueline A., Stacey A., Thomas P., Patricia F., Donna J., Brandy S., Stacy S., and Roger J. failed to satisfy the pre-suit notice requirements under the MPLA, which necessitated the dismissal of their claims against the Pharmacy Respondents. The MLP concluded that the MPLA applied to these claims as pharmacists are "health care providers" under the MPLA, the claims are "medical professional liability actions" per the MPLA, and Petitioners were "person[s]" subject to the MPLA, whether or not they were also "patients." W. Va. Code § 55-7B-2(g), -2(i), -6(a), and -9b. Accordingly, the MLP

held that the named Petitioners' failure to follow the pre-suit requirements was a jurisdictional bar to their claims against the Pharmacy Respondents.

The MLP also concluded that dismissal of Petitioners' underlying claims was appropriate because Petitioners could not establish that a duty of care was owed to the minor children by any of the Respondents, which was fatal to the Petitioners' negligence-based claims. While the MLP previously held that manufacturers and distributors of prescription opioids and pharmacies that self-distribute and dispense prescription opioids owed certain duties of care to government entities in the State of West Virginia, that same rationale could not be applied to individual private Petitioners because it would stretch the concept of duty of care too far. Although the MLP primarily analyzed this issue in the context of Petitioners' allegations of general negligence based on Respondents' alleged conduct, it also determined that its finding of a lack of duty was sufficient to dispose of Petitioners' negligence-based products liability claims based on design defect and failure to warn.

As to proximate cause, the MLP determined that Petitioners could not establish any of their alleged injuries were proximately caused by any conduct of any Respondent. The MLP further determined that pursuant to West Virginia precedent, the alleged injuries were too remote, and that foreseeability of injury alone was not sufficient to establish proximate causation. The lack of remoteness is a separate and distinct element of proximate causation under West Virginia law, and if a Respondent's conduct is too

removed from the alleged harm, it cannot be the proximate cause of the injury. The MLP found that Respondents' alleged conduct was "multiple steps" removed from Petitioners' claimed injuries, which Petitioners acknowledge occurred only after (1) physicians prescribed opioids to birth mothers while they were pregnant; (2) third parties provided illegally obtained opioids to those birth mothers; and/or (3) birth mothers ingested opioids during their pregnancies. Accordingly, the MLP reasoned that establishing proximate cause under the facts herein was defeated by the numerous independent actions of multiple actors over whom Respondents had no control. The MLP concluded that the allegations in the Petitioners' underlying complaints established that the conduct of the birth mothers was the sole proximate cause of the alleged injuries.

As to Petitioners' claims against Respondent Indivior independently, the MLP dismissed said claims, noting that Indivior is the manufacturer of Suboxone and Subutex, buprenorphine medications manufactured, marketed, and used for the treatment of opioid use disorder ("OUD"), not as an opioid prescribed for pain. The MLP concluded that Petitioners' claims against the other Manufacturer Respondents could not be applied to Indivior and there were not sufficient facts alleged to support a reasonable inference that the children's alleged injuries were proximately caused by their birth mothers' use of any Indivior product during their pregnancies.

Next, the MLP dismissed all causes of action alleged by Petitioners pertaining to fraud, civil conspiracy, medical monitoring, and punitive damages. The MLP

concluded that there was not a sufficient showing of proximate causation for the tort claims of fraud, and that the civil conspiracy, medical monitoring, and punitive damages claims were derivative claims that could not survive after the dismissal of Petitioners' underlying tort claims.

Finally, the MLP dismissed Petitioners' claims against Respondent BOP, finding that those claims were barred by the public duty doctrine and by qualified and absolute immunity. Under the public duty doctrine, a governmental entity's liability for certain functions may not be predicated upon the breach of a general duty owed to the public as a whole; instead, only the breach of a duty owed to the particular person is actionable. The only exception to the doctrine is where a special relationship exists such that a state agency could be said to have assumed a special duty to the individual Petitioner. The MLP determined that Petitioners failed to allege that such a special relationship existed. Further, the MLP concluded that Respondent BOP was entitled to qualified and absolute immunity, primarily because Petitioners failed to plead specific facts in their underlying complaints to support their allegations that Respondent BOP violated its regulatory and statutory duties, and that the conclusory statements alleged in Petitioners' underlying complaints were insufficient to avoid dismissal.

On June 27, 2023, the MLP entered an order dismissing Petitioner Trey Sparks' claims against Respondent BOP, Distributor Defendants, and Manufacturer Defendants, with prejudice. Specifically, the MLP concluded that Mr. Sparks cannot

establish standing to bring a public nuisance claim; cannot establish that Respondents owed him a duty of care; his allegations establish that, as a matter of law, the Respondents' conduct is too remote from his alleged injuries to establish proximate causation; his allegations establish that, as a matter of law, his birth mother's conduct is necessarily the sole proximate cause of his alleged injuries; accordingly, his allegations of negligent and intentional misrepresentation and conspiracy should be dismissed; and Respondent BOP was entitled to dismissal under the public duty doctrine and qualified and absolute immunity.

Following the entry of the May 31, 2023, and June 27, 2023, orders dismissing Petitioners' underlying claims, with prejudice, Petitioners filed the instant appeals. This Court entered orders on November 22, 2023, and July 12, 2024, consolidating the cases for briefing and argument.³²

³² Claims of eleven petitioners (Travis B. – Civil Action No. 22-C-5 MSH; Tammy B. – Civil Action No. 22-C-21 MSH; Timothy L. – Civil Action No. 22-C-22 MSH; Kelly M. – Civil Action No. 22-C-23 MSH; Stacey H. – Civil Action No. 22-C-24 MSH; Dianna B. – Civil Action No. 22-C-28 MSH; Stacey A. – Civil Action No. 22-C-30 MSH; Thomas P. – Civil Action No. 22-C-31 MSH; Donna J. – Civil Action No. 22-C-33 MSH; Brandy S. – Civil Action No. 22-C-34 MSH; and Stacey S. – Civil Action No. 22-C-35 MSH) against Respondents Rite Aid of West Virginia, Inc., and Rite Aid of Maryland, Inc., who are undergoing federal bankruptcy proceedings, were severed from 23-ICA-287 by order entered April 16, 2024. Those claims are now docketed as 24-ICA-164 and are not presently before this Court.

II. STANDARD OF REVIEW

Our review of an order granting a motion to dismiss is *de novo*. Syl. Pt. 2, *State ex rel. McGraw v. Scott Runyan Pontiac-Buick, Inc.*, 194 W. Va. 770, 461 S.E.2d 516 (1995) ("Appellate review of a circuit court's order granting a motion to dismiss . . . is *de novo*."). "Generally, findings of fact are reviewed for clear error and conclusions of law are reviewed *de novo*." Syl. Pt. 1, *State ex rel. Cooper v. Caperton*, 196 W. Va. 208, 470 S.E.2d 162 (1996). With this standard in mind, we address Petitioners' arguments on appeal.

III. DISCUSSION

Before this Court, Petitioners collectively assert thirteen assignments of error. Petitioners A.D.A., A.N.C., and Mr. Sparks filed a joint appellate brief that alleged nine assignments of error. The remaining Petitioners filed a joint appellate brief, arguing seven of the same assignments of error in the A.D.A., A.N.C., and Sparks brief, and raising three new issues. We have combined the assignments of error that are duplicative and will address the assignments out of order to group like claims together for efficient organization and disposition. *See generally Tudor's Biscuit World of Am. v. Critchley*, 229 W. Va. 396, 402, 729 S.E.2d 231, 237 (2012) (per curiam) (allowing consolidation of related assignments of error).

MPLA Claims

Petitioners argue that the MLP erred in its May 31, 2023, order when it concluded that Petitioners' claims against the Pharmacy Respondents were barred, as Petitioners failed to satisfy the jurisdictional pre-suit requirements of the MPLA. While we agree that Petitioners' claims against the Pharmacy Respondents were properly dismissed, we find error in the MLP's dismissal of these claims with prejudice. Instead, as supported by West Virginia precedent, such claims should have been dismissed without prejudice. ³³

We begin by analyzing the propriety of the MLP's conclusion that Petitioners' claims against the Pharmacy Respondents triggered the MPLA's pre-suit requirements. We find no error in the MLP's determination that such claims are MPLA

theories. The SCAWV has held that "the West Virginia Legislature's definition of medical professional liability . . . includes liability for damages resulting from the death or injury of a person for *any* tort based upon health care services rendered or which should have been rendered." Syl. Pt. 4, in part, *Gray v. Mena*, 218 W. Va. 564, 625 S.E.2d 326 (2005). Moreover, "medical professional liability" also includes "other claims that may be contemporaneous to or related to the alleged tort or breach of contract or otherwise provided, all in the context of rendering health care services." W. Va. Code § 55-7B-2 (2022). As reflected in the Respondents' brief and the Petitioners' Reply brief filed in 23-ICA-287, the parties now agree that all claims against the Pharmacy Respondents are subject to the MPLA.

claims³⁴ and, thus, any such claims must be filed pursuant to the pre-suit notice requirements in West Virginia Code § 55-7B-6(b). The MPLA prohibits any person from

fil[ing] a medical professional liability action against any health care provider unless, at least thirty days prior to the filing of the action, he or she has served, by certified mail, return receipt requested, a notice of claim on each health care provider the claimant will join in the litigation.

Syl. Pt. 4, *State ex rel. PrimeCare Med. of W. Va. v. Faircloth*, 242 W. Va. 335, 835 S.E.2d 579 (2019); W. Va. Code § 55-7B-6(a), (b). The pre-suit notice requirements of the MPLA "are jurisdictional, and failure to provide such notice deprives a circuit court of subject matter jurisdiction." *Faircloth*, 242 W. Va. at 337, 835 S.E.2d 581, Syl. Pt. 2, in part. Because Petitioners failed to provide the mandatory pre-suit notice, the MLP lacked subject matter jurisdiction over Petitioners' MPLA claims. Accordingly, we find no error in the MLP's dismissal of said claims.

However, we conclude that the MLP erred in dismissing Petitioners' MPLA claims with prejudice. In West Virginia, "a dismissal for lack of jurisdiction is not considered an 'adjudication on the merits' and is therefore generally a dismissal without prejudice." *Tanner v. Raybuck*, 246 W. Va. 361, 368, 873 S.E.2d 892, 899 (2022). Although a circuit court may order dismissal with prejudice if a plaintiff fails to comply

³⁴ As pled in the underlying complaints, the Pharmacy Respondents are "health care provider[s]" as defined by the MPLA. That term includes both "pharmacist[s]" and "health care facilit[ies]." Moreover, the term "health care facility" is defined to include "pharmac[ies]." W. Va. Code § 55-7B-2(g) and -2(f).

with the MPLA's pre-suit notice requirements, dismissals without prejudice are generally favored in such cases. *Id.* at 369, 873 S.E.2d at 900 (citing *Pendleton v. Wexford Health Sources, Inc.*, No. 15-0014, 2015 WL 8232155 (W. Va. Dec. 7, 2015) (memorandum decision)); *Davis v. Mound View Health Care, Inc.*, 220 W. Va. 28, 32, 640 S.E.2d 91, 95 (2006).

Moreover, after determining it did not have subject matter jurisdiction over the MPLA claims, the MLP should have taken "no further action in the case other than to dismiss it from the docket." Syl. Pt. 1, in part, *Hinkle v. Bauer Lumber & Home Bldg. Ctr., Inc.*, 158 W. Va. 492, 211 S.E.2d 705 (1975). Instead, the MLP continued to analyze all claims made in Petitioners' underlying complaints and concluded in a summary fashion that all the claims, including the MPLA claims, were dismissed "with prejudice." Because the May 31, 2023, order does not expressly state the MLP's basis for dismissal of the MPLA claims with prejudice, we are led to conclude that the decision was inextricably bound with and impermissibly influenced by the MLP's decision to dismiss Petitioners' other claims with prejudice.

Accordingly, we affirm the MLP's May 31, 2023, order to the extent that it dismisses the claims against the Pharmacy Respondents, but we vacate the order to the

extent that the dismissal was made with prejudice and remand this matter to the MLP with instructions that these claims be dismissed without prejudice. ³⁵

Public Nuisance Claims

Next, we turn to Petitioners' assertion that the MLP erred when it determined that the Petitioners could not establish standing to bring their underlying public nuisance claims. Under West Virginia law, a public nuisance has been defined as "an act or condition that unlawfully operates to hurt or inconvenience an indefinite number of persons. The distinction between a public nuisance and a private nuisance is that the former affects the general public, and the latter injures one person or a limited number of persons only." Hark v. Mountain Fork Lumber Co., 127 W. Va. 586, 595-96, 34 S.E.2d 348, 354 (1945). Importantly, the Supreme Court of Appeals of West Virginia ("SCAWV") has expressed limitations on the propriety of private individuals maintaining suits for public nuisances. "Ordinarily, a suit to abate a public nuisance cannot be maintained by an individual in his private capacity, as it is the duty of the proper public officials to vindicate the rights of the public." Sharon Steel Corp. v. City of Fairmont, 175 W. Va. 479, 483, 334 S.E.2d 616, 620 (1985) (quoting *Hark*, 127 W. Va. at 596, 34 S.E.2d at 354). Under this standard, a private litigant must establish a "special injury . . . which cannot be fully compensated in an action

³⁵ Because jurisdiction was not established, the other rulings in the MLP's May 31, 2023, order do not apply to the Pharmacy Respondents. However, we acknowledge that the MLP's valid analysis and rationale for dismissing Petitioners' other discrete claims may ultimately apply to the Pharmacy Respondents, as well, following remand.

at law" in order to maintain a suit for public nuisance. *Hark*, 127 W. Va. at 596, 34 S.E.2d at 354; *see also Keystone Bridge Co. v. Summers*, 13 W. Va. 476 (1878). Stated another way, Petitioners acting in their capacity as private citizens lack standing to pursue a public nuisance claim absent a showing of "an injury different from that inflicted upon the public in general, not only in degree, but in character." *Int'l Shoe Co. v. Heatwole*, 126 W. Va. 888, ____, 30 S.E.2d 537, 540 (1944). Petitioners argue herein that their personal injury claims satisfy this "special injury" requirement and that the MLP failed to recognize the type of developmental injuries suffered by the Petitioners who are minor children qualify as "special." We disagree.

Petitioners have not adequately pleaded "special injuries" to satisfy this standing requirement. Their alleged injuries, including symptoms and sequelae of NAS arising from in utero exposure to opioids, are not sufficiently different from those suffered by the general public exposed to opioids, or other infants exposed in utero to opioids, in both "degree" and "character." Similarly, we find that these claims are not sufficiently unique as even Petitioners acknowledge that "thousands of children born every year" are "born addicted to opioids." *See* Joint Appendix at 04589. Moreover, although these causes of action make broad generalized allegations of the existence of a public nuisance, Petitioners seek compensation for the private rights of the alleged affected individuals

rather than abatement of the nuisance in the public's interest. ³⁶ Abatement, an equitable form of relief, is the "act of eliminating or nullifying" the public nuisance. *See* Bryan A. Garner, Black's Law Dictionary (11th ed. 2019). As noted above, several West Virginia state, county, and municipal entities have already brought such cases against opioid

In No. 24-166, the county and municipal plaintiffs filed suit against three distributors of opioids for their role in creating the opioid epidemic by repeatedly shipping large quantities of opioids to pharmacies that the distributors knew or should have known exceeded any legitimate market for the medications. Those plaintiffs asserted that conduct resulted in a public nuisance subject to abatement, including the creation of a proposed fund to redress the harm suffered by the public interest. We clarify that our ruling makes no finding or conclusion as to whether the opioid epidemic itself may validly constitute a public nuisance under West Virginia law. Furthermore, if the SCAWV answers the Certified Question affirmatively and finds that the county and municipality's public nuisance claim is valid, such a determination may not constitute an automatic validation of the public nuisance claims before this Court based on the distinguishing facts and allegations in each case.

We also note the recent decision by the Supreme Court of Ohio in answering a Certified Question submitted by the United States Court of Appeals for the Sixth Circuit, which raised the issue of whether all common-law public nuisance claims arising from the sale of a product have been abrogated by the Ohio Product Liability Act, R.C. 2307.71 et seq. ("OPLA"). In *In re Natl. Prescription Opiate Litigation,* Slip Opinion No. 2024-Ohio-5744, decided December 10, 2024, the Ohio Supreme Court answered affirmatively, holding that OPLA abrogates all common law product liability claims or causes of action, including the public nuisance claims made therein by two Ohio counties against national pharmaceutical chains for their alleged roles in perpetuating the opioid epidemic. As the determination was made by applying Ohio statutory law, it does not affect this Court's decision herein.

³⁶ We are aware that SCAWV has docketed and set for oral argument a Certified Question from the United States Court of Appeals for the Fourth Circuit on the issue of whether, under West Virginia's common law, conditions caused by the distribution of a controlled substance can constitute a public nuisance and, if so, what are the elements of such a public nuisance claim. *City of Huntington and Cabell County Comm'n v. AmerisourceBergen Drug Corporation, et al.*, No. 24-166. It is not clear that the resolution of the Certified Question will be relevant to the instant case, as the claims before the SCAWV are arguably distinguishable from those present here.

manufacturers and settled those claims.³⁷ In the instant case, Petitioners before us seek to recover monetary damages to redress their personal injuries, when they are a select few of many thousands of similarly situated potential claimants. To permit such an action to continue as a public nuisance case is simply contrary to the very purpose of the public nuisance cause of action. Accordingly, we affirm the MLP's dismissal of the Petitioners' claims for public nuisance, as Petitioners cannot establish the necessary "special injury" to meet the standing requirement.

Further, we are not persuaded by Petitioners' argument that the MLP erred in concluding that the public nuisance claims were already resolved through the settlement of previous public nuisance claims brought by political subdivisions. In its May 31, 2023, order, the MLP observed:

Moreover, claims of public nuisance involving NAS have already been resolved through settlement of the public nuisance actions filed by the State of West Virginia and West Virginia cities and counties against the Manufacturer Defendants, Distributor Defendants, and Defendants. Those prior settlement agreements, which this Court approved, provide specifically for treatment and medical monitoring of infants born with NAS. . . . This reinforces the importance of the "special injury" requirement for public nuisance claims - to prevent duplicative, repeated public nuisance claims asserted by private claimants who cannot establish an injury different in degree and character from other members of the public.

³⁷ See City of Huntington and Cabell County Comm'n v. AmerisourceBergen Drug Corporation, et al., No. 24-166.

We find no error in the inclusion of this language in the MLP's order which merely serves to bolster its proper conclusion that a "special injury" must be pleaded in order to maintain a private cause of action for public nuisance. Moreover, we find that any argument that the settlement of public nuisance claims by the political subdivisions constitutes collateral estoppel barring the Petitioners' public nuisance claims is mooted by our conclusion that Petitioners do not have standing to bring such claims. Accordingly, we find no error.

General Negligence Claims

We now turn to the Petitioners' allegation that the MLP erred in concluding that the Respondents owed them no duty of care, and therefore, their general negligence claims could not survive. We find no error in the MLP's ruling as to Petitioners' allegations of general negligence.

It is well-established that to sustain a claim for negligence in West Virginia, a plaintiff must show that the defendant's acts or omissions violated a duty owed to the plaintiff. See Syl. Pt. 3, *Bradley v. Dye*, 247 W. Va. 100, 875 S.E.2d 238 (2022). "No action for negligence will lie without a duty broken." Syl. Pt. 1, *Parsley v. Gen. Motors Acceptance Corp.*, 167 W. Va. 866, 280 S.E.2d 703 (1981). The existence of a duty is a question of law to be determined by the court. *Aikens v. Debow*, 208 W. Va. 486, 491, 541 S.E.2d 576, 581 (2000).

To determine whether a duty is owed, we must look to the foreseeability of harm resulting from the complained-of conduct. "The ultimate test of the existence of a duty to use care is found in the foreseeability that harm may result if it is not exercised." Syl. Pt. 3, in part, *Sewell v. Gregory*, 179 W. Va. 585, 371 S.E.2d 82 (1988). However, the inquiry does not stop there.

Beyond the question of foreseeability, the existence of duty also involves policy considerations underlying the core issue of the scope of the legal system's protection . . . Such considerations include the likelihood of injury, the magnitude of the burden of guarding against it, and the consequences of placing that burden on the defendant.

Aikens, 208 W. Va. at 491, 541 S.E.2d at 581 (quotations omitted); see also Stevens v. MTR Gaming Group, Inc., 237 W. Va. 531, 535, 788 S.E.2d 59, 63 (2016). The SCAWV has spoken on the limits to tort liability mandated by policy considerations, observing:

Tort law is essentially a recognition of limitations expressing finite boundaries of recovery courts and commentators have expressed disdain for limitless liability and have also cautioned against the potential injustices which might result. This Court's obligation is to draw a line beyond which the law will not extend its protection in tort, and to declare, as a matter of law, that no duty exists beyond that court-created line. It is not a matter of protection of a certain class of defendants; nor is it a matter of championing the causes of a certain class of plaintiffs. It is a question of public policy. Each segment of society will suffer injustice, whether situated as plaintiff or defendant, if there are no finite boundaries to liability and no confines within which the rights of plaintiffs and defendants can be determined.

Aikens, 208 W. Va. at 502, 541 S.E.2d at 592.

The MLP considered these principles and determined that it would "stretch[] the concept of due care too far" to hold that Respondents owed a common law duty of care to Petitioners, as it "would allow any private party in this State — no matter how far removed from any [Respondent] or its alleged conduct, and irrespective of the intervening conduct of numerous other actors, including the birth mothers — to claim that [Respondents] . . . owed that party a duty of care[.]" May 31, 2023, Order, p. 18. Petitioners assert that Respondents should have foreseen that their conduct imposed an unreasonable risk to Petitioners and, therefore, Respondents had a resulting duty of care to avoid such conduct. In asking this Court to adopt this reasoning, Petitioners ask that we re-draw the "court-created line" limiting duty, described in *Aikens. Id.* We are not so inclined.

As the SCAWV has previously articulated,

It necessarily falls to the courts to consider all relevant claims of the competing parties; to determine where and upon whom the burden of carrying the risk of injury will fall; and to draw the line, to declare the existence or absence of "duty," in every case, as a matter of law. The temptation is to accede to the arguments of logical connection in every instance of resulting harm while, in fact, the consequences of pure logic would be socially and economically ruinous.

Aikens, 208 W.Va. at 493, 541 S.E.2d at 583. First, as noted above, mere foreseeability alone does not establish a duty of care, so whether any of the Respondents may have foreseen that their conduct could create risks to Petitioners is not dispositive. See Stevens, 237 W. Va. at 535, 788 S.E.2d at 63. Relying on Aikens and our recognition that policy aims must be part of our duty calculus, we focus on our concern of expanding the concept

of duty in tort. We are mindful of the competing policy considerations of providing a remedy to the injured and expanding tort liability almost without limit. "It is always tempting to impose new duties and, concomitantly, liabilities, regardless of the economic and social burden." 57A Am.Jr.2d Negligence § 87.

Significantly, Petitioners' claims involve prescription medications, governed by extensive federal and state regulations. We decline to expand or impose new tort liability on Respondents whose conduct is subject to significant regulation and oversight. *See Stevens*, 237 W. Va. 531, 788 S.E.2d 59 (finding that casino and manufacturer of video lottery terminals have no duty to protect customers from compulsive gambling because gambling industry is heavily regulated in this State); *see also McNair v. Johnson & Johnson*, 241 W. Va. 26, 40-41, 818 S.E.2d 852, 866-67 (2018) (stating SCAWV's "traditional reluctance to impose liability on a party in a heavily regulated industry).

To the extent that Petitioners allege injuries caused by the illicit or illegal obtainment and ingestion of opioids, we find that Petitioners cannot establish a duty of care owed by any Respondent.³⁸ None of the Respondents owe a duty of care to prevent the

 $^{^{38}}$ We are mindful that the criminal conduct of the birth mother is not always a bar to recovery.

A plaintiff's immoral or wrongful conduct does not serve as a common law bar to his or her recovery for injuries or damages incurred as a result of the tortious conduct of another. Unless otherwise provided at law, a plaintiff's conduct must be

criminal activity of a third party. "[A] person usually has no duty to protect others from the criminal activity of a third party because the foreseeability of risk is slight, and because of the social and economic consequences of placing such a duty on a person." *Miller v. Whitworth*, 193 W. Va. 262, 266, 455 S.E.2d 821, 825 (1995). Although there are certain exceptions, which are not invoked in the instant case, "the general proposition [is] that there is no duty to protect against deliberate criminal conduct of third parties." *Strahin v. Cleavenger*, 216 W. Va. 175, 183-84, 603 S.E.2d 197, 205-06 (2004).

As to the birth mothers who were prescribed opioids by their physicians, it is evident that the prescribing physician owed the pregnant patient a duty of care with regard to the prescription and treatment. Further, it is arguable that the pharmacies that filled those prescriptions may have owed those birth mothers a general duty of care as providers of healthcare services. However, as noted above, we have vacated the dismissal with prejudice of the Pharmacy Respondents for lack of jurisdiction and remanded to the MLP for the issuance of an order dismissing those Respondents without prejudice. If, after remand, those causes of action are refiled, Petitioners may be able to establish that the Pharmacy Respondents owed them a duty of care related to filling the subject opioid prescriptions. However, the examination of any such issue is not presently before this Court, as

assessed in accordance with our principles of comparative fault.

Syl. Pt. 5, *Tug Valley Pharmacy, LLC v. All Plaintiffs Below*, 235 W. Va. 283, 773 S.E.2d 627 (2015).

Petitioners did not meet the pre-suit notice requirements of the MPLA. Accordingly, we find no error.

However, with regard to the remaining non-Pharmacy Respondents, we find that there is no general duty of care owed to the Petitioners under the facts alleged in the underlying complaints. Accordingly, we affirm the MLP's dismissal of Petitioners' general negligence allegations on the basis of their failure to establish this essential element of their claims.

Claims Against Respondent McKinsey

We also find it important to address the MLP's duty of care analysis with respect to Respondent McKinsey. McKinsey is a global business strategy consulting firm that provides advice to various industries, including pharmaceutical companies. Six of the underlying complaints named McKinsey entities as Respondents and alleged that McKinsey provided sales and marketing advice to Johnson & Johnson and other opioid manufacturers about opioid products.

Petitioners have not established any duty owed by Respondent McKinsey, in its professional consulting and marketing capacity, to any Petitioner. Indeed, we are aware of no case or legal authority that would compel such a duty and note that Petitioners have cited none. Accordingly, we affirm the MLP's finding that Respondent McKinsey owed

no duty of care to any Petitioner, based on the allegations in the complaints, and affirm the dismissal of Respondent McKinsey, with prejudice.

Products Liability Claims

The MLP's May 31, 2023, and June 27, 2023, orders do not substantively address the products liability claims brought by eighteen Petitioners. As the SCAWV has observed,

Products liability suits typically allege that a manufacturer designed and/or produced a product and put the product into the stream of commerce, and that the product was unsafe or flawed in such a way so as to give rise to the liability of the manufacturer for injuries resulting from the use of the product. The alleged unsafeness or flaw(s) may be as a result of the actual design or construction of the product, or in the adequacy of warnings provided to the user(s) of the product.

Morris v. Crown Equip. Corp., 219 W. Va. 347, 356, 633 S.E.2d 292, 301 (2006). See also Morningstar v. Black and Decker Mfg. Co., 162 W. Va. 857, 888, 253 S.E.2d 666, 682 (1979) (recognizing that "a defective product may fall into three broad . . . categories: design defectiveness; structural defectiveness; and use defectiveness arising out of the lack of, or the inadequacy of, warnings, instructions and labels."). In the subject complaints, Petitioners alleged claims against those defendants "engaged in the business of the design, development, manufacture, testing, packaging, promotion, marketing, distribution, labeling, and/or sale of opioid products." See Joint Appendix at 00469. The enumerated claims involve allegations of failure to warn, negligent misrepresentation, defective design,

and unreasonably dangerous design. "Product liability actions may be premised on three independent theories – strict liability, negligence, and warranty. Each theory contains different elements which plaintiffs must prove in order to recover." Syl. Pt. 6, in part, *Ilosky* v. Michelin Tire Corp., 172 W. Va. 435, 307 S.E.2d 603 (1983).

Here, we find that some of the Petitioners have made products liability allegations that sound in negligence and strict liability. As the orders on appeal contain no meaningful analysis, findings of fact, or conclusions of law supporting the dismissal of these claims, we find error in the general dismissal with prejudice of the products liability claims. Accordingly, we reverse the dismissal of such claims.³⁹

Proximate Cause

We turn next to Petitioners' contention that the MLP erred by finding that Petitioners could not establish that any Respondents' conduct was a proximate cause of

³⁹ We note that this holding is not in conflict with our holding above affirming the MLP's finding that Petitioners' general negligence claims fail for their inability to establish a general duty of care owed by Respondents. The allegations in the products liability claims necessarily invoke different duties of care owed by Respondents regarding the design of their products, or in preparing the warnings for their products, for example, that are not implicated in the general negligence claims alleged in the underlying complaints.

Moreover, the duty of care analysis is not applicable to Petitioners' claims that sound in strict liability. "[T]he lack of a duty of care is not determinative of a strict liability claim, whose viability depends on 'whether the involved product is defective in the sense that it is not reasonably safe for its intended use." *Stevens v. MTR Gaming Group, Inc.*, 237 W. Va. 531, 538, 788 S.E.2d 59, 66 (2016) (quoting Syl. Pt. 4, in part, *Morningstar v. Black & Decker Mfg. Co.*, 162 W. Va. 857, 253 S.E.2d 666 (1979)).

their injuries with respect to any of the negligence claims. Proximate cause is an element of a negligence claim, defined as "that cause which in actual sequence, unbroken by any independent cause, produced the wrong complained of, without which the wrong would not have occurred." Syl. Pt. 4, *Spencer v. McClure*, 217 W. Va. 442, 618 S.E.2d 451 (2005) (citation omitted). The SCAWV has clarified that "a plaintiff's burden of proof is to show that a defendant's breach of a particular duty of care was a proximate cause of the plaintiff's injury, not the sole proximate cause." *Mays v. Chang*, 213 W. Va. 220, 224, 579 S.E.2d 561, 565 (2003).

Here, the MLP found that the injuries alleged by Petitioners were too remote from Respondents' conduct for the conduct to be considered a proximate cause of the harm. Under West Virginia law, proximate cause is distinguished from a remote cause of injury because "remote causes of injury . . . do not constitute actionable negligence." *Webb v. Sessler*, 135 W. Va. 341, 349, 63 S.E.2d 65, 69 (1950). If a defendant's alleged conduct is too remote from the alleged harm, it cannot be a proximate cause even if it was foreseeable. *Id.* at 348-49, 63 S.E.2d at 68-69; *Aikens v. Debow*, 208 W. Va. at 492, 541 S.E.2d at 582. In the case sub judice, the MLP found that Respondents' conduct was:

multiple steps removed from [petitioners'] claimed injuries, which [petitioners] admit occurred only after (1) physicians prescribed opioids to birth mothers while they were pregnant with the allegedly injured Minors; (2) in some cases, third parties provided illegally obtained opioids to those birth mothers; and (3) birth mothers ingested medically prescribed opioids and/or illegally obtained opioids during their pregnancies with the Minors.

While this conduct by the physicians and birth mothers may have been sufficient to sever the chain of causation from the allegedly negligent conduct of a consulting or marketing agency like Respondent McKinsey, 40 this same description of prescribed medications being ingested by pregnant patients may not defeat proximate causation in the products liability context against a Manufacturing Respondent, for example (or even in a MPLA claim against a Pharmacy or Pharmacist). For instance, if in a products liability claim against a Manufacturing Respondent, Petitioners alleged that the manufacturer failed to properly warn physicians and patients of the risks of opioids during pregnancy, a pregnant patient's ingestion of medications her doctor lawfully prescribed would not in and of itself be a significant intervening cause that defeats proximate causation.

Similarly, we find error in the MLP's conclusion that the sole proximate cause of all Petitioners' alleged injuries was their birth mothers' ingestion of opioids. Although all Petitioners indeed complain of harms that resulted from birth mothers' ingestion of opioids, we disagree that this conduct automatically operates as a sole proximate cause in all cases.

⁴⁰ Indeed, although we affirmed the dismissal of the McKinsey Respondents on the basis of no duty of care, we likewise could affirm the dismissal on the basis of no proximate cause. The conduct alleged by McKinsey (offering marketing advice to opioid manufacturers) is too attenuated from the harms alleged by the petitioners to establish proximate cause. Moreover, the complaints do not make any allegations that any of the marketing or consulting conduct by McKinsey was even targeted to reach pregnant women. Even if the conduct were not too attenuated, Petitioners must allege something more specific and targeted to their "unique" demographic.

In support of that finding, the MLP cited Syllabus Point 12 of *Marcus v*. *Staubs*, 230 W. Va. 127, 736 S.E.2d 360 (2012), stating that the "actions of the birth mothers therefore 'constitute[] a new effective cause and operate[] independently of any other act, making [them] and [them] only, the proximate cause of the injury[.]" However, this citation was incomplete, and important context was missing. *Marcus* concerned the operation of an intervening cause that breaks the chain of causation where there are multiple tortfeasors, each guilty of separate acts of negligence. The full quotation, not included in the MLP order, defines an intervening cause in that context:

An intervening cause, in order to relieve a person charged with negligence in connection with an injury, must be a negligent act, or omission, which constitutes a new effective cause and operates independently of any other act, making it and it only, the proximate cause of the injury.

Id. at 139, 736 S.E.2d at 372. (citations and quotations omitted). In the underlying cases on appeal, there is nothing in the record to suggest that the conduct of birth mothers who ingested prescribed opioids was necessarily in every case a "negligent act, or omission" such that it would serve as the sole intervening proximate cause of the alleged injuries in the suits at bar.

Accordingly, we vacate the MLP's finding that all Petitioners cannot establish proximate causation as a matter of law for all claims and encourage the MLP to conduct further analysis of this issue, if necessary, on remand.⁴¹

Claims Against the West Virginia Board of Pharmacy

Petitioners argue that the MLP erred in dismissing their claims against Respondent BOP under the public duty doctrine and qualified immunity. Petitioners allege, in their underlying complaints, that the BOP violated state laws in failing to meet its duty to identify abnormal or unusual results or practices uncovered in the review of records in the Controlled Substance Monitoring Program, among its other statutory and regulatory duties.

The public duty doctrine is a defense to a negligence claim based on the absence of a duty owed. Under the public duty doctrine, a "governmental entity is not liable because of its failure to enforce regulatory or penal statutes." *Benson v. Kutsch*, 181 W. Va. 1, 3, 380 S.E.2d 36, 38 (1989). The basis for the doctrine is the principle "that it is impractical to require a public official to be responsible for every infraction of regulatory legislation that requires inspection or enforcement from his office." *Id*. We find that

⁴¹ We clarify that nothing in this holding is intended to supersede or conflict with our finding that Respondents owe no general duty of care to Petitioners, and intend only for additional consideration of proximate cause by the MLP, as necessary, to apply to the claims which are reversed or vacated herein.

this principle clearly applies to the alleged actions of Respondent BOP, particularly where Petitioners attempt to bring a negligence claim against Respondent BOP for its failure to enforce its regulatory duties.

The only recognized exception to this doctrine is the special relationship exception. "If a special relationship exists between a local governmental entity and an individual which gives rise to a duty to such individual, and the duty is breached causing injuries, then a suit may be maintained against such entity." *Benson*, Syl. Pt. 3. In the case sub judice, Petitioners make no allegations that would establish any such "special relationship." Accordingly, we find the public duty doctrine applies and these claims are barred.

We further find that West Virginia Code § 29-12A-1 through -18 (1986), which addresses the wanton or reckless conduct of an employee exception cited by Petitioners, applies only to political subdivisions and not to state agencies such as Respondent BOP. *See* W. Va. Code § 29-12A-1 (The article's "purposes are to limit liability of political subdivisions and provide immunity to political subdivisions in certain instances . . ."). Therefore, we find that this exception does not protect Petitioners from the application of the public duty doctrine and the resulting dismissal of their claims against Respondent BOP.

Finding the public duty doctrine defeats these claims, our inquiry needs go no further. "Where the public duty doctrine would apply, there is simply no duty and therefore no need to inquire as to the existence of immunity." *Walker v. Meadows*, 206 W. Va. 78, 83, 521 S.E.2d 801, 806 (1999). The SCAWV has long held that the doctrine of public duty "is not based on immunity from existing liability. Instead, it is based on the absence of duty in the first instance." *Holsten v. Massey*, 200 W. Va. 775, 782, 490 S.E.2d 864, 871 (1997).

However, even if Respondent BOP did owe a duty of care to Petitioners, we would find that Petitioners' alleged claims against Respondent BOP are also barred by qualified immunity. Qualified immunity is a bar to recovery where "an objectively reasonable official, situated similarly to the defendant, could have believed that his conduct did not violate the plaintiff's constitutional rights, in light of clearly established law and the information possessed by the defendant at the time of the allegedly wrongful conduct." *Hutchison v. City of Huntington*, 198 W. Va. 139, 149, 479 S.E.2d 649, 659 (1996).

The SCAWV has established the analysis to determine whether qualified immunity applies. First, a court must determine whether the acts or omissions are legislative, judicial, executive, or administrative policy-making acts, or whether the acts or omissions involve discretionary governmental functions. *See* Syl. Pt. 10, *W. Va. Reg'l Jail and Correctional Facility Auth. v. A.B.*, 234 W. Va. 492, 766 S.E.2d 751 (2014). To the extent they are from the legislative, judicial, executive, or administrative policy-making

acts, both the State and the individual official involved enjoy absolute immunity. Syl. Pt. 7, *Parkulo v. W. Va. Bd. of Probation and Parole*, 199 W. Va. 161, 483 S.E.2d 507 (1996). Those acts which fall within the category of discretionary functions must be demonstrated to be:

in violation of clearly established statutory or constitutional rights or laws of which a reasonable person would have known or are otherwise fraudulent, malicious or oppressive. . . . In absence of such a showing, both the State and its officials or employees charged with such acts or omissions are immune from liability.

A.B., 234 W. Va. at 497, 766 S.E.2d at 756, Syl. Pt. 11. Moreover, qualified immunity "is broad and protects 'all but the plainly incompetent or those who knowingly violate the law." W. Va. State Police v. Hughes, 238 W. Va. 406, 411, 796 S.E.2d 193, 198 (2017).

Here, Petitioners make unsupported allegations that Respondent BOP neglected its duties to perform investigatory functions pursuant to statutory and regulatory authorities. In the absence of factual allegations in support of these conclusory statements, we are left to conclude that these functions necessarily involve discretionary governmental functions. As Petitioners cite no regulation or statutory law that requires any specific, mandatory method or action by which Respondent BOP must conduct its investigatory duties, we find that any decisions about whether to investigate or how to investigate are discretionary acts that "do not violate a clearly established law" and, accordingly, are subject to qualified immunity.

To the extent that any of these allegations arise from "administrative policy-making acts or omissions," we find that the doctrine of absolute immunity further bars those allegations. Accordingly, we affirm the MLP's dismissal of Petitioners' underlying claims against Respondent BOP.

Fraud and Intentional Misrepresentation

Next, we turn to the assignments of error regarding the MLP's dismissal of Petitioners' fraud and intentional conduct claims. Petitioners allege that the MLP erred in dismissing the fraud claims to the extent that the dismissal includes their claims for intentional misrepresentation. Petitioners contend that the MLP reached that conclusion solely on the basis of an erroneous proximate cause analysis. We disagree.

Under West Virginia law,

[t]he essential elements in an action for fraud are: "(1) that the act claimed to be fraudulent was the act of the defendant or induced by him; (2) that it was material and false; that plaintiff relied upon it and was justified under the circumstances in relying upon it; and (3) that he was damaged because he relied upon it."

Syl. Pt. 1, *Lengyel v. Lint*, 167 W. Va. 272, 280 S.E.2d 66 (1981) (quoting *Horton v. Tyree*, 104 W. Va. 238, ____, 139 S.E. 737, 738 (1927)). Under Rule 9(b) of the West Virginia Rules of Civil Procedure, in a pleading alleging fraud, "the circumstances constituting fraud or mistake shall be stated with particularity." W. Va. R. Civ. P. 9(b). "[F]raud or mistake must be alleged in the appropriate pleading with particularity and the failure to do

so precludes the offer of proof thereof during the trial." Syl. Pt. 1, in part, *Hager v. Exxon Corp.*, 161 W. Va. 278, 241 S.E.2d 920 (1978).

Here, while Petitioners' complaints include numerous specific allegations on the first element of fraud, they are completely lacking on the latter two elements. Indeed, these complaints simply allege generally that the birth mothers relied on alleged misrepresentations—without identifying which of the many alleged misrepresentations the birth mother specifically relied on—and that the Petitioners suffered damages as a result. *See* Joint Appendix 1506; 2842-43. Accordingly, as there is a lack of particularity in these claims by Petitioners, we find no issue with the MLP's resultant dismissal of such claims.

Civil Conspiracy Claims

Related to the previous argument, Petitioners argue that the MLP erred in dismissing their civil conspiracy claims. The MLP dismissed the claims on the basis that conspiracy is not a stand-alone claim and depends on an underlying tort. *See O'Dell v. Stegall*, 226 W. Va. 590, 625, 703 S.E.2d 561, 596 (2010) (stating that a civil conspiracy must be based on an underlying tort). The MLP reasoned that because it dismissed all underlying torts, the civil conspiracy claims failed as a matter of law. Petitioners now argue that they set forth detailed allegations of civil conspiracy in their complaints, and rely on their arguments against dismissal of the underlying torts to urge reinstatement of the conspiracy claims.

Upon review, Petitioners' allegations of conspiracy are substantively related to their fraud and intentional misrepresentation claims, which, as noted above, do not survive as a matter of law. Furthermore, "conspiracy is an intentional act, not a negligent one." Mallamo v. Town of Rivesville, 197 W. Va. 616, 624, 477 S.E.2d 525, 533 (1996) (modified on other grounds by *Smith v. Burdette*, 211 W. Va. 477, 566 S.E.2d 614 (2002)); Harrison v. City of Charleston, No. 11-0598, 2011 WL 8193583, at *2 (W. Va. Nov. 28, 2011) (memorandum decision) ("[C]onspiracy is an intentional act, not negligence."). Courts in other jurisdictions have explicitly recognized the contradiction between civil conspiracy and negligence. See, e.g., United States v. Sdoulam, 398 F.3d 981, 987 (8th Cir. 2005) ("[O]ne cannot conspire to commit a negligent or unintentional act."); Sonnenreich v. Philip Morris Inc., 929 F. Supp. 416, 419 (S.D. Fla. 1996) ("Logic and case law dictate that a conspiracy to commit negligence is a non sequitur."). For the same reasons we find Petitioners' intentional misrepresentation claims fail, the related and dependent conspiracy claims also fail. Accordingly, we find no error in the MLP's dismissal of Petitioner's civil conspiracy claims.

Punitive Damages and Medical Monitoring Claims

We turn next to Petitioners' assignments of error regarding the MLP's dismissal of punitive damages and medical monitoring. The MLP dismissed these claims on the basis that all are dependent on an underlying tort. *See Bower v. Westinghouse Elec. Corp.*, 206 W. Va. 133, 142, 522 S.E.2d 424, 433 (1999) (Underlying liability must be

established based upon a recognized tort prior to liability attaching for medical monitoring); *Lyon v. Grasselli Chem. Co.*, 106 W. Va. 518, 146 S.E. 57, 58 (1928) ("[T]he right to recover punitive damages in any case is not the cause of action itself, but a mere incident thereto."). Because the MLP dismissed all the underlying torts, it found dismissal of these causes of action was likewise appropriate.

In conformity with our decision to reverse the dismissal of the products liability claims, we likewise vacate the dismissal of the counts for punitive damages and medical monitoring in those corresponding complaints. As the tort claims underlying the products liability causes of action (and potentially the claims against the Pharmacy Respondents, should they be refiled) are revived, these derivative, dependent causes of action may also be viable upon remand. However, we must be clear that we make no findings or conclusions herein regarding the merits of these claims, and note that said claims may ultimately be dismissed by the MLP.

Accordingly, we vacate the dismissals with prejudice as to punitive damages and medical monitoring and remand those claims to the MLP for further proceedings.

Claims Against Respondent Indivior

Next, we address Petitioners' assignment of error that the MLP erroneously dismissed Respondent Indivior, the manufacturer of Suboxone and Subutex, medications used to treat OUD. In their briefing, Petitioners argue that the MLP misapprehended the

interdependence of opioid use, which leads to addiction, and the use of Suboxone and Subutex, which are used to treat opioid addiction but also cause addiction. Petitioners' briefs also allege that certain of the Petitioners' use of Respondent Indivior's products should support a reasonable inference that the alleged injuries were proximately caused by Indivior. However, we find no support for a reasonable inference that Respondent Indivior's products caused the alleged harms when those injuries were explicitly alleged to be the result of NAS in infants born with opioid dependency, not as the result of treatment for any such opioid dependency.⁴² Accordingly, we affirm the MLP's dismissal of Respondent Indivior.

Amendment of Pleadings

Finally, we briefly address Petitioners' allegation that the MLP erred in refusing leave to amend their complaints under Rule 15 of the West Virginia Rules of Civil Procedure. Petitioners argue that under our liberal pleading standards, the MLP should have denied the motions to dismiss, or in the alternative, permitted them to amend their complaints to survive dismissal and proceed with discovery. Respondents argue that Petitioners did not preserve this argument below, so we should not consider it herein. Although we find no evidence in the record of a pending motion for leave to amend any of

⁴² Similarly unavailing is Petitioners' position at oral argument that Indivior conspired with the other Manufacturer Respondents to increase sales of opioids to promote addiction to the drug and expand the market for its OUD treatment products. This argument was not sufficiently pled in the underlying complaints, and is mooted by our determination that Petitioners' conspiracy claims fail as a matter of law.

Petitioners' complaints, Petitioners' counsel stated on the record during a March 24, 2023, status conference that the MLP "should allow us to maybe amend complaints, to resolve these issues on summary judgment when we have a full factual record." *See* JA at 00329. We find this oral statement sufficient to preserve the argument for appeal before this Court; however, we are not persuaded by its substance and find no error by the MLP in declining to permit amendment of the complaints. As the SCAWV has indicated,

A trial court is vested with a sound discretion in granting or refusing leave to amend pleadings in civil actions. Leave to amend should be freely given when justice so requires, but the action of a trial court in refusing to grant leave to amend a pleading will not be regarded as reversible error in the absence of a showing of an abuse of the trial court's discretion in ruling upon a motion for leave to amend.

Syl. Pt. 2, *Donahue v. Mammoth Restoration and Cleaning*, 246 W. Va. 398, 874 S.E.2d 1 (2022) (quotations and citations omitted). A trial court may exercise its discretion to deny a motion for leave to amend where such an amendment would be a futile gesture. *See id.*; *see also Cal. Teachers' Ret. Sys. v. Blankenship*, 240 W. Va. 623, 631-32, 814 S.E.2d 549, 557-58 (2018); *Pyles v. Mason Cnty. Fair, Inc.*, 239 W. Va. 882, 889, 806 S.E.2d 806, 813 (2017). We find that the MLP was not obligated to refuse Respondents' motions to dismiss on this basis or affirmatively offer Petitioners the opportunity to amend their complaints in response to the motions to dismiss, particularly where amendment would be futile as the claims failed as a matter of law. Accordingly, we find no abuse of discretion or other error by the MLP, to the extent not already addressed above.

IV. CONCLUSION

For the foregoing reasons, we affirm, in part, reverse, in part, vacate, in part, and remand for further proceedings consistent with this opinion.⁴³

Affirmed, in Part, Reversed, in Part, Vacated, in Part, and Remanded.

⁴³ In both the May 31, 2023, order and the June 27, 2023, order, the MLP found that, because it was dismissing all of Petitioners' claims for the specific reasons addressed in those orders, it was unnecessary to address various additional grounds for dismissal the Respondents raised. These additional grounds included the learned intermediary doctrine, the product-identification rule, and preemption. Although this Court is reversing the MLP's dismissal of Petitioners' products liability claims, nothing in this opinion should be construed as a ruling on the merits of those grounds for dismissal not addressed by the MLP.