IN THE INTERMEDIATE COURT OF APPEALS OF WEST VIRGINIA

Travis Blankenship, Next Friend and Guardian of Minor Child Z.D.B., (L) Petitioner. ICA EFiled: Jun 21 2024 01:25PM EDT Transaction ID 73454544

Docket No. 23-ICA-287

v. McKesson Corporation, et al., Respondents.

BRIEF OF RESPONDENTS MCKESSON CORP., ABBVIE INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., ALLERGAN FINANCE, LLC, AMERISOURCEBERGEN CORP., AMERISOURCEBERGEN DRUG CORP., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, ANDA INC., AUROBINDO PHARMA USA, INC., AUROLIFE PHARMA LLC, CARDINAL HEALTH INC., CVS PHARMACY, INC., CVS INDIANA, L.L.C., CVS RX SERVICES, INC., CVS TN DISTRIBUTION, L.L.C., WEST VIRGINIA CVS PHARMACY, L.L.C., H. D. SMITH LLC, H. D. SMITH HOLDINGS LLC, H. D. SMITH HOLDING CO., HIKMA PHARMACEUTICALS USA INC., INDIVIOR INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., THE KROGER CO., KVK-TECH, INC., NORAMCO, TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., SK CAPITAL PARTNERS, LP, SK CAPITAL MANAGEMENT IV, LP, SUN PHARMACEUTICAL INDUSTRIES, INC., SUN PHARMACEUTICAL INDUSTRIES LTD., RANBAXY LABORATORIES LTD., RANBAXY LABORATORIES INC., RANBAXY USA, INC., WALGREENS BOOTS ALLIANCE, INC., WALGREEN CO., WALGREEN EASTERN CO., INC., WALMART INC., WATSON LABORATORIES, INC., AND WEST VIRGINIA BOARD OF PHARMACY

Jeffrey M. Wakefield (WVSB #3894) Amy Rothman Malone (WVSB #10266) FLAHERTY SENSABAUGH BONASSO PLLC 200 Capitol Street Charleston, WV 25301 (304) 345-0200 jwakefield@flahertylegal.com

Timothy C. Hester (pro hac vice) COVINGTON & BURLING LLP One CityCenter 850 Tenth Street, NW Washington, DC 20001 (202) 662-6000 thester@cov.com

Counsel for McKesson Corporation

Additional Counsel Listed on Next Page

Patricia M. Bello (WVSB #11500) Tim J. Yianne (WVSB #8623) LEWIS BRISBOIS BISGAARD & SMITH, LLP 707 Virginia Street E., Ste. 1400 Charleston, West Virginia 25301 (304) 553-0166 patricia.Bello@lewisbrisbois.com tim.yianne@lewisbrisbois.com

Counsel for Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.

Gretchen M. Callas (WVSB #7136) Candice M. Harlow (WVSB #12496) JACKSON KELLY PLLC Post Office Box 553 Charleston, West Virginia 25322 (304) 340-1000 gcallas@jacksonkelly.com charlow@jacksonkelly.com

Robert A. Nicholas (pro hac vice) Joseph J. Mahady (pro hac vice) Anne R. Bohnet (pro hac vice) REED SMITH LLP 1717 Arch Street, Suite 3100 Philadelphia, PA 19130 (215) 851-8100 rnicholas@reedsmith.com jmahady@reedsmith.com abohnet@reedsmith.com

Kim M. Watterson (pro hac vice) REED SMITH LLP 225 Fifth Avenue Pittsburgh, PA 15222 (412) 288-3131 kwatterson@reedsmith.com

Counsel for AmerisourceBergen Drug Corp. and AmerisourceBergen Corporation (n/k/a Cencora, Inc. Wm. Scott Wickline (WVSB# 6100) Pence Law Firm PLLC 10 Hale Street, 4th Floor Charleston, WV 25301 (304) 345-7250 scott@pencefirm.com

Jeffrey D. Geoppinger (pro hac vice)
UB GREENSFELDER LLP
312 Walnut Street, Suite 1400
Cincinnati, Ohio 45202-4029
(513) 698-500
jgeoppinger@ubglaw.com

Counsel for Defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC

John H. Tinney, Jr., Esquire (WVSB# 6970) Keith A. Jones, Of Counsel (WVSB# 1923) HENDRICKSON & LONG, PLLC 214 Capitol Street Charleston, WV 25339 (304) 346-5500 jtinney@handl.com kjones@handl.com

Lauren E. O'Donnell, Esquire (pro hac vice)
BLANK ROME LLP
One Logan Square
130 N. 18th Street
Philadelphia, PA 19103
(215) 569-5735
lauren.odonnell@blankrome.com

Counsel for Anda, Inc.

Wm. Scott Wickline (WVSB# 6100) PENCE LAW FIRM PLLC 10 Hale Street, 4th Floor Charleston, WV 25301 (304) 345-7250 scott@pencefirm.com

Counsel for Specially Appearing Defendants Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC Steven R. Ruby (WVSB #10752)
Raymond S. Franks II (WVSB #6523)
CAREY DOUGLAS KESSLER & RUBY PLLC
707 Virginia Street East, Suite 901
Charleston, WV 25301
Telephone: (304) 345-1234
sruby@cdkrlaw.com
rfranks@cdkrlaw.com

Jennifer G. Wicht (pro hac vice)
William J. Donnelly (pro hac vice)
Williams and Connolly LLP
680 Maine Avenue, SW
Washington, DC 20024
(202) 434-5000
jwicht@wc.com
wdonnelly@wc.com

Counsel for Cardinal Health, Inc.

Carte P. Goodwin (WVSB #8039) Joseph M. Ward (WVSB #9733) Alex J. Zurbuch (WVSB #12838)

FROST BROWN TODD LLC

500 Virginia Street East, Suite 1100

Charleston, WV 25301 Telephone: 304-348-2419

Fax: 304-345-0115

Email: cgoodwin@fbtlaw.com Email: jward@fbtlaw.com Email: azurbuch@fbtlaw.com

Paul B. Hynes, Jr., (*pro hac vice*) Margarita K. O'Donnell (*pro hac vice*) Christopher R. MacColl (*pro hac vice*)

ZUCKERMAN SPAEDER LLP 1800 M Street, NW STE 1000

Washington, DC 20036 Telephone: 202-778-1800

Email: phynes@zuckerman.com Email: modonnell@zuckerman.com Email: cmaccoll@zuckerman.com

Counsel for CVS Pharmacy, Inc., CVS Indiana, L.L.C., CVS Rx Services, Inc., CVS TN Distribution, L.L.C., West Virginia CVS Pharmacy, L.L.C. Todd A. Mount (WVSB #6939) SHAFFER & SHAFFER, PLLC 330 State Street Madison, WV 25130 (304) 369-0511 tmount@shafferlaw.net

Brian T. Himmel (pro hac vice) REED SMITH LLP 225 Fifth Avenue Pittsburgh, PA 15222 (412) 288-3131 bhimmel@reedsmith.com

Counsel for H. D. Smith LLC, H. D. Smith Holdings, LLC, and H. D. Smith Holding Company

Trisha R. Hudkins (WVSB #12667) BERNSTEIN-BURKLEY, P.C. 32 20th Street, Suite 301 Wheeling, WV 26003 (412) 456 8105 thudkins@bernsteinlaw.com

Counsel for Hikma Pharmaceuticals USA Inc.

Mychal S. Schulz (WV Bar #6092)
Robert M. Stonestreet (WV Bar #9370)
Austin D. Rogers (WV Bar #13919)
BABST CALLAND, P.C.
300 Summers Street, Suite 1000
Charleston, WV 25301
681-265-8888
681-205-8814 (fax)
mschulz@babstcalland.com
rstonestreet@babstcalland.com
arogers@babstcalland.com

Maria R. Durant (pro hac vice) HOGAN LOVELLS US LLP 125 High Street, Suite 2010 Boston, MA 02110 617-371-1024 617-371-1037 (fax) maria.durant@hoganlovells.com

Counsel for Indivior Inc.

Marc E. Williams (WVSB #4062) Robert L. Massie (WVSB #5743) Shaina D. Massie (WVSB # 13018)

Alexander C. Frampton (WVSB # 13398)

NELSON MULLINS RILEY &

SCARBOROUGH LLP

949 Third Avenue, Suite 200

Huntington, WV 25701

(304) 526-3500

marc.williams@nelsonmullins.com bob.massie@nelsonmullins.com shaina.massie@nelsonmullins.com alex.frampton@nelsonmullins.com

Counsel for Johnson & Johnson and Janssen Pharmaceuticals, Inc.

Ronda L. Harvey Esq. (WVSB #6326) Ashley Hardesty Odell, Esq. (WVSB #9380) Fazal A. Shere, Esq. (WVSB #5433) Aaron C. Boone, Esq. (WVSB #9479) Ryan S. Moore, Esq. (WVSB #14155) BOWLES RICE LLP 600 Quarrier Street Charleston, West Virginia 25301 (304) 347-1100

rharvey@bowlesrice.com ahardestyodell@bowlesrice.com fshere@bowlesrice.com

aboone@bowlesrice.com rmoore@bowlesrice.com

Counsel for The Kroger Co.

Bryant J. Spann (WVSB #8628) Robert H. Akers (WVSB #9622) Susan W. Romaine (WVSB #9936) THOMAS COMBS & SPANN, PLLC

P.O. Box 3824

Charleston, WV 25338-3824

Tel: 304.414.1800 bspann@tcspllc.com rakers@tcspllc.com swromaine@tcspllc.com

Counsel for Walgreens Boots Alliance, Inc., Walgreen Co., and Walgreen Eastern Co., Inc. Teresa J. Dumire, Esq. (WVSB #8032) Margaret E. Lewis, Esq. (WVSB #10329)

KAY CASTO & CHANEY PLLC

50 Clay Street, Suite 100

Morgantown, WV 26501

Phone: (304) 225-0970 tdumire@kaycasto.com mlewis@kaycasto.com

John D. Hoblitzell, III, Esq. (WVSB #9346)

KAY CASTO & CHANEY PLLC

PO Box 2031

Charleston, WV 25327

Phone: (304) 345-8900 jdhoblitzell@kaycasto.com

Jennifer L. Maloney, Esq. (Pro hac vice) BAKER STERCHI COWDEN & RICE LLC 100 North Broadway, Suite 2100

St. Louis, MO 63102 Phone: (314) 345-5000 jmaloney@bakersterchi.com

Thomas E. Rice, Esq. (*pro hac vice*) John A. Watt, Esq. (*pro hac vice*)

BAKER STERCHI COWDEN & RICE LLC

2400 Pershing Road, Suite 500

Kansas City, MO 64108

(816) 471-2121

rice@bakersterchi.com watt@bakersterchi.com

Counsel for KVK-Tech, Inc.

Justin C. Taylor (WVSB #8014)

BAILEY & WYANT, PLLC

500 Virginia Street, East, Suite 600

Post Office Box 3710

Charleston, West Virginia 25337-3710

(304) 345-4222

jtaylor@baileywyant.com

Counsel for West Virginia Board of Pharmacy

Jon B. Orndorff (WVSB 7763)
Kelly Calder Mowen (WVSB 12220)
Gordon L. Mowen, II (WVSB 12277)
ORNDORFF MOWEN PLLC
135 Corporate Centre Drive, Suite 524
Scott Depot, WV 25560
(866) 481-2765
Jon.Orndorff@om-pllc.com
Kelly.Mowen@om-pllc.com
Gordon.Mowen@om-pllc.com

Jenny A. Hergenrother (pro hac vice) ALSTON & BIRD LLP One Atlantic Center 1201 West Peachtree Street, Suite 4900 Atlanta, GA 30309 (404) 881-4977 Jenny.Hergenrother@alston.com

Counsel for NORAMCO

Alexander Macia (WVSB #6077)
Tai Shadrick Kluemper (WVSB #12261)
SPILMAN THOMAS & BATTLE, PLLC
300 Kanawha Boulevard, East (25301)
Post Office Box 273
Charleston, WV 25321-0273
(304) 340-3835 (Mr. Macia)
(304) 357-4476 (Ms. Kluemper)
amacia@spilmanlaw.com
tkluemper@spilmanlaw.com

Christopher Lovrien (pro hac vice)
Shirlethia V. Franklin (pro hac vice)
Anthony J. Dick (pro hac vice)
Krista Perry Heckmann (pro hac vice)
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
(202) 879-3939
cjlovrien@jonesday.com
sfranklin@jonesday.com
ajdick@jonesday.com
kperryheckmann@jonesday.com

Counsel for Walmart Inc.

John H. Tinney, Jr. (WVSB# 6970) Keith A. Jones (WVSB# 1923) HENDRICKSON & LONG, PLLC 214 Capitol Street Charleston, WV 25339 (304) 346-5500 jtinney@handl.com kjones@handl.com

Terry M. Henry (pro hac vice) BLANK ROME LLP One Logan Square 130 N. 18th Street Philadelphia, PA 19103 (215) 569-5644 terry.henry@blankrome.com

Counsel for Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. and specially appearing Teva Pharmaceutical Industries Ltd.

Michael G. Connelly (WVSB #10682)
TROUTMAN PEPPER HAMILTON SANDERS LLP
501 Grant Street
Suite 300
Pittsburgh, PA 15219-2507
(412) 454-5000
michael.connelly@troutman.com

Counsel for Sun Pharmaceutical Industries, Inc., Ranbaxy Laboratories Inc., Ranbaxy USA, Inc. and specially appearing defendants Sun Pharmaceutical Industries Ltd. and Ranbaxy Laboratories, Ltd. Pamela C. Deem (WVSB# 976) Luci R. Wellborn (WVSB# 5531) KAY CASTO & CHANEY PLLC 707 Virginia Street, East, Suite 1500 Charleston, WV 25301 (304) 345-8900 pdeem@kaycasto.com lwellborn@kaycasto.com

Matthew D. Elshiaty (WVSB #12535) KAY CASTO & CHANEY PLLC 150 Clay Street, Suite 100 Morgantown, WV 26501 (304) 225-0970 melshiaty@kaycasto.com

Frank J. Favia, Jr. (pro hac vice) SIDLEY AUSTIN LLP One South Dearborn Street Chicago, IL 60603 (312) 853-0326 ffavia@sidley.com

Lauren E. Gumerove (*pro hac vice*) SIDLEY AUSTIN LLP 1001 Brickell Bay Drive, Suite 900 Miami, FL 33131 (305) 391-5219 lgumerove@sidley.com

Counsel for SK Capital Partners, LP and SK Capital Management IV, LP

TABLE OF CONTENTS

STAT	EMEN	T OF THE CASE	1
SUMI	MARY	OF ARGUMENT	2
STAT	EMEN	T REGARDING ORAL ARGUMENT AND DECISION	5
ARGI	JMENT	Γ	2 5 5 5 1 13 13 15 16 19 22 22
I.		MLP CORRECTLY DETERMINED THAT THE MPLA BARS NTIFFS' CLAIMS AGAINST PHARMACY DEFENDANTS	5
	A.	The MPLA Squarely Applies to Plaintiffs' Claims.	5
	B.	Plaintiffs' Contrary Arguments Fail.	9
II.		MLP CORRECTLY DISMISSED PLAINTIFFS' CLAIMS AGAINST VIOR	12
	A.	The MLP Correctly Held That Indivior Is Independently Entitled to Dismissal As A Matter Of Law	13
	В.	The MLP Correctly Held That Plaintiffs Failed to Establish Proximate Causation As To The Claims Against Indivior	13
	C.	The MLP Correctly Dismissed Plaintiffs' Civil Conspiracy Claims Against Indivior	15
III.		MLP CORRECTLY HELD THAT DEFENDANTS DID NOT OWE A Y OF CARE TO PLAINTIFFS	16
IV.		MLP CORRECTLY HELD THAT PLAINTIFFS CANNOT ESTABLISH KIMATE CAUSATION	19
V.		MLP CORRECTLY DISMISSED PLAINTIFFS' CLAIMS AGAINST THE Γ VIRGINIA BOARD OF PHARMACY	22
VI.		MLP CORRECTLY DISMISSED PLAINTIFFS' MEDICAL ITORING CLAIMS	22
VII.		MLP CORRECTLY HELD THAT PLAINTIFFS CANNOT PROCEED I THEIR CIVIL CONSPIRACY CLAIMS	23
VIII.	THE	MLP CORRECTLY DISMISSED PLAINTIFFS' FRAUD CLAIMS	23

IX.	THE MLP CORRECTLY DISMISSED PLAINTIFFS' CLAIM FOR PUNITIVE DAMAGES	23
X.	THE MLP CORRECTLY DISMISSED PLAINTIFFS' CLAIMS WITH PREJUDICE	23
CON	CLUSION	25

TABLE OF AUTHORITIES

Page(s)
Cases
A.D.A. v. Johnson & Johnson et al., Civil Action No. 23-ICA-275
A.N.C. v. Johnson & Johnson et al., Civil Action No. 23-ICA-2761
ACA Fin. Guar. Corp. v. City of Buena Vista, 917 F.3d 206 (4th Cir. 2019)24
Aikens v. Debow, 208 W. Va. 486, 541 S.E.2d 576 (2000)
Blankenship v. Ethicon, Inc., 221 W. Va. 700, 656 S.E.2d 451 (2007)
Bower v. Westinghouse Elec. Corp., 206 W. Va. 133, 522 S.E.2d 424 (1999)
Bowles v. CVS Pharm., No. 1:19-CV-154, 2019 WL 7556265 (N.D. W. Va. Dec. 20, 2019)
Cartwright v. McComas, 223 W. Va. 161, 672 S.E.2d 297 (2008)11
State ex rel. Charleston Area Medical Center, Inc. v. Thompson, 248 W.Va. 352, 888 S.E.2d 852 (W.Va. 2023)
<i>In re E.B.</i> , 229 W. Va. 435, 729 S.E.2d 270 (2012)
E.K. v. W. Virginia Dep't of Health, No. 16-0773, 2017 WL 5153221 (W. Va. Nov. 7, 2017)16
Evans v. Farmer, 148 W. Va. 142, 133 S.E.2d 710 (1963)22
Goodwin v. Bayer Corp., 218 W. Va. 215, 624 S.E.2d 562 (2005)9
Jones v. Trustees of Bethany College, 177 W.Va. 168, 351 S.E.2d 183 (1986)9

Marcus v. Staubs, 230 W. Va. 127, 736 S.E.2d 360 (2012)	20
Mayor & City Council of Balt. V. BP P.L.C., 31 F.4th 178 (4th Cir. 2022), cert. denied, 143 S.Ct. 1795 (2023)	10
McNair v. Johnson & Johnson, 241 W. Va. 26, 818 S.E.2d 852 (2018)	4
Metro v. Smith, 146 W. Va. 983, 124 S.E.2d 460 (1962)	19
State ex rel. Miller v. Stone, 216 W. Va. 379, 607 S.E.2d 485 (2004)	11, 18, 20
State of West Virginia ex rel. Morrisey v. Crab Orchard Pharmacy, Inc., No. 17-C-12-D (W. Va. Cir. Ct. Raleigh Cnty. Mar. 8, 2019)	7
State of West Virginia ex rel. Morrisey v. Judy's Drug Store, Inc., No. 16-C-54 (W. Va. Cir. Ct. Hardy Cnty. Nov. 8, 2019)	7
Mountaineer Fire & Rescue Equip., LLC v. City Nat'l Bank of W. Virginia, 244 W. Va. 508, 854 S.E.2d 870 (2020)	15
O'Dell v. Stegall, 226 W. Va. 590, 703 S.E.2d 561 (W. Va. 2010)	23
Pendleton v. Wexford Health Sources, Inc., No. 15-0014, 2015 WL 8232155 (W. Va. Dec. 7, 2015)	12
State ex rel. PrimeCare Medical of West Virginia, Inc. v. Faircloth, 242 W. Va. 335, 835 S.E.2d 579 (2019)	
Roche v. Lincoln Prop. Co., 175 F. App'x 597 (4th Cir. 2006)	23
Sager v. Duvert, 249 W. Va. 221, 895 S.E.2d 76 (2023)	7
Sparks v. Johnson & Johnson et al., Civil Action No. 23-ICA-307	1, 5
State ex rel. Hope Clinic, PLLC v. McGraw,	
245 W.Va. 171, 858 S.E.2d 221 (2021)	8
Stevens v. MTR Gaming Grp., Inc., 237 W. Va. 531, 788 S.E.2d 59 (2016)	16, 17, 18

Tanner v. Raybuck, 246 W.Va. 361, 873 S.E.2d 892 (2022)	8, 11
Teter v. Old Colony Co., 190 W. Va. 711, 441 S.E.2d 728 (1994)	9
Estate of Van Emburgh by and through Van Emburgh v. United States, 95 F.4th 795 (4th Cir. 2024)	10
Vogt v. Am. Arb. Ass'n, No. 19-0676, 2020 WL 3469214 (W. Va. June 25, 2020)	25
State ex rel. W. Va. Univ. Hosps., Inc. v. Scott, 246 W. Va. 184, 866 S.E.2d 350 (2021)	7, 8
State ex rel. W. Virginia Div. of Corr. & Rehab. v. Ferguson, 248 W. Va. 471, 889 S.E.2d 44 (2023)	6
Wal-Mart Stores East, L.P. v. Ankrom, 244 W. Va. 437, 854 S.E.2d 257 (2020)	19
Webb v. Sessler, 135 W. Va. 341, 63 S.E.2d 65 (1950)	19, 20
Whitlow v. Bd. of Educ. of Kanawha Cnty., 190 W.Va. 223, 438 S.E.2d 15 (1993)	10
Statutes	
West Virginia Medical Professional Liability Act, W. Va. Code § 55-7B-1 et se	eg3. 6. 7. 8. 10

GLOSSARY

Term	Definition
Prior Appeal	The prior consolidated appeal in A.D.A. v. Johnson & Johnson et al., 23-ICA-275, A.N.C. v. Johnson & Johnson et al., 23-ICA-276, and Sparks v. Johnson & Johnson et al., Civil Action No. 23-ICA-307.
Defendants' Prior Brief	Brief filed on January 19, 2024 in the Prior Appeal by various Defendants who are also parties to this brief. TID 71838012.
Minors	The term "Minors" includes both minor children on whose behalf Plaintiffs are suing as next friends, and individuals who are no longer minors but allegedly suffer from the effects of NAS due to their birth mothers' use and misuse of opioids during pregnancy.

The Mass Litigation Panel ("MLP") dismissed the Plaintiffs' claims as a matter of law on multiple independent grounds. JA94–128; JA157–178. The MLP's carefully reasoned ruling is fully supported by well-established case law and Plaintiffs' own allegations. The Court should affirm the MLP's dismissal of these cases.

STATEMENT OF THE CASE

In two substantively identical orders issued on May 31, 2023 and June 27, 2023 (collectively, "Final Order"), the MLP dismissed 21 separate complaints filed by or on behalf of individuals ("Minors") who allegedly suffer from the effects of Neonatal Abstinence Syndrome ("NAS") due to their birth mothers' use and misuse of opioids during their pregnancies. The MLP dismissed each complaint on the same grounds, JA94–128; JA157–178, and all Plaintiffs appealed. However, 18 of the 21 appeals were stayed because of bankruptcy proceedings involving Rite Aid, one of the defendants in those cases. While those 18 appeals were stayed, the parties completed consolidated briefing in the three appeals not subject to the stay (the "Prior Appeal").

After briefing was complete on the Prior Appeal, the 18 Plaintiffs in this appeal moved to sever Rite Aid from their appeals and to lift the bankruptcy stay.³ In support, Plaintiffs argued that the Prior Appeal "included assignments of error that overlap with those of [Plaintiffs] but did not

¹ Eighteen cases are consolidated in this appeal, all of which appear under the case number 23-ICA-287.

² The cases in the prior appeal were *A.D.A. v. Johnson & Johnson et al.*, Civil Action No. 23-ICA-275, *A.N.C. v. Johnson & Johnson et al.*, Civil Action No. 23-ICA-276, and *Sparks v. Johnson & Johnson et al.*, Civil Action No. 23-ICA-307.

³ TID 72599383.

include assignments of error related to the [Plaintiffs'] pharmacy claims and defendant Indivior" and that it "is imperative that briefing commence on the assignments of error not included in the brief of the three" Plaintiffs in the Prior Appeal.⁴

On April 16, 2024, this Court granted Plaintiffs' motion to sever Rite Aid and lift the stay on the remaining claims.⁵ Notwithstanding their request for briefing "on the assignments of error not included" in the Prior Appeal, Plaintiffs have also revisited issues that were fully aired in the Prior Appeal, often relying on identical authorities to make the identical arguments raised in the Prior Appeal. To avoid burdening the Court, Defendants will not simply repeat arguments from the Prior Appeal but will instead highlight the specific points needed to respond to Plaintiffs in this appeal. Defendants also expressly incorporate the arguments made in the brief of the defendants in the Prior Appeal ("Defendants' Prior Brief"). TID 71838012. To the extent Plaintiffs raise any argument identical to an argument already made in the Prior Appeal, Defendants will rely on the arguments raised in Defendants' Prior Brief.

STATEMENT OF FACTS

The Statement of Facts in Defendants' Prior Brief sets out the relevant facts governing this appeal. To avoid duplication, Defendants will not repeat it here.

SUMMARY OF ARGUMENT

The MLP's Final Order dismissing Plaintiffs' claims is based on multiple independent and equally dispositive grounds, some of which are applicable to all Defendants, and some of which

⁵ TID 72758724.

⁴ TID 72599383, at 3.

are applicable only to certain Defendants as set out below. None of Plaintiffs' arguments supports reversal.

These appeals raise a new assignment of error specific to Pharmacy Defendants, but Plaintiffs' claims against the Pharmacy Defendants necessarily fail because, in addition to the other grounds for dismissal that are applicable to all Defendants, Plaintiffs did not comply with the presuit requirements for bringing a claim under the West Virginia Medical Professional Liability Act, W. Va. Code § 55-7B-1 et seq. ("MPLA"), including serving a notice and a screening certificate of merit by a qualified expert. Further, Plaintiffs' arguments that some of their claims do not fall within the scope of the MPLA were not raised before the MLP and are therefore waived; and in any case these arguments are contradicted by the plain language of the MPLA and its amendments.

Likewise, Plaintiffs now raise a new assignment of error specific to Defendant Indivior, but the MLP's finding that Indivior is independently entitled to dismissal should be affirmed for several reasons stemming from the fact that the only Indivior products at issue in this litigation are Schedule III buprenorphine-based medications used to treat opioid use disorder ("OUD")—not Schedule II opioids for the treatment of pain. Plaintiffs fail to acknowledge or address this critical distinction between Indivior and other Defendants in their complaints. Likewise, they fail to establish any proximate causation as to Indivior specifically for any of the Minors' alleged injuries, and moreover fail to allege sufficient facts to support a civil conspiracy claim against Indivior.

Plaintiffs' arguments applicable to all Defendants fare no better. As explained in Defendants' Prior Brief, the MLP correctly held that Defendants did not owe a duty of care to the Plaintiffs in this case under West Virginia law. JA113–17. Plaintiffs' argument that duty requires only a "foreseeable and unreasonable risk of harm" misstates the law. West Virginia law firmly

establishes that the existence of a duty of care turns not only on the foreseeability of harm but also the remoteness of the alleged injury, the duties of intervening intentional and criminal actors, and the compelling policy consideration of avoiding "limitless liability" for pharmaceutical manufacturers, distributors, and pharmacies operating in a highly regulated field. *See McNair v. Johnson & Johnson*, 241 W. Va. 26, 39, 818 S.E.2d 852, 865 (2018) (quotation omitted). West Virginia law makes clear that the MLP was correct in its evaluation of these factors and in its conclusion that they weigh decisively against imposing a duty of care in the circumstances presented here.

The MLP also correctly dismissed Plaintiffs' claims for lack of proximate causation. Plaintiffs cannot establish proximate causation as a matter of law, both because their alleged injuries are too remote from Defendants' alleged conduct, JA117-120, and because according to the allegations set out in the complaints, the actions of the birth mothers were the sole proximate cause of the Minors' alleged injuries. The MLP properly resolved this issue as a matter of law where, as here, the complaints establish a lack of proximate causation.

Plaintiffs' claims against the West Virginia Board of Pharmacy ("WVBOP") were correctly dismissed as well, for the reasons fully addressed in the WVBOP's brief in the Prior Appeal and incorporated here by reference.

Because the MLP properly dismissed Plaintiffs' substantive tort claims, the MLP likewise properly dismissed Plaintiffs' claims for medical monitoring, conspiracy, and punitive damages—none of which can stand without underlying torts to support them. And because Plaintiffs' fraud claims cannot proceed without proximate cause, the MLP properly dismissed them, as well.

Finally, Plaintiffs fail to show that the MLP abused its discretion by dismissing their claims with prejudice and without leave to amend. Plaintiffs failed to preserve this issue for appeal because they never filed a motion for leave to amend, even after the MLP issued its April 17, 2023 Order dismissing Plaintiffs' claims and before the MLP issued its Final Order on May 31, 2023 (or its subsequent order in the *Sparks* case on June 27, 2023). In any event, despite repeated opportunities to do so, Plaintiffs have never identified a single claim that could be salvaged by amended pleading.

STATEMENT REGARDING ORAL ARGUMENT AND DECISION

Defendants respectfully request that the issues raised on this appeal be addressed in oral argument pursuant to Rule 20 of the West Virginia Rules of Appellate Procedure and be consolidated with argument on the Prior Appeal. To ensure a full consideration of the issues raised on the combined appeals, Defendants submit that the Court should allow 30 minutes per side for oral argument with respect to issues that apply across all defendants, with an additional 10 minutes per side allocated to Pharmacy Defendants, Indivior Inc., and the West Virginia Board of Pharmacy, to be allocated among Defendants as appropriate.

ARGUMENT

I. THE MLP CORRECTLY DETERMINED THAT THE MPLA BARS PLAINTIFFS' CLAIMS AGAINST PHARMACY DEFENDANTS.

A. The MPLA Squarely Applies to Plaintiffs' Claims.

The MPLA provides that "no person may file a medical professional liability action against any health care provider without complying with" certain pre-suit requirements, including serving on the provider both a notice and a screening certificate of merit by a qualified expert. W. Va.

Code § 55-7B-6. The MPLA's pre-suit requirements apply whenever a party "(1) sues a 'health care provider' or 'health care facility' for (2) 'medical professional liability' as those terms are defined under the Act." Syl. Pt. 5, *State ex rel. W. Virginia Div. of Corr. & Rehab. v. Ferguson*, 248 W. Va. 471, 889 S.E.2d 44, 46 (2023).

The MLP correctly held that Plaintiffs' MPLA claims are barred because Plaintiffs failed to comply with the statute's notice and certificate provisions. To begin, the Pharmacy Defendants are "health care provider[s]." The MPLA defines "health care provider" to encompass a "health care facility" including "any . . . pharmacy . . . in and licensed, regulated, or certified by the State of West Virginia under state or federal law . . . and any related entity to the health care facility." W. Va. Code § 55-7B-2(g) & (f); see id. § 55-7B-2(o) (defining "[r]elated entity" to include "any corporation . . . which owns . . . any part of a health provider or health care facility"). Retail chain pharmacies like the Pharmacy Defendants thus "meet[] the definition of a 'health care facility' and [are] thereby . . . health care provider[s]" protected by the MPLA. Bowles v. CVS Pharm., No. 1:19-CV-154, 2019 WL 7556265, at *5-6 (N.D. W. Va. Dec. 20, 2019).

Plaintiffs' lawsuits are "medical professional liability action[s]" under the MPLA. The statute broadly defines the term "medical professional liability" to mean "any liability for damages resulting from the death or injury of a person for any tort . . . based on health care services rendered, or which should have been rendered, by a health care provider or health care facility to a patient," as well as "other claims that may be contemporaneous to or related to the alleged tort . . . or otherwise provided, all in the context of rendering health care services." W. Va. Code § 55-7B-2(i). The MPLA defines "health care" expansively to encompass all acts done in furtherance of medical care, including administrative processes and alleged corporate negligence such as failure

to document, report, train or supervise. *See id.* § 55-7B-2(e); *State ex rel. W. Va. Univ. Hosps.*, *Inc. v. Scott*, 246 W. Va. 184, 191–93, 197–99, 866 S.E.2d 350, 357–59, 363–65 (2021).

The MPLA squarely applies to claims against a pharmacy for dispensing prescription medications because such claims seek to impose "liability for damages ... based on health care services rendered, or which should have been rendered." Id. See, e.g., Bowles, 2019 WL 7556265 at *1–2; 6/8/22 Order & 6/14/22 Order, In re: National Prescription Opiate Litigation, No. 1:17md-2804, Docs. #4502, 4516 (N.D. Ohio 2022), JA1852, 2298; Order Certifying Questions, State of West Virginia ex rel. Morrisey v. Judy's Drug Store, Inc., No. 16-C-54 (W. Va. Cir. Ct. Hardy Cnty. Nov. 8, 2019), JA 668; Order, State of West Virginia ex rel. Morrisey v. Crab Orchard Pharmacy, Inc., No. 17-C-12-D (W. Va. Cir. Ct. Raleigh Cnty. Mar. 8, 2019), JA683; see also Sager v. Duvert, 249 W. Va. 221, 895 S.E.2d 76 (2023) (applying MPLA statute of limitations to claim that medical providers overprescribed and improperly filled prescriptions for controlled substances known to have addictive qualities). Indeed, the MPLA expressly states that claims based on "dispens[ing] of controlled substances" are subject to its protections. W. Va. Code § 55-7B-5(d) ("No action related to the ... dispensation of controlled substances may be maintained against a health care provider pursuant to this article by or on behalf of a person whose damages arise as a proximate result of a violation of the Uniform Controlled Substances Act" unless the plaintiff proves "that the health care provider dispensed . . . a controlled substance or substances in violation of state or federal law, and that such . . . dispensation in violation of state or federal law was a proximate cause of the injury or death.").

Because Plaintiffs' tort claims seek to hold Pharmacy Defendants liable for damages resulting from personal injury based on the health care services they allegedly rendered (or should

have rendered) when dispensing opioid medications, the claims fall squarely within the MPLA. See, e.g., Blankenship Compl. ¶¶ 155, 304–99, 411–29, Prayer for Relief (alleging that Pharmacy Defendants ignored red flags at the point of sale and before dispensing, failed to provide sufficient warning about prescription opioid medications, and failed to properly train their employees).⁶ And Plaintiffs admit they did not comply with the MPLA pre-suit requirements. JA110-13. Accordingly, the MLP correctly dismissed their claims for lack of subject matter jurisdiction. See State ex rel. PrimeCare Medical of West Virginia, Inc. v. Faircloth, 242 W. Va. 335, 835 S.E.2d 579 (2019) ("Failure to [do so] deprives a circuit court of subject matter jurisdiction."); see also, e.g., State ex rel. Hope Clinic, PLLC v. McGraw, 245 W.Va. 171, 858 S.E.2d 221 (2021) (same); Tanner v. Raybuck, 246 W.Va. 361, 873 S.E.2d 892 (2022) (failure to comply with MPLA's presuit requirements cannot be cured and a court must immediately dismiss the suit).

⁶ All of Plaintiffs' claims against Pharmacy Defendants are covered by the MPLA because they are "contemporaneous to or related to [an] alleged tort" that is "based on health care services rendered, or which should have been rendered" by Pharmacy Defendants in the "context of rendering health care services." W. Va. Code § 55-7B-2(i); see Scott, 246 W.Va. at 194, 886 S.E.2d at 360 ("The 'health care' claim is the 'anchor;" it gets you in the door of MPLA application to allow for inclusion of claims that are 'contemporaneous to or related to' that claim, but still must be in the overall context of rendering health care services."); id. at 194–99, 246 W.Va. at 360–65 (applying MPLA to incorporate negligence claims such as failure to document, spoliation of evidence, failure to report, failure to train, failure to supervise, failure to have proper protocols, and failure to correct, because those claims were at least factually related to medical treatment provided to a minor child by the provider, if not anchor claims themselves); State ex rel. Charleston Area Medical Center, Inc. v. Thompson, 248 W.Va. 352, 361, 888 S.E.2d 852, 861 (W.Va. 2023) (applying MPLA to ancillary privacy claim based on unauthorized disclosure of medical information because it was contemporaneous and related to anchor claim that hospital had been negligent in connection with handling of fetal remains as a result of a stillbirth delivery).

B. Plaintiffs' Contrary Arguments Fail.

Plaintiffs no longer dispute any of this analysis—they do not deny that Pharmacy Defendants are "health care providers" under the current version of the MPLA, nor do they dispute that their lawsuits are "medical professional liability actions" that trigger its pre-suit requirements. Instead, they raise two arguments, both of which are meritless.

First, Plaintiffs argue for the first time on appeal that the MPLA does not apply to a subset of their claims that purportedly arose before the 2015 amendments to the MPLA, which made clear that the MPLA applies to pharmacies. Br. at 24–25. Plaintiffs forfeited this argument, which in any event is wrong. It is well settled that "a plaintiff may forfeit an argument in favor of subject matter jurisdiction." Estate of Van Emburgh by and through Van Emburgh v. United States, 95 F.4th 795, 800 (4th Cir. 2024) (citing Mayor & City Council of Balt. V. BP P.L.C., 31 F.4th 178, 202 (4th Cir. 2022) (holding argument in support of jurisdiction was forfeited because it was not sufficiently developed before the district court), cert. denied, 143 S.Ct. 1795 (2023)). Plaintiffs forfeited this argument for subject matter jurisdiction because they said nothing to the MLP about the 2015 amendments supposedly not applying to some of their claims. Because Plaintiffs never presented this theory for subject matter jurisdiction to the MLP, they cannot raise it now. Estate

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⁷ Plaintiffs argue that even for claims brought on behalf of children born *after* the 2015 amendments, the claims still arose *before* then because the mothers were using opioids and defendants were allegedly contributing to the opioid crisis before then. *See* Br. at 25. But it is well settled that a tort claim does not accrue until an alleged injury occurs. *See*, *e.g.*, Syl. pt. 1, *Jones v. Trustees of Bethany College*, 177 W.Va. 168, 351 S.E.2d 183 (1986) (medical malpractice/negligence); *Teter v. Old Colony Co.*, 190 W. Va. 711, 722, 441 S.E.2d 728, 739 (1994) (fraud); *Goodwin v. Bayer Corp.*, 218 W. Va. 215, 220, 624 S.E.2d 562, 567 (2005) (products liability). And since the complaints here allege that the children were injured at birth, their claims did not accrue until after the 2015 amendments had been enacted..

of Van Emburgh, 95 F.4th at 800; see also In re E.B., 229 W. Va. 435, 468, 729 S.E.2d 270, 303 (2012) ("When a case has proceeded to its ultimate resolution below, it is manifestly unfair for a party to raise new issues [before this Court]. . . . [T]here is also a need to have the issue refined, developed, and adjudicated by the trial court, so that we may have the benefit of its wisdom." (quoting Whitlow v. Bd. of Educ. of Kanawha Cnty., 190 W.Va. 223, 226, 438 S.E.2d 15, 18 (1993)).

In any event, the argument is also meritless. The MPLA itself makes clear that the 2015 amendments "apply to *all causes of action* alleging medical professional liability which are *filed on or after* July 1, 2015," W. Va. Code §55-7B-10(b) (emphases added)—not just those that *arose* from events occurring after 2015. In this respect, the 2015 amendments differ from the 2017 amendments to the MPLA, which were expressly made applicable only to "causes of action alleging medical professional liability which ar[o]se or accrue[d] on or after July 1, 2017." *Id.* § 55-7B-10(c). Plainly, the Legislature knows exactly how to limit the applicability of a MPLA amendment to causes of action that arise from events post-dating the amendment if that is what it wants to do. Plaintiffs ignore this distinction entirely. Indeed, they do not even mention Section 10(b), and they do not argue that it does not govern their claims.

Even if Plaintiffs had tried to challenge the validity of Section 10(b)'s timing provision, they would fail. The Supreme Court of Appeals of West Virginia has repeatedly made clear that, when it comes to the effective date of MPLA provisions, courts "are undoubtedly bound to adhere to such a direct expression of legislative intent." In doing so, moreover, the Court has held that other amendments to the MPLA applied based on the filing date of a lawsuit. *Cartwright v. McComas*, 223 W. Va. 161, 167, 672 S.E.2d 297, 303 (2008) (2003 MPLA amendments applied

based on filing date); *State ex rel. Miller v. Stone*, 216 W. Va. 379, 384, 607 S.E.2d 485, 490 (2004) (2003 MPLA amendments applied to later-filed claim that had accrued before amendments); *Blankenship v. Ethicon, Inc.*, 221 W. Va. 700, 703, 656 S.E.2d 451, 454 (2007) (2001 MPLA amendments applied based on filing date); *compare State ex rel. PrimeCare Med. of W. Virginia, Inc*, 242 W. Va. at 340 & n.4, 835 S.E.2d at 584 & n.4 (2017 amendments expressly applied based on claim accrual). Because all of Plaintiffs' suits were filed after 2015,⁸ the post-2015 version of the MPLA applies.

Second, Plaintiffs contend that the MLP erred in dismissing the claims against Pharmacy Defendants with prejudice. Br. at 26. But the Supreme Court of Appeals has "decline[d] to hold that dismissal with prejudice is never proper where a plaintiff fails to comply with the pre-suit notice requirements of the MPLA." Tanner, 246 W. Va. at 368–69, 873 S.E.2d at 899–900; see id. at 368–69, 873 S.E.2d at 899–900 (precedent treating ambiguous MPLA dismissals as dismissals without prejudice "implies that the circuit court may dismiss such action with prejudice"). Indeed, dismissal with prejudice has been found proper where a plaintiff's pre-suit filings "did not represent a good faith and reasonable effort to further the purposes of the MPLA," namely, "preventing the making and filing of frivolous medical malpractice claims and lawsuits; and promoting the pre-suit resolution of non-frivolous medical malpractice claims." Pendleton v.

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⁸ Blankenship, 22-C-05 (filed Jan. 14, 2022); Otwell, 22-C-20 (filed Mar. 28, 2022); Boswell, 22-C-21 (filed Mar. 28, 2022); Lambert, 22-C-22 (filed Mar. 28, 2022); Mangus, 22-C-23 (filed Mar. 28, 2022); Harris, 22-C-24 (filed Mar. 28, 2022); Woolwine, 22-C-25 (filed March 28, 2022); Whited, 22-C-26 (filed Mar. 28, 2022); Adkins, 22-C-27 (filed Mar. 28, 2022); Brooks, 22-C-28 (filed Mar. 28, 2022); Adams, 22-C-29 (filed Mar. 28, 2022); Anderson, 22-C-30 (filed Mar. 28, 2022); Paynter, 22-C-31 (filed Mar. 28, 2022); Fuller, 22-C-32 (filed Mar. 28, 2022); Johnson, 22-C-33 (filed Mar. 28, 2022); Swift, 22-C-34 (filed Mar. 28, 2022); Stacey, 22-C-35 (filed Mar. 28, 2022); Johnson, 22-C-36 (filed Mar. 28, 2022).

Wexford Health Sources, Inc., No. 15-0014, 2015 WL 8232155 at *3 (W. Va. Dec. 7, 2015) (memorandum decision) (upholding dismissal with prejudice).

Here, Plaintiffs did not make reasonable, good-faith efforts to comply with the MPLA. To the contrary, they made no effort whatsoever to comply with it, despite its clear application to their claims. Nor did Plaintiffs seek to rectify their failure when Pharmacy Defendants raised the MPLA in their motion to dismiss. This alone supports dismissal with prejudice. Moreover, allowing Plaintiffs to re-file their lawsuits after complying with the MPLA—even assuming that they could find a medical professional willing to file the requisite certificate of merit—would be futile. The MLP correctly held that there were many other reasons to dismiss all of Plaintiffs' claims against all Defendants, as addressed below. No provision of the MPLA requires this Court to compel the parties and the MLP to waste time re-processing Plaintiffs' doomed claims.

II. THE MLP CORRECTLY DISMISSED PLAINTIFFS' CLAIMS AGAINST INDIVIOR.

This Court should affirm the MLP's dismissal of Plaintiffs' claims against Indivior for three reasons beyond those that apply to all Defendants. First, Indivior's unique status in this litigation as a manufacturer of OUD-treatment products entitles it to independent dismissal as a matter of law. Second, Plaintiffs failed to allege sufficient facts to support a reasonable inference that the Minors' alleged injuries were proximately caused by their birth mothers' use of any Indivior product during their pregnancies. And third, Plaintiffs failed to allege sufficient facts to support a claim against Indivior for any civil conspiracy.

A. The MLP Correctly Held That Indivior Is Independently Entitled to Dismissal As A Matter Of Law

As an initial matter, the MLP correctly held that Indivior is entitled to dismissal because it, unlike other Manufacturer Defendants, does *not* manufacture Schedule II opioids for chronic pain. Rather, Indivior manufactures "Suboxone and Subutex, which are Schedule III buprenorphinebased medications indicated for the treatment of OUD, not for the treatment of chronic pain." JA121. As the MLP found: "Plaintiffs allege that the Minors' birth mothers' addictions were initiated and caused by the use of opioids indicated for chronic pain before they ever used an Indivior product to treat their OUD." Id. In fact, Plaintiffs admitted as much at oral argument, conceding: "You're right, no one started their addiction with a Subutex strip." JA259. Plaintiffs acknowledge this same point in their brief. See Br. at 27-28. Accordingly, the record is clear that no Indivior product initiated or caused the opioid addiction that allegedly afflicted the Minors' birth mothers, as the MLP explicitly recognized in its Final Order. JA121. The Minors' birth mothers were only prescribed Indivior's buprenorphine-based Schedule III products after they developed OUD. For this reason, Plaintiffs' claims against Indivior should be dismissed because their allegations regarding other Manufacturer Defendants cannot be applied to Indivior. See JA121.

B. The MLP Correctly Held That Plaintiffs Failed to Establish Proximate Causation As To The Claims Against Indivior

For the reasons addressed in Section IV below and in Defendants' Prior Brief, this Court should affirm the MLP's holding that Plaintiffs failed to establish proximate cause as to *any* Defendant. In addition, the MLP's holding should be affirmed for several additional reasons specific to Indivior.

The Court should affirm the dismissal of Plaintiffs' claims against Indivior for lack of proximate cause for at least one of the following reasons: (1) the complaint does not allege the birth mother *consumed* an Indivior product during pregnancy⁹; or (2) even if the complaint alleges the birth mother used an Indivior product during pregnancy, the complaint explicitly states the birth mother consumed *multiple additional* opioid products during pregnancy.¹⁰ JA2615–21.

For these additional reasons, Plaintiffs fail to show proximate cause as to any cause of action against Indivior. Therefore, this Court should affirm the dismissal of claims not only as to all Defendants but also as to Indivior for these additional reasons.

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⁹ Allegations that a birth mother consumed generic buprenorphine are not sufficient to allege proximate causation as to Indivior because Indivior did not produce or market generic buprenorphine products. Plaintiffs cannot plead that a birth mother was prescribed or consumed generic "Buprenorphine," then, for the first time on appeal, assert that any reference to "Buprenorphine" should be taken to mean Indivior's branded products Suboxone and Subutex. Br. at 27–33. Plaintiffs make specific allegations regarding Suboxone and Subutex for the first time on appeal, but they never defined "Buprenorphine" in any complaint to encompass Indivior's products. *See generally* JA2423–2507; JA2785–2871; JA2933–3016; JA3097–03180; JA4022–4103. Plaintiffs cannot try to rewrite their complaints now with arguments such as: "The Complaint is not clear that the 'Buprenorphine treatment' was not Suboxone." Br. at 32.

¹⁰ Plaintiffs Fuller, Harris, Whited and Woolwine's claims must fail because the Complaints do not allege that the Minors' birth mother consumed any of Indivior's products during their pregnancy. *See* JA4023 6, 8; *Id.* ¶ 220; JA2786 ¶ 7; JA2829–30 ¶¶ 234, 238; JA2828 ¶ 6, 8; JA4064 ¶ 220; JA3139 ¶ 221; JA2934 ¶ 1; JA2979 ¶ 227; JA2934 ¶¶ 1, 6. Plaintiff Lambert's claims must also fail because her Complaint does not allege that the Minors' birth mother ever used an Indivior product during her pregnancy with the older Minor, and admits that, while she alleges she did use Subutex during her pregnancy with the younger Minor, she *also* used *numerous* other opioid products not manufactured by Indivior throughout both of her pregnancies. *See* JA2424 ¶¶ 5–7, JA2465 ¶ 221.

C. The MLP Correctly Dismissed Plaintiffs' Civil Conspiracy Claims Against Indivior

Plaintiffs' civil conspiracy claims should be dismissed as to all Defendants for the reasons stated in Section VII below, and also for the following additional reasons specific to Indivior.

In particular, the purported conspiracy alleged in the Complaints is for the promotion and marketing of opioids for the treatment of *pain*. *See* JA4065–66 ¶¶ 232–33; JA2830–31¶¶ 239–40; JA2979–80 ¶¶ 228–29; JA2465–66 ¶¶ 222-23; JA3139–40 ¶¶ 222–23. Yet Plaintiffs fail to allege any facts demonstrating Indivior was part of the alleged *pain-centered* conspiracy. Plaintiff's allegations regarding other Manufacturing Defendants' alleged conspiracy do not encompass Indivior because Indivior's products Suboxone and Subutex are Schedule III buprenorphine-based medications intended for the treatment of OUD—which are unlike the products of other Manufacturing Defendants intended for the treatment of *pain*. For this additional reason, the Court should affirm the dismissal of Plaintiffs' civil conspiracy claims against Indivior, as the MLP explicitly recognized in its opinion. *See* JA121.

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In their opening brief, apparently recognizing the shortcoming in their Complaints, Plaintiffs improperly rely on their own statements made at oral argument to claim that Indivior was part of the alleged conspiracy to promote opioids for the treatment of pain. Plaintiffs say that Indivior must have been part of this conspiracy because increased marketing and sales of opioids for pain increased the number of people who become addicted to opioids, which in turn resulted in a larger market relying on products that "treat the addiction or OUD." Br. at 27–28, 29 n.159, 33; *see also id.* at 30 n.161. The complaints, however, contain none of these allegations—which, even if taken as true, still fail to allege any cognizable claim of conspiracy against Indivior. It is well established under West Virginia law that "[o]nly matters contained in the pleading can be considered on a motion to dismiss under Rule 12(b) R.C.P." *Mountaineer Fire & Rescue Equip., LLC v. City Nat'l Bank of W. Virginia*, 244 W. Va. 508, 854 S.E.2d 870, 876 (2020). Moreover, "matters outside the pleadings include statements of counsel at oral argument raising new facts not alleged in pleadings." *E.K. v. W. Virginia Dep't of Health*, No. 16-0773, 2017 WL 5153221, at *4 n.4 (W. Va. Nov. 7, 2017) (citation omitted). This Court likewise cannot consider these attenuated arguments now for the first time on appeal.

III. THE MLP CORRECTLY HELD THAT DEFENDANTS DID NOT OWE A DUTY OF CARE TO PLAINTIFFS.

These 18 Plaintiffs do not dispute that the decision whether a duty was owed in a given case "must be rendered by the court as a matter of law." *See Aikens v. Debow*, 208 W. Va. 486, 491, 541 S.E.2d 576, 581 (2000). However, Plaintiffs argue, contrary to West Virginia precedent, that the foreseeability of a given risk is the exclusive consideration in determining whether a duty is owed. This is flatly wrong, as the MLP's decision makes clear. In dismissing Plaintiffs' claims, the MLP did not ignore the element of foreseeability, but instead correctly held that ""[i]mportantly... the existence of duty *also involves* policy considerations underlying the core issue of the scope of the legal system's protection." JA114 (emphasis added, quoting *Stevens v. MTR Gaming Grp., Inc.*, 237 W. Va. 531, 535, 788 S.E.2d 59, 63 (2016) (quotation omitted)). Applying this standard, the MLP appropriately considered additional "pertinent factors," such as "the likelihood of injury, the magnitude of the burden of guarding against it, and the consequences of placing that burden on the defendant." JA114.

As discussed in Defendants' Prior Brief (at 28–33), these factors overwhelmingly support the MLP's decision. The MLP correctly recognized that, if the "manufacturers, distributors, and pharmacies (along with the WVBOP and McKinsey, a consulting firm)" owed these private plaintiffs a duty of care, that duty would similarly extend to "any private party in this State" who suffers harm caused by the conduct of those suffering from opioid addiction—"no matter how far removed from any Defendant or its alleged conduct, and irrespective of the intervening conduct of numerous other actors, including the birth mothers." JA115.

The lack of a duty of care in these circumstances follows from the Supreme Court of Appeals decision in *Stevens*, which relied on public-policy considerations to hold that casinos and manufacturers of gambling devices did not owe a duty to prevent harms resulting from gambling addiction. 237 W. Va. at 538, 788 S.E.2d at 66. Although such harms are foreseeable, the Court held that imposing a common-law tort duty would interfere with the detailed regulatory scheme applicable to casinos, which already strikes the proper balance between the harms and benefits of casino gambling. Id. So too with prescription opioid medications: there is a detailed regulatory scheme that takes into account both the benefits of pain relief and the dangers of addiction, and accordingly governs how such medications should be manufactured, distributed, prescribed, and dispensed. In light of that regulatory scheme, imposing common-law tort duties for manufacturers and distributors of prescription medications, and the pharmacies who fill the prescriptions that doctors write, would be contrary to public policy. To be sure, doctors have a duty of care to prescribe such medications lawfully and responsibly, and birth mothers have a duty of care not to illegally obtain and use opioids, or otherwise to abuse such medications during pregnancy. But if they violate those duties, the resulting harms are not attributable to the companies that manufactured or distributed the medications or filled the prescriptions the doctors wrote.

Plaintiffs do not seriously contest that these policy considerations support the MLP's dismissal for lack of duty. Their argument based on public policy considerations consists of only a one-sentence assertion that the risk of addiction to minors *in utero* is high, that the burden imposed on Defendants is "no greater than they already face," and that "there is an absence of adverse consequences of placing the burden on the Defendants." Br. at 39. This unsupported sentence does not address the fundamental public policy concern that would result if a duty is

extended here. Such a duty would interfere with the carefully developed federal and state regulatory systems that are already in place governing the relevant activities of Defendants, and which would impose liability on Defendants "no matter how far removed from any Defendant or its alleged conduct, and irrespective of the intervening conduct of numerous other actors, including the birth mothers." JA115. West Virginia case law makes clear that the presence of an extensive regulatory system governing the products at issue weighs heavily against imposing a duty in such circumstances. *See Stevens*, 237 W. Va. at 538, 788 S.E.2d at 66.

Plaintiffs also argue against a strawman, claiming that the MLP "reached the incorrect conclusion that any intervening act, even foreseeable ones, relieves the Defendants from owing a duty of care." Br. at 39 (emphasis in original). In reality, the MLP reached no such conclusion. Rather, it found that three specific intervening actors—the doctors who allegedly prescribed opioids to the birth mothers, the birth mothers who allegedly took prescription or illicit opioids while pregnant and, in some cases, third parties who provided illegally-obtained opioids to the birth mothers —owed their own duties of care to the Minors to prevent harm arising from their own intentional acts. JA115-16, 119. The MLP then contrasted these intentional intervening actors with Defendants—who had no ability to control the prescribing decisions of physicians, the drug use of the birth mothers, or the illegal acts of third parties—and found that "Defendants do not owe a duty of care to prevent individuals from illicitly obtaining opioids through those individuals' own illegal conduct or through illegal conduct by third parties who divert opioids after they have left Defendants' or third parties' custody and control." Id. (citing Miller v. Whitworth, 193 W. Va. 262, 266, 455 S.E.2d 821,825). In consideration of the policy arguments above, the attenuated chain of causation between Defendants and Plaintiffs' alleged harm, and the specific intervening acts of prescribing doctors, birth mothers, and third parties who provided illegally-obtained opioids to the birth mothers, the MLP's decision that no duty ran specifically from Defendants to these individual Plaintiffs was clearly correct and should be affirmed. *See* Defendants' Prior Brief at 31–33.

IV. THE MLP CORRECTLY HELD THAT PLAINTIFFS CANNOT ESTABLISH PROXIMATE CAUSATION

Plaintiffs' proximate causation argument is based on a misreading of the MLP's order. Notwithstanding the MLP's unambiguous finding that "Plaintiffs' alleged injuries are too remote from Defendants' conduct to establish proximate causation," JA117, Plaintiffs argue that the MLP "simply referred to its actual conclusion . . . by a different name 'Remoteness' to avoid the requisite foreseeability analysis." Br. at 42. This wholly misstates what the MLP held. In fact, the MLP found a lack of proximate causation based not on a lack of foreseeability but because the actions of Defendants were "remote as distinguished from proximate, and, therefore, not actionable" as a matter of law. *Webb v. Sessler*, 135 W. Va. 341, 348–49, 63 S.E.2d 65, 69 (1950); *see* Defendants' Prior Brief at 8–14.

The MLP's decision mirrors the standard set out in *Wal-Mart Stores East, L.P. v. Ankrom*, 244 W. Va. 437, 450–51, 854 S.E.2d 257, 270–71 (2020), a case Plaintiffs cite, Br. at 22. That case discussed the rule that a negligent or intentional intervening cause may break the chain of causation if it was not foreseeable by the initial actor. Contrary to Plaintiffs' argument, the decision did not address the separate element of remoteness and did not overrule the decades of West Virginia precedent establishing the role of remoteness in evaluating proximate cause. *See, e.g., Metro v. Smith*, 146 W. Va. 983, 990, 124 S.E.2d 460, 464 (1962) (a defendant's conduct

"must be a proximate, *not a remote*, cause of injury" to establish proximate causation (emphasis added)); *Aikens v. Debow*, 208 W. Va. 486, 492, 541 S.E.2d 576, 582 (2000) ("[T]he doctrine of remoteness is a component of proximate caus[ation]" (quotation omitted)); *Webb*, 135 W. Va. at 349, 63 S.E.2d at 69 ("remote causes of the injury . . . do not constitute actionable negligence"). 12

Plaintiffs also criticize the MLP for failing to distinguish between Plaintiffs whose mothers "illegally obtained opioids" during pregnancy, and those who only ingested "prescribed opioids." Br. at 41–42. Not so. To start, this argument itself implicitly recognizes that the MLP's decision was unassailable for those Plaintiffs whose mothers engaged in intentional criminal behavior that proximately caused the harm in question. *See, e.g., Miller*, 193 W. Va. at 266; 455 S.E.2d at 826 (recognizing that intervening criminal conduct typically negates liability). In any case, as the MLP recognized, there is no way to lawfully use opioid medications during pregnancy without a prescription. JA115-116. Thus, even birth mothers who did not engage in criminal activity necessarily must have obtained prescriptions from doctors to use opioids during pregnancy, which necessarily and proximately caused each Minor's alleged NAS. JA120. In that situation, the doctors' decisions to prescribe opioid medications for use during pregnancy (in addition to the birth mothers' decision to continue using those medications during pregnancy) are intentional acts that "constitute[] a new effective cause and operate[] independently of any other act, making

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¹² The MLP's decision is also entirely consistent with West Virginia law governing products liability claims, and with the MLP's past orders concerning political subdivisions. Defendants have already addressed Plaintiffs' arguments on these subjects in Defendants' Prior Brief at 9–12, 15–16.

[them] and [them] only, the proximate cause of the injury." *Marcus v. Staubs*, 230 W. Va. 127, 139, 736 S.E.2d 360, 372 (2012) (quotation omitted).

Plaintiffs also assert that the MLP's holding "would provide sellers and manufacturers of prescription drugs with blanket immunity against all product liability claims premised on birth defects, no matter how negligent or even fraudulent." Br. at 42. But Plaintiffs' claims are not based on any allegations or theory that any particular opioid medications were defective or that such a defect caused Plaintiffs' alleged harms, so it is wrong to suggest that the MLP's decision would extend to provide "blanket immunity" beyond the facts of these cases. Instead, the MLP's decision is based on the Plaintiffs' own factual allegations in these specific cases. Those factual allegations make clear that Plaintiffs were not directly harmed by using the products in question, but instead by the actions of third parties, including, in particular, the intentional actions of prescribing doctors, the birth mothers, and possibly other third parties who engaged in the criminal diversion of prescription opioid medications. Under these facts, and in light of the multi-link causation theories involved, the MLP's dismissal was entirely consistent with West Virginia law. See Defendants' Prior Brief at 14–16.

Finally, because Plaintiffs themselves alleged the causal chain at issue here, and because those allegations would not allow a reasonable person to draw a different conclusion, proximate cause was appropriately decided as a matter of law by the MLP and need not be reserved for the jury. *See Evans v. Farmer*, 148 W. Va. 142, 143, 133 S.E.2d 710, 711 (1963).

V. THE MLP CORRECTLY DISMISSED PLAINTIFFS' CLAIMS AGAINST THE WEST VIRGINIA BOARD OF PHARMACY

Plaintiffs' arguments with respect to the WVBOP are not substantively different from the arguments made by the plaintiffs in the Prior Appeal. The WVBOP's briefing on the issues in its "Response Brief of the West Virginia Board of Pharmacy" filed in the Prior Appeal clearly refutes and sets forth numerous legal reasons why this Court should affirm the MLP's decision. Therefore, the WVBOP incorporates by reference the "Response Brief of the West Virginia Board of Pharmacy" filed in the Prior Appeal. That brief is fully responsive to Plaintiffs' arguments here and demonstrates that the MLP was entirely correct in dismissing claims against the WVBOP under the Public Duty Doctrine and the doctrines of Qualified Immunity and Absolute Immunity. Beyond the MLP's holdings specific to the WVBOP, the Court should affirm the dismissal of Plaintiffs' claims against the WVBOP for the additional reasons addressed here and in Defendants' Prior Brief.

VI. THE MLP CORRECTLY DISMISSED PLAINTIFFS' MEDICAL MONITORING CLAIMS

As Plaintiffs recognize, Br. at 26, the MLP's dismissal of their claims for medical monitoring was based on its dismissal of all of their other claims, which are addressed elsewhere in this brief and in Defendants' Prior Brief. As the MLP noted: "Although a plaintiff may 'as a matter of pleading, assert a separate cause of action based upon medical monitoring,' 'liability must be established" through application of existing theories of tort liability. JA122 (*quoting Bower v. Westinghouse Elec. Corp.*, 206 W. Va. 133, 142, 522 S.E.2d 424, 433 (1999)). Because the MLP's dismissal of those other claims was fully supported, Plaintiffs' medical monitoring claims cannot proceed.

VII. THE MLP CORRECTLY HELD THAT PLAINTIFFS CANNOT PROCEED WITH THEIR CIVIL CONSPIRACY CLAIMS

Plaintiffs acknowledge (Br. at 45) that their claims for civil conspiracy should be dismissed if they fail to state a claim on the alleged torts underlying the putative conspiracy. *See, e.g., O'Dell v. Stegall,* 226 W. Va. 590, 625, 703 S.E.2d 561, 596 (2010) ("a civil conspiracy must be based on some underlying tort or wrong"). Because the MLP correctly dismissed Plaintiffs' tort claims, their claims for civil conspiracy likewise cannot proceed. *See* Defendants' Prior Brief at 33.

VIII. THE MLP CORRECTLY DISMISSED PLAINTIFFS' FRAUD CLAIMS

Plaintiffs' allegations of "fraud" require a showing of proximate causation. *See* Defendants' Prior Brief at 34. For this reason, as explained above and in Defendants' Prior Brief, the MLP correctly dismissed Plaintiffs' fraud claims upon concluding that they had failed to sufficiently plead proximate causation. JA172.

IX. THE MLP CORRECTLY DISMISSED PLAINTIFFS' CLAIM FOR PUNITIVE DAMAGES

Plaintiffs acknowledge that their claims for punitive damages "are not intended as a standalone cause of action." Br. at 48. For that reason, because the MLP's decision to dismiss Plaintiffs' underlying tort claims was fully supported, Plaintiffs' punitive damages claims cannot proceed. *See, e.g., Roche v. Lincoln Prop. Co.*, 175 F. App'x 597, 606 (4th Cir. 2006) (dismissing punitive damages claim because plaintiff's "underlying" common law claims were barred).

X. THE MLP CORRECTLY DISMISSED PLAINTIFFS' CLAIMS WITH PREJUDICE

The MLP's decision to dismiss Plaintiffs' complaints with prejudice and without leave to amend was correct for two independent reasons. First, Plaintiffs never moved for leave to amend.

If Plaintiffs do not move for leave to amend in the trial court, they cannot raise that issue for the first time on appeal. *See*, *e.g.*, *In re E.B.*, 229 W. Va. 435, 467, 729 S.E.2d 270, 302 (2012) ("[T]his Court will not pass on a nonjurisdictional question which has not been decided by the trial court in the first instance.") (quotation omitted). Because a trial court "does not abuse its discretion by declining to grant a request to amend when it is not properly made as a motion," *ACA Fin. Guar. Corp. v. City of Buena Vista*, 917 F.3d 206, 218 (4th Cir. 2019), it cannot be reversible error for a trial court to dismiss with prejudice when Plaintiffs never moved for leave to amend. *See* Defendants' Prior Brief at 34–35.

While Plaintiffs now say that they raised amendment during oral argument before the MLP (Br. at 50), they *never* requested leave to amend to address or cure any of the deficiencies identified in briefing on the motion to dismiss. Instead, they made only passing comments that they might want to change the "emphasis" of certain complaints (JA247) or add facts or claims after the close of discovery (JA329, JA331). Critically, after making those remarks, Plaintiffs specifically and expressly *disavowed* any intent to amend the Complaints. JA353.

In any event, the crucial point is that Plaintiffs never asked the MLP for leave to amend despite having ample opportunity to do so. The MLP issued an initial Order dismissing Plaintiffs' Complaints on April 17, 2023, and did not issue its Final Order dismissing the Complaints with prejudice until May 31, 2023. In that six-week window, Plaintiffs did not move for leave to amend, even as they filed objections to the MLP's Order before it was issued on May 31, 2023. Having waived this issue before the MLP, Plaintiffs cannot raise it for the first time on appeal as an assignment of error. *See In re E.B.*, 229 W. Va. at 467, 729 S.E.2d at 302.

Second, and apart from having waived the issue, Plaintiffs fail to make any showing of what amendment would accomplish. They do not identify a single factual allegation they would add if amendment were permitted, nor do they even attempt to explain how any such amendment would alter the MLP's rationale for dismissal of their claims. *See ACA Fin.*, 917 F.3d at 218 (affirming denial of leave to amend where plaintiffs "never indicated what amendments they were seeking" and "never identified any facts they sought to include in an amendment"). This failure is particularly notable because Defendants highlighted this exact same deficiency in Defendants' Prior Brief (at 36) three months ago. Despite all of this time to consider the point, these 18 Plaintiffs *still* fail to identify *any* additional allegations they believe would alter the MLP's dismissal of their claims.

In any case, amendment would be futile because the MLP dismissed Plaintiffs' claims based on purely legal deficiencies arising from Plaintiffs' own allegations—deficiencies that cannot be cured by amendment, including Plaintiffs' failure to plead proximate cause or the existence of a duty running from Defendants to Plaintiffs. *See Vogt v. Am. Arb. Ass'n*, No. 19-0676, 2020 WL 3469214, at *3 (W. Va. June 25, 2020) (upholding denial of leave to amend where amendment would have been futile). In fact, Plaintiffs do not even argue that they could avoid the MLP's dispositive legal rulings through amendment.

In short, for all these reasons, the MLP correctly dismissed Plaintiffs' claims without leave to amend.

CONCLUSION

For the foregoing reasons, and the reasons set out separately in the Defendants' Prior Brief, the Court should affirm the MLP's order dismissing Plaintiffs' claims with prejudice.

Jeffrey M. Wakefield (WVSB #3894) Amy Rothman Malone (WVSB #10266) FLAHERTY SENSABAUGH BONASSO PLLC 200 Capitol Street Charleston, WV 25301 (304) 345-0200 jwakefield@flahertylegal.com

Timothy C. Hester (pro hac vice) COVINGTON & BURLING LLP One CityCenter 850 Tenth Street, NW Washington, DC 20001

(202) 662-6000 thester@cov.com

/s/ Timothy C. Hester

Counsel for McKesson Corporation

Patricia M. Bello (WVSB #11500)
Tim J. Yianne (WVSB #8623)
LEWIS BRISBOIS BISGAARD & SMITH, LLP
707 Virginia Street E., Ste. 1400
Charleston, West Virginia 25301
(304) 553-0166
patricia.Bello@lewisbrisbois.com
tim.yianne@lewisbrisbois.com

Counsel for Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.

John H. Tinney, Jr., Esquire (WVSB# 6970) Keith A. Jones, Of Counsel (WVSB# 1923) HENDRICKSON & LONG, PLLC 214 Capitol Street Charleston, WV 25339 (304) 346-5500 jtinney@handl.com kjones@handl.com

Lauren E. O'Donnell, Esquire (pro hac vice)
BLANK ROME LLP
One Logan Square
130 N. 18th Street
Philadelphia, PA 19103
(215) 569-5735
lauren.odonnell@blankrome.com

Counsel for Anda, Inc.

Wm. Scott Wickline (WVSB# 6100) Pence Law Firm PLLC 10 Hale Street, 4th Floor Charleston, WV 25301 (304) 345-7250 scott@pencefirm.com

Jeffrey D. Geoppinger (pro hac vice) UB GREENSFELDER LLP 312 Walnut Street, Suite 1400 Cincinnati, Ohio 45202-4029 (513) 698-500 jgeoppinger@ubglaw.com

Counsel for Defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC

Wm. Scott Wickline (WVSB# 6100) PENCE LAW FIRM PLLC 10 Hale Street, 4th Floor Charleston, WV 25301 (304) 345-7250 scott@pencefirm.com

Counsel for Specially Appearing Defendants Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC Gretchen M. Callas (WVSB #7136) Candice M. Harlow (WVSB #12496) JACKSON KELLY PLLC Post Office Box 553 Charleston, West Virginia 25322 (304) 340-1000 gcallas@jacksonkelly.com charlow@jacksonkelly.com

Robert A. Nicholas (pro hac vice)
Joseph J. Mahady (pro hac vice)
Anne R. Bohnet (pro hac vice)
REED SMITH LLP
1717 Arch Street, Suite 3100
Philadelphia, PA 19130
(215) 851-8100
rnicholas@reedsmith.com
jmahady@reedsmith.com
abohnet@reedsmith.com

Kim M. Watterson (pro hac vice) REED SMITH LLP 225 Fifth Avenue Pittsburgh, PA 15222 (412) 288-3131 kwatterson@reedsmith.com

Counsel for AmerisourceBergen Drug Corp. and AmerisourceBergen Corporation (n/k/a Cencora, Inc.

Marc E. Williams (WVSB #4062)
Robert L. Massie (WVSB #5743)
Shaina D. Massie (WVSB # 13018)
Alexander C. Frampton (WVSB # 13398)
NELSON MULLINS RILEY &
SCARBOROUGH LLP
949 Third Avenue, Suite 200
Huntington, WV 25701
(304) 526-3500
marc.williams@nelsonmullins.com
bob.massie@nelsonmullins.com
shaina.massie@nelsonmullins.com
alex.frampton@nelsonmullins.com

Counsel for Johnson & Johnson and Janssen Pharmaceuticals. Inc.

Todd A. Mount (WVSB #6939) SHAFFER & SHAFFER, PLLC 330 State Street Madison, WV 25130 (304) 369-0511 tmount@shafferlaw.net

Brian T. Himmel (pro hac vice) REED SMITH LLP 225 Fifth Avenue Pittsburgh, PA 15222 (412) 288-3131 bhimmel@reedsmith.com

Counsel for H. D. Smith LLC, H. D. Smith Holdings, LLC, and H. D. Smith Holding Company

Trisha R. Hudkins (WVSB #12667) BERNSTEIN-BURKLEY, P.C. 32 20th Street, Suite 301 Wheeling, WV 26003 (412) 456 8105 thudkins@bernsteinlaw.com

Counsel for Hikma Pharmaceuticals USA Inc.

Mychal S. Schulz (WV Bar #6092)
Robert M. Stonestreet (WV Bar #9370)
Austin D. Rogers (WV Bar #13919)
BABST CALLAND, P.C.
300 Summers Street, Suite 1000
Charleston, WV 25301
681-265-8888
681-205-8814 (fax)
mschulz@babstcalland.com
rstonestreet@babstcalland.com
arogers@babstcalland.com

Maria R. Durant (pro hac vice) HOGAN LOVELLS US LLP 125 High Street, Suite 2010 Boston, MA 02110 617-371-1024 617-371-1037 (fax) maria.durant@hoganlovells.com

Counsel for Indivior Inc.

Steven R. Ruby (WVSB #10752) Raymond S. Franks II (WVSB #6523) CAREY DOUGLAS KESSLER & RUBY PLLC 707 Virginia Street East, Suite 901 Charleston, WV 25301 Telephone: (304) 345-1234 sruby@cdkrlaw.com rfranks@cdkrlaw.com

Jennifer G. Wicht (pro hac vice)
William J. Donnelly (pro hac vice)
Williams and Connolly LLP
680 Maine Avenue, SW
Washington, DC 20024
(202) 434-5000
jwicht@wc.com
wdonnelly@wc.com

Counsel for Cardinal Health, Inc.

Ronda L. Harvey Esq. (WVSB #6326)
Ashley Hardesty Odell, Esq. (WVSB #9380)
Fazal A. Shere, Esq. (WVSB #5433)
Aaron C. Boone, Esq. (WVSB #9479)
Ryan S. Moore, Esq. (WVSB #14155)
BOWLES RICE LLP
600 Quarrier Street
Charleston, West Virginia 25301
(304) 347-1100
rharvey@bowlesrice.com
ahardestyodell@bowlesrice.com
fshere@bowlesrice.com
aboone@bowlesrice.com
rmoore@bowlesrice.com

Counsel for The Kroger Co.

Teresa J. Dumire, Esq. (WVSB #8032)
Margaret E. Lewis, Esq. (WVSB #10329)
KAY CASTO & CHANEY PLLC
50 Clay Street, Suite 100
Morgantown, WV 26501
Phone: (304) 225-0970
tdumire@kaycasto.com
mlewis@kaycasto.com

John D. Hoblitzell, III, Esq. (WVSB #9346) KAY CASTO & CHANEY PLLC PO Box 2031 Charleston, WV 25327 Phone: (304) 345-8900 jdhoblitzell@kaycasto.com

Jennifer L. Maloney, Esq. (Pro hac vice)
BAKER STERCHI COWDEN & RICE LLC
100 North Broadway, Suite 2100
St. Louis, MO 63102
Phone: (314) 345-5000
jmaloney@bakersterchi.com

Thomas E. Rice, Esq. (pro hac vice)
John A. Watt, Esq. (pro hac vice)
BAKER STERCHI COWDEN & RICE LLC
2400 Pershing Road, Suite 500
Kansas City, MO 64108
(816) 471-2121
rice@bakersterchi.com
watt@bakersterchi.com

Counsel for KVK-Tech, Inc.

Carte P. Goodwin (WVSB #8039) Joseph M. Ward (WVSB #9733) Alex J. Zurbuch (WVSB #12838)

FROST BROWN TODD LLC

500 Virginia Street East, Suite 1100

Charleston, WV 25301 Telephone: 304-348-2419

Fax: 304-345-0115

Email: cgoodwin@fbtlaw.com Email: jward@fbtlaw.com Email: azurbuch@fbtlaw.com

Paul B. Hynes, Jr., (*pro hac vice*) Margarita K. O'Donnell (*pro hac vice*) Christopher R. MacColl (*pro hac vice*)

ZUCKERMAN SPAEDER LLP 1800 M Street, NW STE 1000

Washington, DC 20036 Telephone: 202-778-1800

Email: phynes@zuckerman.com Email: modonnell@zuckerman.com Email: cmaccoll@zuckerman.com

Counsel for CVS Pharmacy, Inc., CVS Indiana, L.L.C., CVS Rx Services, Inc., CVS TN Distribution, L.L.C., West Virginia CVS Pharmacy, L.L.C.

Bryant J. Spann (WVSB #8628) Robert H. Akers (WVSB #9622) Susan W. Romaine (WVSB #9936) THOMAS COMBS & SPANN, PLLC

P.O. Box 3824

Charleston, WV 25338-3824

Tel: 304.414.1800 bspann@tcspllc.com rakers@tcspllc.com swromaine@tcspllc.com

Counsel for Walgreens Boots Alliance, Inc., Walgreen Co., and Walgreen Eastern Co., Inc. Justin C. Taylor (WVSB #8014)
BAILEY & WYANT, PLLC
500 Virginia Street, East, Suite 600
Post Office Box 3710

Charleston, West Virginia 25337-3710

(304) 345-4222

itaylor@baileywyant.com

Counsel for West Virginia Board of Pharmacy

John H. Tinney, Jr. (WVSB# 6970) Keith A. Jones (WVSB# 1923) HENDRICKSON & LONG, PLLC 214 Capitol Street Charleston, WV 25339 (304) 346-5500 jtinney@handl.com kjones@handl.com

Terry M. Henry (pro hac vice) BLANK ROME LLP One Logan Square 130 N. 18th Street Philadelphia, PA 19103 (215) 569-5644 terry.henry@blankrome.com

Counsel for Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. and specially appearing Teva Pharmaceutical Industries Ltd.

Michael G. Connelly (WVSB #10682) TROUTMAN PEPPER HAMILTON SANDERS LLP 501 Grant Street Suite 300 Pittsburgh, PA 15219-2507 (412) 454-5000

michael.connelly@troutman.com

Counsel for Sun Pharmaceutical Industries, Inc., Ranbaxy Laboratories Inc., Ranbaxy USA, Inc. and specially appearing defendants Sun Pharmaceutical Industries Ltd. and Ranbaxy Laboratories, Ltd. Jon B. Orndorff (WVSB 7763)
Kelly Calder Mowen (WVSB 12220)
Gordon L. Mowen, II (WVSB 12277)
ORNDORFF MOWEN PLLC
135 Corporate Centre Drive, Suite 524
Scott Depot, WV 25560
(866) 481-2765
Jon.Orndorff@om-pllc.com
Kelly.Mowen@om-pllc.com
Gordon.Mowen@om-pllc.com

Jenny A. Hergenrother (pro hac vice)
ALSTON & BIRD LLP
One Atlantic Center
1201 West Peachtree Street, Suite 4900
Atlanta, GA 30309
(404) 881-4977
Jenny.Hergenrother@alston.com

Counsel for NORAMCO

Alexander Macia (WVSB #6077)
Tai Shadrick Kluemper (WVSB #12261)
SPILMAN THOMAS & BATTLE, PLLC
300 Kanawha Boulevard, East (25301)
Post Office Box 273
Charleston, WV 25321-0273
(304) 340-3835 (Mr. Macia)
(304) 357-4476 (Ms. Kluemper)
amacia@spilmanlaw.com
tkluemper@spilmanlaw.com

Christopher Lovrien (pro hac vice)
Shirlethia V. Franklin (pro hac vice)
Anthony J. Dick (pro hac vice)
Krista Perry Heckmann (pro hac vice)
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
(202) 879-3939
cjlovrien@jonesday.com
sfranklin@jonesday.com
ajdick@jonesday.com
kperryheckmann@jonesday.com

Counsel for Walmart Inc.

Pamela C. Deem (WVSB# 976) Luci R. Wellborn (WVSB# 5531) KAY CASTO & CHANEY PLLC 707 Virginia Street, East, Suite 1500 Charleston, WV 25301 (304) 345-8900 pdeem@kaycasto.com lwellborn@kaycasto.com

Matthew D. Elshiaty (WVSB #12535) KAY CASTO & CHANEY PLLC 150 Clay Street, Suite 100 Morgantown, WV 26501 (304) 225-0970 melshiaty@kaycasto.com

Frank J. Favia, Jr. (pro hac vice) SIDLEY AUSTIN LLP One South Dearborn Street Chicago, IL 60603 (312) 853-0326 ffavia@sidley.com

Lauren E. Gumerove (pro hac vice) SIDLEY AUSTIN LLP 1001 Brickell Bay Drive, Suite 900 Miami, FL 33131 (305) 391-5219 lgumerove@sidley.com

Counsel for SK Capital Partners, LP and SK Capital Management IV, LP

CERTIFICATE OF SERVICE

Pursuant to W. Va. Rule 38A(q), I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the Intermediate Court of Appeals for West Virginia via the Court's e-filing system on June 21, 2024.

I certify that all participants in the case are registered with the Court's e-filing system and that service will be accomplished by the Court's e-filing system.

Dated: June 21, 2024 /s/ Amy Rothman Malone

Amy Rothman Malone (WVSB #10266)
FLAHERTY SENSABAUGH BONASSO PLLC
200 Capitol Street
Charleston, WV 25301
(304) 345-0200
(304) 345-0260 - fax
amalone@flahertylegal.com