

IN THE SUPREME COURT OF THE STATE OF DELAWARE

LEBANON COUNTY)
EMPLOYEES' RETIREMENT)
FUND and TEAMSTERS LOCAL)
443 HEALTH SERVICES &)
INSURANCE PLAN,)

No. 22, 2023

Plaintiffs-Below, Appellants,

Court Below: Court of Chancery of the
State of Delaware

v.

STEVEN H. COLLIS, RICHARD W.)
GOCHNAUER, LON R.)
GREENBERG, JANE E. HENNEY,)
M.D., KATHLEEN W. HYLE,)
MICHAEL J. LONG, HENRY W.)
MCGEE, ORNELLA BARRA, D.)
MARK DURCAN, and CHRIS)
ZIMMERMAN,)

C.A. No. 2021-1118-JTL

**PUBLIC INSPECTION VERSION
FILED APRIL 10, 2023**

Defendants-Below, Appellees,

-and-

AMERISOURCEBERGEN)
CORPORATION,)

Nominal Defendant-Below,)
Appellee.)

APPELLANTS' OPENING BRIEF

PRICKETT, JONES & ELLIOTT, P.A.
Samuel L. Closic (Bar No. 5468)
Eric J. Juray (Bar No. 5765)
Robert B. Lackey (Bar No. 6843)
1310 King Street
Wilmington, Delaware 19801
(302) 888-6500

BERNSTEIN LITOWITZ BERGER
& GROSSMANN LLP
Gregory V. Varallo (Bar No. 2242)
Andrew Blumberg (Bar No. 6744)
500 Delaware Avenue, Suite 901
Wilmington, Delaware 19801
(302) 364-3600

Counsel for Plaintiffs-Below/Appellants

TABLE OF CONTENTS

	<u>Page No.</u>
TABLE OF CITATIONS.....	iii
NATURE OF PROCEEDINGS	1
SUMMARY OF ARGUMENT.....	7
STATEMENT OF FACTS.....	8
A. America’s Opioid Epidemic and AmerisourceBergen’s Booming Opioid Distribution Business	8
B. AmerisourceBergen’s Legal Obligations as an Opioid Distributor	9
C. The Board Fails to Implement and Supervise Adequate Diversion Controls.....	10
D. The Board Approves a “Revised OMP” Designed to Decrease the Number of Flagged and Reported Suspicious Orders	16
E. Defendants Take No Action to Address CSA Compliance Despite A Flood of Litigations and Regulatory Actions	19
F. Plaintiffs File Suit	22
1. Plaintiffs’ Red-Flags Claim	22
2. Plaintiffs’ <i>Massey</i> Claim.....	23
G. A West Virginia Court Finds that the Company Did Not Violate the CSA in Parts of West Virginia Based on a Novel Interpretation of the CSA.....	23
H. The Opinion	25
I. The DOJ Complaint	26
J. The Trial Court Denies Plaintiffs’ Motion for Reconsideration.....	29
ARGUMENT	31
I. THE TRIAL COURT ERRED IN FINDING THAT IT IS IMPOSSIBLE TO INFER THAT THE COMPANY VIOLATED THE CSA	31

A.	Questions Presented	31
B.	Scope of Review	31
C.	Merits of Argument	31
1.	Legal Standard	32
2.	The Trial Court Properly Held that the Four Corners of the Complaint State a Claim	33
3.	The Trial Court Improperly Relied on the <i>West Virginia Decision</i> to Deprive Plaintiffs the Reasonable Inferences to Which They Are Entitled	34
a.	The Trial Court Erred By Relying on Delaware Rule of Evidence 202 to Consider Extrinsic Evidence	34
b.	The Trial Court Erred by Giving Dispositive Weight to the <i>West Virginia Decision</i>	37
c.	Giving Dispositive Weight to the <i>West Virginia Decision</i> Creates an Unworkable Regime	42
4.	The Complaint’s Well-Pled Allegations That Defendants Opted for <i>Less</i> Regulatory Compliance in the Face of Red Flags Establishes Bad Faith Regardless of Whether the Company Violated the CSA	44
II.	THE TRIAL COURT ERRED BY NOT REVISITING ITS DECISION AFTER THE DOJ COMPLAINT	47
A.	Questions Presented	47
B.	Scope of Review	47
C.	Merits of Argument	47
	CONCLUSION	52

TABLE OF CITATIONS

	Page(s)
CASES	
<i>In re Boeing Co. Derivative Litig.</i> , 2021 WL 4059934 (Del. Ch. Sept. 7, 2021).....	44
<i>Brehm v. Eisner</i> , 746 A.2d 244 (Del. 2000).....	32
<i>City of Huntington v. AmerisourceBergen Drug Corp.</i> , 609 F. Supp. 3d 408 (S.D.W. Va. 2022)	<i>passim</i>
<i>Constr. Indus. Laborers Pension Fund v. Bingle</i> , 2022 WL 4102492 (Del. Ch. Sept. 6, 2022).....	44
<i>Fawcett v. State</i> , 697 A.2d 385 (Del. 1997).....	34, 37
<i>Graham v. Allis-Chalmers Mfg. Co.</i> , 188 A.2d 125 (Del. Ch. 1963)	44
<i>Grobow v. Perot</i> , 1988 WL 127094 (Del. Ch. Nov. 25, 1988).....	48
<i>Inter-Mktg. Grp. USA, Inc. v. Armstrong</i> , 2020 WL 756965 (Del. Ch. Jan. 31, 2020)	42
<i>Kuhn Constr., Inc. v. Diamond State Port Corp.</i> , 990 A.2d 393 (Del. 2010).....	33
<i>Lebanon Cnty. Emps’ Ret. Fund v. AmerisourceBergen Corp.</i> , 2020 WL 132752 (Del. Ch. Jan. 13, 2020)	22
<i>Lenois v. Sommers</i> , 268 A.3d 220 (Del. 2021).....	47
<i>Levine v. Smith</i> , 591 A.2d 194 (Del. 1991).....	29, 47, 48

<i>Masters Pharm., Inc. v. Drug Enf't Admin.</i> , 861 F.3d 206 (D.C. Cir. 2017)	<i>passim</i>
<i>Olenik v. Lodzinski</i> , 208 A.3d 704 (Del. 2019).....	31
<i>Rales v. Blasband</i> , 634 A.2d 927 (Del. 1993).....	32
<i>Reiter v. Fairbank</i> , 2016 WL 6081823 (Del. Ch. Oct. 18, 2016).....	44
<i>Louisiana Mun. Police Ems. ' Ret. Sys. v. Pyott</i> , 46 A.3d 313 (Del. Ch. 2012)	42
<i>In re Santa Fe Pac. Corp. S'holder Litig.</i> , 669 A.2d 59 (Del. 1995).....	34, 35, 37
<i>Stone v. Ritter</i> , 911 A.2d 362 (Del. 2006).....	32
<i>Teamsters Loc. 443 Health Servs. & Ins. Plan v. Chou</i> , 2020 WL 5028065 (Del. Ch. Aug. 24, 2020).....	45
<i>United Food & Com. Workers Union & Participating Food Indus. Emps.</i> <i>Tri-State Pension Fund v. Zuckerberg</i> , 262 A.3d 1034 (Del. 2021).....	32
<i>United Food & Com. Workers Union v. Zuckerberg</i> , 250 A.3d 862 (Del. Ch. 2020)	32
<i>Unitrin, Inc. v. Am. Gen. Corp.</i> , 651 A.2d 1361 (Del. 1995).....	47
<i>Vanderbilt Income & Growth Assocs., L.L.C. v. Arvida/JMB Managers, Inc.</i> , 691 A.2d 609 (Del. 1996).....	33, 34
<i>In re Walt Disney Co. Derivative Litig.</i> , 825 A.2d 275 (Del. Ch. 2003)	45

RULES

Supr. Ct. R. 12(b)(6).....34
Supr. Ct. R. 23.11, 31, 43
Supr. Ct. R. 60(b)*passim*

OTHER AUTHORITIES

D.R.E. 20135, 36, 37
D.R.E. 20236, 37
21 U.S.C. §842(c)(1)(B).....29
28 C.F.R. §85.5.....29
Dietrich Knauth, *West Virginia Cities Reach \$400 Mln Opioid Distributor Settlement*, <https://www.reuters.com/business/healthcare-pharmaceuticals/west-virginia-cities-reach-400-mln-opioid-distributor-deal-2022-08-01/>, Reuters (Aug. 1, 2022, 4:19 PM).....25, 39
Eldon E. Fallon et. al., *Bellwether Trials in Multidistrict Litigation*, 82 Tul. L. Rev. 2323 (2008).....41
Homeland Security & Governmental Affairs Committee, Fueling an Epidemic, Report Three: A Flood of 1.6 Billion Doses of Opioids in Missouri and the Need for Stronger DEA Enforcement, Ranking Member’s Office, U.S. Senate (July 2018).21
Justice Department Files Nationwide Lawsuit Against AmerisourceBergen Corp. and Subsidiaries for Controlled Substances Act Violations (the “DOJ New Release”), U.S. Dep’t of Just. (Dec. 29, 2022), <https://www.justice.gov/opa/pr/justice-department-files-nationwide-lawsuit-against-amerisourcebergen-corp-and-subsidiaries>27
Southwood Pharms., Inc., 72 Fed. Reg. 36,487 (DEA July 3, 2007).....40

NATURE OF PROCEEDINGS

This derivative action on behalf of AmerisourceBergen Corporation (“AmerisourceBergen” or the “Company”) asserts breach of fiduciary duty claims against Company directors and officers for (i) consciously ignoring red flags of non-compliance with the Company’s regulatory obligation to prevent the unlawful diversion of opioids (*i.e.*, a “Red-Flags Claim”) and (ii) taking affirmative steps to reduce the Company’s compliance with its regulatory obligations (*i.e.*, a “Massey Claim”). Plaintiffs appeal from the trial court’s Memorandum Opinion dismissing the Complaint under Court of Chancery Rule 23.1 and from the trial court’s Memorandum Opinion Denying the subsequent Rule 60(b) motion for relief from the aforementioned Judgement and Order.

AmerisourceBergen is a major wholesale distributor of opioid pain medication whose conduct has contributed to America’s tragic opioid epidemic. By 2017, AmerisourceBergen had been sued approximately 1,800 times by State Attorneys General, states, cities, counties, sovereign Native American tribes, and others in a massive multidistrict litigation (“Opioid MDL”) for claims relating to the Company’s inadequate compliance with the Controlled Substances Act of 1970 and its implementing regulations (“CSA”). In 2021, AmerisourceBergen agreed to pay over \$6 billion as part of a nationwide settlement to largely resolve the Opioid MDL. In addition, AmerisourceBergen has spent hundreds of millions of dollars settling

other lawsuits and over \$1 billion in defense costs. These costs—which pale in comparison to the human cost of the opioid epidemic—continue to rise due to ongoing litigations.

Plaintiffs detailed complaint,¹ based largely on the Company’s books and records, explains how the Company’s officers and directors consciously ignored red flags of misconduct and declined to take any meaningful action until its 2021 partial settlement of the Opioid MDL. The trial court found that the Complaint’s well-pled allegations support a pleading stage inference that the Company’s officers and directors knowingly pursued a business plan that prioritized profits over legal and regulatory compliance despite being aware of countless red flags of potential non-compliance with the CSA. To use the trial court’s words, the “directors did not just see red flags; they were wrapped in them.”²

Defendants moved to dismiss the Complaint, arguing that Plaintiffs’ claims were untimely and that Plaintiffs failed to adequately plead demand futility. The

¹ A25, Verified Stockholder Derivative Complaint (Trans. ID 67186283) (the “Complaint” or “¶”).

² Memorandum Opinion, *Lebanon County Employees' Ret. Fund v. Collis*, No. 2021-1118-JTL, 2022 WL 17841215, at *16 (Dec. Ch. Dec. 22, 2022) (Trans. ID 68694654) (the “Opinion” or “Op.”). A copy of the Opinion is filed herewith as Exhibit A.

trial court rejected those arguments based on the four corners of the Complaint, finding that the Complaint adequately pled that:

defendants knew that AmerisourceBergen was reporting astoundingly low levels of suspicious orders, understood that was the whole purpose of the Revised OMP, and went through the motions of providing oversight, while consciously deciding not to take any action until the 2021 Settlement so that they could use changes to the Revised OMP and their oversight policies as part of the settlement currently [sic]. . . . At the pleading stage, the court must adopt the plaintiff-friendly inference, *so the complaint would survive the motion to dismiss.*³

That should have ended the analysis and the motion to dismiss should have been denied.

But the trial court instead latched on to extrinsic evidence to deny Plaintiffs the inferences to which they are entitled. To wit, the trial court gave dispositive weight to a bellwether decision of the United States District Court for the Southern District of West Virginia (the “*West Virginia Decision*”),⁴ which was issued after the Complaint was filed and which held that AmerisourceBergen’s conduct—*i.e.*, the same conduct that was at the heart of the litigations that AmerisourceBergen settled for over \$7 billion—did not cause a public nuisance because it did not violate

³ Op. at *2.

⁴ *City of Huntington v. AmerisourceBergen Drug Corp.*, 609 F. Supp. 3d 408 (S.D.W. Va. 2022).

the CSA in one West Virginia city and one West Virginia county. Relying solely on that decision, the trial court held that it was not reasonably inferable that the Company violated the CSA (in West Virginia or elsewhere), and that the Complaint therefore must be dismissed.

This is an unusual appeal insofar as the issue is not whether the Complaint's allegations state a claim. Rather, the issue on appeal is far narrower: whether the trial court erred by concluding that it is not reasonably inferable, based on the totality of the allegations and facts properly before it, that the Company violated the CSA. Plaintiffs submit that it did for three reasons.

First, the trial court impermissibly credited the *West Virginia Decision* for the truth of the matter. A trial court can consider extrinsic evidence only if it is incorporated by reference into the complaint, is subject to judicial notice, or if the court is *not* relying on the extrinsic evidence to establish the truth of its contents. None of those limited exceptions applied to the *West Virginia Decision*'s factual finding that the Company complied with the CSA.

Second, if the trial court were permitted to credit the *West Virginia Decision*'s factual findings, the trial court still erred by finding based solely on the *West Virginia Decision* that the Company did not violate the CSA. Even if the trial court believed that the *West Virginia Decision* supports a stronger inference that the Company

complied with its legal obligations than the Complaint’s well-plead factual allegations supports the opposite inference, the trial court was required (but failed) to credit the plaintiff-friendly inference.

The trial court’s determination to give dispositive weight to the factual findings of a non-final, bellwether decision is problematic for the additional reason that it renders demand futility a moving target with changing outcomes based on timing. Such a rule is unworkable. What if the foreign decision is reversed on appeal? What if a different foreign jurisdiction reaches a different conclusion and finds regulatory violations? What if, as here, *after* the foreign jurisdiction finds no regulatory violations, the United States Department of Justice (“DOJ”) files a complaint alleging the opposite? These examples illustrate the trial court’s error of looking beyond the four corners of the Complaint to non-final factual findings in a tangentially related action.

Third, in denying Plaintiffs’ Rule 60(b) motion for reconsideration based on the DOJ filing referenced above, the trial court erred by refusing to consider in its assessment of the sufficiency of the Complaint the DOJ’s determination—based on a multi-year investigation by the United States Drug Enforcement Agency (“DEA”)—that AmerisourceBergen repeatedly violated the CSA. The trial court’s determination that it could not consider the ***DOJ’s conclusion*** that

AmerisourceBergen violated the CSA was based on an unduly narrow definition of “newly discovered evidence.”⁵ If the trial court was going to consider a West Virginia judge’s view of whether the Company violated the CSA in assessing the sufficiency of the Complaint, equity required that it also consider the DOJ’s view.

For these reasons, as discussed in more detail below, the trial court’s decision should be reversed.

⁵ Memorandum Opinion, *Lebanon County Employees' Ret. Fund v. Collis*, No. 2021-1118-JTL, 2023 WL 2582399, at *7-10 (Dec. Ch. Mar. 21, 2023) (Trans. ID 69593105) (the “Rule 60(b) Opinion” or “Rule 60(b) Op.”). A copy of this Opinion is filed herewith as Exhibit B.

SUMMARY OF ARGUMENT

1. While the trial court found that Plaintiffs pled particularized facts sufficient to state claims against AmerisourceBergen’s directors and officers, it refused to credit the plaintiff-friendly inferences flowing from the Complaint’s well-pled allegations based on extrinsic evidence—namely, the non-final *West Virginia Decision*. That was legal error both because the trial court was not permitted to consider extrinsic evidence for the truth of the matter and because, even if it were, the *West Virginia Decision* does not support the inescapable conclusion that the Company complied with the CSA.

2. The DOJ’s determination that the Company violated the CSA was “newly discovered evidence” that the trial court could have considered in assessing the sufficiency of the Complaint’s allegation. The trial court’s refusal to do so was reversible error.

STATEMENT OF FACTS

A. America's Opioid Epidemic and AmerisourceBergen's Booming Opioid Distribution Business

For more than two decades, the United States has been ravaged by an opioid epidemic,⁶ described by the United States Surgeon General as an “urgent health crisis.”⁷ Opioid pain pills are highly addictive and misuse often is fatal.⁸ Opioids have killed hundreds of thousands of Americans.⁹ In 2019 alone, the United States reported 50,963 opioid-related overdose deaths.¹⁰ In 2020, that number jumped to 69,710.¹¹ The overwhelming majority of drug overdoses are now opioid overdoses.¹²

Beginning in the late 1990's, AmerisourceBergen and other pharmaceutical distributors began to aggressively distribute opioid prescription medications for immense profits.¹³ Sales of prescription opioids nearly quadrupled between 1999

⁶ A52-53, ¶59.

⁷ A55, ¶65.

⁸ A53, ¶60.

⁹ Op. at *5.

¹⁰ A52-53, ¶59.

¹¹ *Id.*

¹² *Id.*

¹³ A53, ¶60.

and 2014.¹⁴ As addiction levels increased, pharmacies—often referred to as “pill mills”—diverted prescription opioids to illegal markets for non-medical use.¹⁵

B. AmerisourceBergen’s Legal Obligations as an Opioid Distributor

AmerisourceBergen is a “Big Three” wholesaler of pharmaceutical drugs, including opioids, along with Cardinal Health, Inc. and McKesson Corporation.¹⁶ The “Big Three” receive approximately 85-90% of all wholesale pharmaceutical revenue in the United States,¹⁷ with AmerisourceBergen holding about a third of the wholesale pharmaceutical market.¹⁸

Through the DEA, AmerisourceBergen and the other pharmacy wholesalers are licensed to distribute opioids so long as they comply with the CSA.¹⁹ Pursuant to the CSA and other governing laws and regulations, AmerisourceBergen has affirmative legal obligations to adopt, implement and oversee policies and practices to prevent the unlawful diversion of opioid prescriptions.²⁰ These policies and

¹⁴ A53-54, ¶¶61.

¹⁵ A54, ¶62.

¹⁶ A56, ¶¶67.

¹⁷ *Id.*

¹⁸ *Op. at* *4.

¹⁹ A31-32, ¶3; *Op. at* *4.

²⁰ *Op. at* *4

practices must effectively identify suspicious orders and ensure that the company does not fulfill such orders unless it conducts sufficient investigation to confirm they will not be diverted to non-medical use.²¹ The DEA’s “No Shipping Requirement” forbids AmerisourceBergen from completing an order flagged as suspicious unless and until the Company can determine that the order is not likely to be diverted into illicit channels.²² Opioid distributors are required to report to the DEA all suspicious orders, including orders that are of unusual size or frequency, and those that deviate from a normal pattern.²³

C. The Board Fails to Implement and Supervise Adequate Diversion Controls

To help fight the opioid epidemic, the DEA heightened scrutiny of opioid distribution practices.²⁴ In 2007, the DEA issued an Order to Show Cause and Immediate Suspension that suspended AmerisourceBergen’s license to distribute controlled substances through its Florida distribution center, citing AmerisourceBergen’s failure to maintain controls against diversion of a prescription

²¹ *Id.*

²² A62, ¶82; Op. at *4 (citing *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206, 212-13 (D.C. Cir. 2017)).

²³ Op. at *4.

²⁴ Op. at *5.

opiate.²⁵ Months later, the DEA lifted its suspension after AmerisourceBergen entered into a settlement in which the Company agreed to adopt an improved order monitoring program for distribution of controlled substances (the “2007 Settlement”).²⁶ To fulfill its obligations under the 2007 Settlement, AmerisourceBergen implemented an order monitoring program that flagged orders as suspicious that exceeded static quantity thresholds and thus required an investigatory review prior to shipment (the “OMP”).²⁷ As discussed below, AmerisourceBergen later scrapped the OMP in favor of an order monitoring program with a second trigger designed to flag fewer orders for review.

That same year, as part of its plan to secure more independent pharmacy customers, AmerisourceBergen agreed to acquire Belco Drug Corporation (“Belco”) for \$235 million shortly before Belco entered into a Consent Judgment with the DEA (the “Belco Consent Judgment”) for violations of the CSA.²⁸ Since the 2007 Settlement and the Belco Consent Judgment, the Board has been on notice

²⁵ A62-63, ¶¶83-84.

²⁶ A63-66, ¶¶85-92.

²⁷ A100, ¶166; Op. at *8.

²⁸ A66-68, ¶¶93-99.

of AmerisourceBergen’s positive compliance obligations and the problems with AmerisourceBergen’s anti-diversion programs.²⁹

In 2010, the Board approved AmerisourceBergen’s “Independent Pharmacy Strategy” to maximize sales in the independent pharmacy market, in which AmerisourceBergen had significant bargaining power. Independent pharmacy sales carry a high profit margin for AmerisourceBergen because independent pharmacies lack the bargaining power held by chain pharmacies.³⁰ Independent pharmacies are more likely to dispense opioids for non-medical use because they have fewer financial resources to invest in anti-diversion programs, further boosting AmerisourceBergen’s profits.³¹

By 2011, as demonstrated by the sharp uptick in sales to independent pharmacies, management became focused on increasing efficiency in the Company’s sales process and expanding its network of independent pharmacy customers.³² The Board discussed mechanisms to maximize the independent pharmacy business, such as [REDACTED]

²⁹ A68, ¶¶98-99.

³⁰ A57-58, ¶71.

³¹ Op. at *5.

³² Op. at *6.

[REDACTED] “[c]rea[ting] a ‘light touch’ franchise model,” and “[f]acilitating ‘friendly landings.’”³³ Despite the increasing diversion risks associated with onboarding additional independent pharmacies, Defendants did not make a comparable investment in AmerisourceBergen’s anti-diversion programs to offset these risks.³⁴

AmerisourceBergen’s division of Corporate Securities and Regulatory Affairs (“CSRA”) [REDACTED]

[REDACTED]³⁵ AmerisourceBergen’s Internal Audit unit was understaffed and underfunded compared to the average Fortune 500 company.³⁶ Instead of improving diversion controls, increasing oversight functions, or hiring more compliance staff, the Company invested millions of dollars in lobbying for more relaxed distribution regulations, such as one law that made it virtually

³³ A77-78, ¶119.

³⁴ A77-78, ¶¶119-20; Op. at *6.

³⁵ A69-70, ¶¶102-03.

³⁶ A83-84, ¶130.

impossible for the DEA to stop a suspicious shipment or immediately suspend a distributor's license.³⁷

In 2011, AmerisourceBergen's anti-diversion program was headed by Defendant Chris Zimmerman, who was promoted in 2012 to Chief Compliance Officer and Senior Vice President for CSRA.³⁸ In 2011, Zimmerman emailed senior members of his anti-diversion team the lyrics for "Pillbillies," a parody song mocking opioid addicts.³⁹ When Florida passed pill mill legislation, Zimmerman emailed "Watch out Georgia and Alabama, there will be a max exodus of Pillbillies heading north."⁴⁰ When Kentucky passed pharmacy regulations to limit the abuse of controlled substances, Zimmerman wrote to his team: "One of the hillbilly's must have learned how to read :-)."⁴¹ Until October 2018, Zimmerman oversaw AmerisourceBergen's order monitoring program and was tasked with referring

³⁷ A108-09, ¶¶185-86.

³⁸ Op. at *6.

³⁹ A72-73, ¶109.

⁴⁰ A73, ¶110.

⁴¹ A82, ¶128.

problems to the Audit Committee.⁴² Zimmerman’s emails demonstrate the callous attitude of AmerisourceBergen’s top leadership tasked with preventing diversion.

Meanwhile, AmerisourceBergen was reporting a practically non-existent number of suspicious orders to the DEA—a *fraction of a percent* of all annual opioid orders.⁴³ The Audit Committee learned of the Company’s shockingly low rate of suspicious orders reported to the DEA in 2012 but did not obtain the annual statistics again until mid-2017.⁴⁴ In 2012, the Audit Committee and the Board also became aware of a DOJ investigation into AmerisourceBergen’s opioid distribution practices.⁴⁵ In 2013, the DOJ issued a grand jury subpoena to AmerisourceBergen’s independent auditors.⁴⁶

From 2010 to 2015, despite receiving occasional updates on the escalating DOJ opioid investigation and the torrent of civil opioid lawsuits, the Board received just one presentation on diversion control and failed to take any positive action.⁴⁷

⁴² Op. at *6.

⁴³ A38-39, ¶¶18-19; A82-83, ¶129.

⁴⁴ A38, ¶19; A82-83, ¶129; A100, ¶167; A123, ¶215.

⁴⁵ A36-37, ¶¶12-13.

⁴⁶ A37, ¶14.

⁴⁷ A37, ¶15.

The Audit Committee members were regularly updated on the DOJ investigation and the opioid lawsuits, but they also failed to undertake any positive action regarding diversion control.⁴⁸

D. The Board Approves a “Revised OMP” Designed to Decrease the Number of Flagged and Reported Suspicious Orders

During this time, AmerisourceBergen adopted the Revised OMP that resulted in an exponential reduction in the already miniscule number of suspicious orders reported.⁴⁹ The Revised OMP added a “second test” that compared a customer’s individual order size *against* that customer’s historical order pattern.⁵⁰ The new trigger would only fail if a customer’s current order was out of line with its most recent orders.⁵¹ “Ultimately, both tests need to fail for an order to be flagged for investigation.”⁵²

In March 2015, Zimmerman made a presentation to the Audit Committee about the Revised OMP.⁵³ “As depicted in the Venn Diagram presented to the Audit

⁴⁸ A37-38, ¶¶16-17.

⁴⁹ A100-101, ¶¶166-69.

⁵⁰ Op. at *8; A100, ¶166.

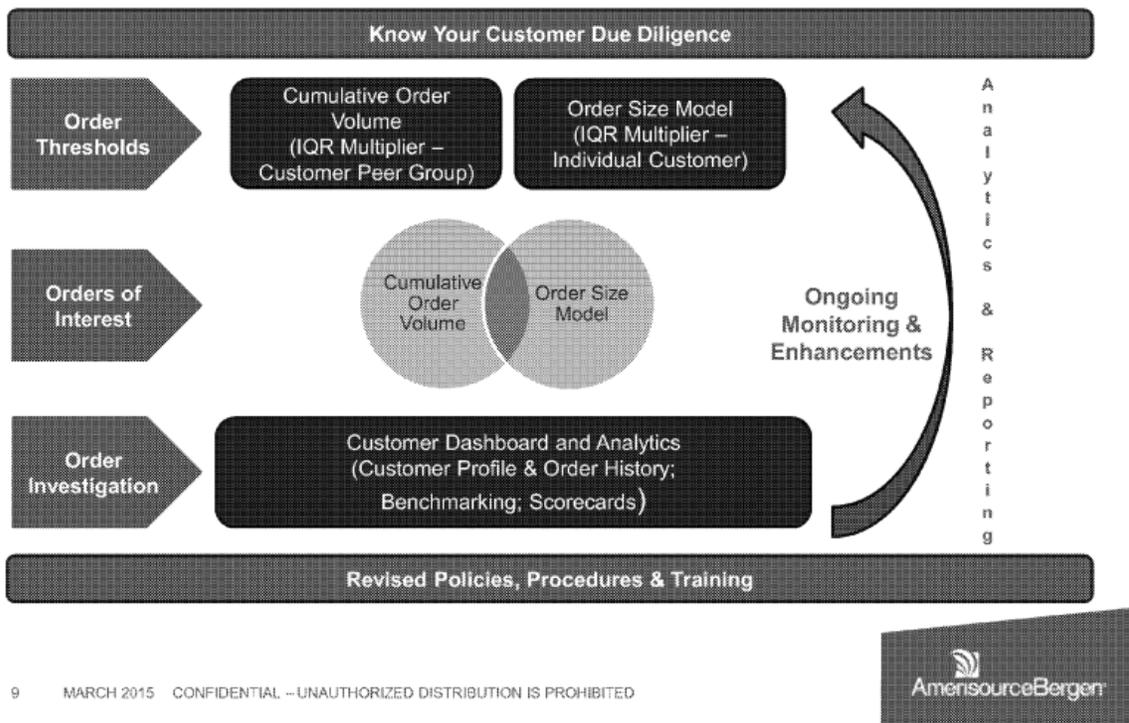
⁵¹ Op. at *8.

⁵² *Id.*

⁵³ Op. at *7.

Committee, the double-trigger would inevitably result in a small fraction of AmerisourceBergen's orders being flagged for investigation."⁵⁴ The Audit Committee reported to the Board management's report on the Revised OMP, and the Revised OMP subsequently went into effect.⁵⁵

II. Diversion Control Program - Enhanced Systems & Processes
 Integrated approach to order monitoring



CONFIDENTIAL INSPECTION MATERIAL

LEBANON_010776

⁵⁴ Op. at *8.

⁵⁵ *Id.*

As intended, the Revised OMP resulted in a dramatic decline in the number of suspicious orders flagged. Specifically, AmerisourceBergen reported **14,003** suspicious orders in **2014**, but only **1,892** suspicious orders in 2015.⁵⁶

In August 2015, AmerisourceBergen engaged FTI Consulting, Inc. to conduct a review of how the Company investigated orders of interest. FTI identified numerous deficiencies, “including a lack of resources, a lack of formal training, inconsistent policies, and communication breakdowns.”⁵⁷

In 2016, the Company reported only **139** orders.⁵⁸ These drastic reductions occurred as AmerisourceBergen filled millions of additional orders for controlled substances.⁵⁹ The impact of the Revised OMP on suspicious order reporting is shown in the chart below:⁶⁰

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

Percentage of Orders Flagged and Reported to the DEA				
	2013	2014	2015	2016
Orders Placed	13,580,197	20,777,594	22,560,652	24,067,791
Orders of Interest	60,499	78,707	83,407	48,888
Orders Reported	24,103	14,003	1,892	139
Percent of All Orders Flagged (derived)	0.445%	0.379%	0.370%	0.203%
Percent of All Orders Reported (derived)	0.177%	0.067%	0.008%	0.006%

E. Defendants Take No Action to Address CSA Compliance Despite A Flood of Litigations and Regulatory Actions

By 2017, State Attorneys General, states, cities, counties, sovereign Native American tribes, and others had filed more than 1,800 lawsuits alleging that AmerisourceBergen and other distributors violated the laws for monitoring and distributing opioids and thereby helped fuel the opioid crisis.⁶¹ These lawsuits were consolidated in the Opioid MDL. By that time, the DOJ had also opened criminal and civil investigations into AmerisourceBergen’s CSA compliance.⁶²

In August 2017, Zimmerman presented to the Board about the Company’s anti-diversion efforts. That presentation noted the infinitesimal level of suspicious

⁶¹ A39, ¶22.

⁶² A32-33, ¶6.

orders flagged by the Revised OMP.⁶³ Instead of addressing CSA compliance, the Board focused on how to change the public perception of AmerisourceBergen’s role in the opioid crisis through public relations and lobbying efforts.⁶⁴

In April 2018, “the Audit Committee reviewed an audit of the Revised OMP, which the minutes described as something that the Audit Committee was doing ‘for the first time.’”⁶⁵

Later that year, following investigations into opioid distribution practices, the U.S. Congress published multiple reports identifying problems with AmerisourceBergen’s CSA compliance. The U.S. Congress Committee for Energy and Commerce published a report identifying significant problems with AmerisourceBergen’s compliance with the CSA in West Virginia.⁶⁶ Separately, the U.S. Senate Committee on Homeland Security and Government Affairs concluded that, in Missouri, AmerisourceBergen “consistently failed to meet [its] reporting

⁶³ Op. at *9.

⁶⁴ *Id.*

⁶⁵ Op. at *10.

⁶⁶ A133-39, ¶¶238-46 (citing *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, U.S. Congress Energy and Commerce Committee (December 2018)).

obligations” under the CSA and its abysmal reporting levels stood out among the Big Three.⁶⁷

In 2019, AmerisourceBergen’s officers and directors learned that [REDACTED]

[REDACTED]⁶⁸ Nevertheless, management and the Board continually failed to reform AmerisourceBergen’s anti-diversion programs, focusing instead on increasing sales to independent pharmacies.

In 2021, AmerisourceBergen agreed to pay **\$6.4 billion** in a national settlement of multidistrict litigation against the Company and other major opioid distributors (the “2021 Settlement”).⁶⁹ In the 2021 Settlement, AmerisourceBergen agreed to remedy problems in the Revised OMP and to require direct Board oversight of the program. AmerisourceBergen also agreed to improve policies for order monitoring and due diligence and switch to model-based thresholds that would

⁶⁷ A133, ¶237; (citing *Homeland Security & Governmental Affairs Committee, Fueling an Epidemic, Report Three: A Flood of 1.6 Billion Doses of Opioids in Missouri and the Need for Stronger DEA Enforcement*, Ranking Member’s Office, U.S. Senate (July 2018)).

⁶⁸ A127-31, ¶¶228-31.

⁶⁹ Op. at *1, *11.

“actually identify and stop suspicious orders.”⁷⁰ Besides the jaw-dropping cost of the 2021 Settlement, AmerisourceBergen has paid hundreds of millions of dollars to settle other lawsuits and has accumulated over \$1 billion in defense costs.⁷¹

F. Plaintiffs File Suit

Plaintiffs brought derivative claims against certain of AmerisourceBergen’s officers and directors under both a Red-Flags Theory and a *Massey* Theory. Plaintiffs’ allegations reflect their lengthy pre-suit investigation, which included review of AmerisourceBergen’s internal Board minutes and Board-level materials obtained following a fiercely litigated books and records demand.⁷²

1. Plaintiffs’ Red-Flags Claim

The Complaint alleges that the Company’s officers and directors encountered a multitude of red flags indicating that AmerisourceBergen was not complying with its anti-diversion obligations under federal and state law.⁷³ As the trial court found, the Company continued to report “incomprehensibly low” numbers of suspicious orders despite the ongoing congressional investigations, criminal investigations,

⁷⁰ *Id.*

⁷¹ Op. at *1.

⁷² See *Lebanon Cnty. Emps’ Ret. Fund v. AmerisourceBergen Corp.*, 2020 WL 132752 (Del. Ch. Jan. 13, 2020), *aff’d*, 243 A.3d 417 (Del. 2020).

⁷³ Op. at *1.

lawsuits by many state attorneys general, and deluge of civil lawsuits.⁷⁴ The Complaint alleges, and the trial court concluded, that Defendants consciously ignored these red flags by failing to implement stronger programs for identifying and reporting suspicious orders until the 2021 Settlement.⁷⁵

2. Plaintiffs' *Massey* Claim

The Complaint alleges that Defendants undertook a series of actions, such as adopting the flawed Revised OMP and expanding distribution networks without improving anti-diversion controls, that support a pleading-stage inference that Defendants intentionally prioritized profits over compliance.⁷⁶

G. A West Virginia Court Finds that the Company Did Not Violate the CSA in Parts of West Virginia Based on a Novel Interpretation of the CSA

After Plaintiffs filed their brief opposing Defendants' motion to dismiss, on July 4, 2022, a West Virginia federal court issued the *West Virginia Decision*. Following a bench trial, the West Virginia Court held that the City of Huntington ("Huntington") and the Cabell County Commission ("Cabell") failed to prove that AmerisourceBergen and the other distributors "caused a public nuisance in [their]

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ Op. at *2.

localities.”⁷⁷ That holding was based, in part, on a “finding of fact” that the Company’s anti-diversion programs did not violate the CSA.⁷⁸ Notably, the West Virginia Court did not discuss the impact of the Revised OMP and cited documents and testimony of only one defendant, Zimmerman⁷⁹—*i.e.*, the same person that the trial court here found to be not suitable to hold his positions of Chief Compliance Officer and Senior Vice President in charge of Corporate Securities and Regulatory Affairs.⁸⁰

The *West Virginia Decision* is currently on appeal to the United States Court of Appeals for the Fourth Circuit.⁸¹ On appeal, Huntington and Cabell argue that the West Virginia Court applied an overly narrow interpretation of the CSA with “no basis in law” and in contravention of “the CSA and its regulations as interpreted by

⁷⁷ *West Virginia Decision*, 609 F. Supp. 3d at 413.

⁷⁸ *Id.* at 425.

⁷⁹ A362 (Page-Proof Brief for Appellants, *City of Huntington v. AmerisourceBergen Drug Corp.* (No. 22-1819) (4th Cir., Dec. 27, 2022) (“*West Virginia Decision Appeal*”).

⁸⁰ *Op.* at *6.

⁸¹ *City of Huntington v. AmerisourceBergen Drug Corp.*, No. 22-1819 (4th Cir. Aug. 4, 2022).

the D.C. Circuit in *Masters [Pharmaceuticals, Inc. v. DEA]*, 861 F.3d 206 (D.C. Cir. 2017)], the [Opioid] MDL court, and [the] DEA.”⁸²

Roughly three weeks after the *West Virginia Decision*, on July 31, 2022, AmerisourceBergen and other distributors agreed to pay \$400 million to settle with West Virginia municipalities that sued the Company for its role in the opioid crisis (excluding the plaintiffs in the *West Virginia Decision*).⁸³

H. The Opinion

On December 22, 2022, the trial court issued the Opinion granting Defendants’ motion to dismiss. The trial court held that:

Standing alone, the avalanche of investigations and lawsuits without any apparent response until the 2021 Settlement would support a well-pled Red-Flags Claim. Likewise, the series of decisions that culminated in the Revised OMP, along with the decision to keep that framework in place until the 2021 Settlement, would support a well-pled *Massey* Claim.⁸⁴

Nevertheless, the Opinion dismissed the Complaint because it concluded based on the *West Virginia Decision* that “it is not possible to infer that the Company

⁸² A426, *West Virginia Decision Appeal* at 46.

⁸³ Dietrich Knauth, *West Virginia Cities Reach \$400 Mln Opioid Distributor Settlement*, <https://www.reuters.com/business/healthcare-pharmaceuticals/west-virginia-cities-reach-400-mln-opioid-distributor-deal-2022-08-01/>, Reuters (Aug. 1, 2022, 4:19 PM).

⁸⁴ Op. at *2.

failed to comply with its anti-diversion obligations.”⁸⁵ The trial court reached that conclusion despite, *e.g.*, the \$7 billion in settlements discussed herein and despite the fact that the *West Virginia Decision* addressed only the Company’s compliance with the CSA in Huntington and Cabell, West Virginia. Respecting the fact that the *West Virginia Decision* related to only Huntington and Cabell, the trial court assumed that because “the opioid problem in West Virginia was the worst in the nation and that Huntington and Cabell County were among the worst localities in West Virginia,”⁸⁶ “[i]f there was anywhere that AmerisourceBergen could have been held liable for not complying with its order-diversion obligations, that was the place.”⁸⁷

I. The DOJ Complaint

After the Opinion was issued, on December 29, 2022, the DOJ filed a complaint against AmerisourceBergen in the U.S. District Court for the Eastern District of Pennsylvania (the “DOJ Complaint”).⁸⁸ The DOJ Complaint was the culmination of a years-long investigation by the DEA, the DOJ Civil Division’s

⁸⁵ Op. at *3, *17.

⁸⁶ Op. at *17.

⁸⁷ *Id.*

⁸⁸ A493.

Consumer Protection Branch, and multiple U.S. Attorneys’ Offices.⁸⁹ According to the DOJ, AmerisourceBergen “had a legal obligation to report suspicious orders to the [DEA], and our complaint alleges that the company’s repeated and systemic failure to fulfill this simple obligation helped ignite an opioid epidemic that has resulted in hundreds of thousands of deaths over the past decade.”⁹⁰

The DOJ Complaint alleges that beginning in 2014, AmerisourceBergen intentionally designed the Revised OMP so that orders that previously were flagged as suspicious to the DEA would instead be shipped without review or reporting.⁹¹ Within two years of AmerisourceBergen’s adoption of the Revised OMP, AmerisourceBergen’s suspicious order reports dropped by 99%.⁹² As a result of the Revised OMP, AmerisourceBergen filed **350** suspicious orders reports while

⁸⁹A473, Justice Department Files Nationwide Lawsuit Against AmerisourceBergen Corp. and Subsidiaries for Controlled Substances Act Violations (the “DOJ New Release”), U.S. Dep’t of Just. (Dec. 29, 2022), <https://www.justice.gov/opa/pr/justice-department-files-nationwide-lawsuit-against-amerisourcebergen-corp-and-subsidiaries> (“DOJ Press Release”) at 2. The DOJ Complaint and press release announcing the lawsuit are part of the record in Plaintiffs’ Motion for Relief from Judgment and Order Pursuant to Rule 60(B), filed January 9, 2023, before the initial Notice of Appeal was filed. A493-A576 (DOJ Complaint), A771-74 (DOJ Press Release).

⁹⁰ A772, DOJ Press Release.

⁹¹ A525-27, DOJ Complaint at ¶¶179-95.

⁹² *Id.* at A535, ¶251.

AmerisourceBergen’s two major competitors filed **200,000** and **40,000** suspicious order reports, respectively.⁹³

The DOJ Complaint further alleges that AmerisourceBergen violated the CSA *hundreds of thousands* of times by failing to report suspicious orders to the DEA.⁹⁴ Moreover, according to the DOJ Complaint, AmerisourceBergen “fail[ed] to report to DEA controlled-substance orders that Defendants’ order monitoring programs’ thresholds flagged for human review and that Defendants shipped even though their reviewers did not dispel suspicion.”⁹⁵ AmerisourceBergen maintained “little documentation ... related to purported reviews,” and even that documentation showed, *inter alia*, that the recorded comments (i) “‘provide ‘demonstrably false’ or ‘implausible’ reasons for allegedly dispelling suspicion’” (citing *Masters*, 861 F.3d at 218–19); (ii) “lack any justification whatsoever for dispelling suspicion, indicating that no investigations even occurred” (citing *Masters*, 861 F.3d at 218 (“finding that ‘the lack of documentation was evidence that the [investigation] never took place’”)); or (iii) “otherwise evince, at best, a cursory and pro forma review.”⁹⁶

⁹³ *Id.* at A535, ¶¶251-52.

⁹⁴ A772, DOJ Press Release at 1.

⁹⁵ *Id.* at A563, ¶443.

⁹⁶ *Id.* at A564, ¶447.

The DOJ Complaint seeks billions of dollars in damages.⁹⁷

J. The Trial Court Denies Plaintiffs’ Motion for Reconsideration

On January 9, 2023, Plaintiffs filed a motion for reconsideration pursuant to Court of Chancery Rule 60(b) (the “Rule 60(b) Motion”).⁹⁸ Plaintiffs argued that the DOJ’s “*decision to file* the DOJ Complaint with allegations supported by years of government investigations and that substantially overlap with Plaintiffs’ allegations, undercut the Court’s holding that because of the West Virginia Decision ‘it is not possible to infer that the Company failed to comply with its anti-diversion obligations.’”⁹⁹

On March 21, 2023, the trial court issued a Memorandum Opinion denying the Rule 60(b) Motion (the “Rule 60(b) Opinion”).¹⁰⁰ To assess the sufficiency of the Rule 60(b) Motion, the trial court applied the five-factor test set out in *Levine v. Smith*, 591 A.2d 194, 202 (Del. 1991).¹⁰¹ In considering the first element of the *Levine* test, whether newly discovered evidence has come to the movant’s

⁹⁷ See *Id.*; 21 U.S.C. §842(c)(1)(B), 28 C.F.R. §85.5 (cited in A573, the DOJ Complaint at ¶506).

⁹⁸ A472-A758; see also A3, Trans. ID 68826131.

⁹⁹ A472-73, Rule 60(b) Motion at 1 (quoting Op. at *3).

¹⁰⁰ See *Supra* note 5.

¹⁰¹ See Rule 60(b) Opinion at *6-11.

knowledge since entry of the judgment movant seeks relief from, the court first distinguished between “newly discovered evidence” and “new evidence.”¹⁰² According to the trial court, “newly discovered evidence,” which the trial court is permitted to consider, is evidence that existed at the time of the judgment while “new evidence,” which the trial court is not permitted to consider, is a new fact that did not exist at the time of judgment.¹⁰³

The trial court then determined that the DOJ’s decision to sue AmerisourceBergen for violations of the CSA was new evidence, rather than newly discovered evidence, and therefore could not support relief under Rule 60(b). According to the trial court, “the [filing of the] DOJ Complaint is ‘new evidence’” because “the filing itself took place after the judgment.”¹⁰⁴ The trial court did not reach the question of whether it would have come out differently on the motion to dismiss had it been permitted to consider the DOJ’s determination that the Company violated the CSA hundreds of thousands of times.¹⁰⁵

¹⁰² *Id.* at *6-8.

¹⁰³ *Id.* at *6.

¹⁰⁴ *Id.* at *8.

¹⁰⁵ *Id.* at *2, *5-6, *9.

ARGUMENT

I. THE TRIAL COURT ERRED IN FINDING THAT IT IS IMPOSSIBLE TO INFER THAT THE COMPANY VIOLATED THE CSA

A. Questions Presented

Whether the trial court erred in dismissing the Complaint where it held that the Complaint's well-pled allegations were sufficient to meet the requirements of Rule 23.1, but then refused to credit those well-pled allegations based on the non-binding *West Virginia Decision*, which concerned a public nuisance claim and which is pending appeal to the Fourth Circuit?¹⁰⁶

B. Scope of Review

The standard of review of a decision granting a motion to dismiss is *de novo*. *Olenik v. Lodzinski*, 208 A.3d 704, 714 (Del. 2019).

C. Merits of Argument

The trial court correctly found that the Complaint's well-pled allegations were sufficient to establish demand futility for Plaintiffs' Red-Flags and *Massey* Claims. At that point, the inquiry should have ended, and the trial court should have denied Defendants' motion to dismiss. Instead, the trial court reversibly erred by looking beyond the four corners of the Complaint to extrinsic evidence—*i.e.*, the *West*

¹⁰⁶ Op. at *16-17. Appellants preserved this issue at A297-323 (Transcript of Oral Argument on Defendants' Motions to Dismiss (Sept. 23, 2022)).

Virginia Decision, crediting that extrinsic evidence for the truth of the matter, and resolving competing inferences in Defendants’ favor to dismiss the Complaint.

1. Legal Standard

The threshold question on a motion to dismiss a derivative action is whether “demand is excused because the directors are incapable of making an impartial decision regarding whether to institute ... litigation.” *Stone v. Ritter*, 911 A.2d 362, 367 (Del. 2006). “[D]emand is excused as futile if the complaint alleges particularized facts creating a ‘reasonable doubt that, as of the time the complaint is filed,’ a majority of the demand board ‘could have properly exercised its independent and disinterested business judgment in responding to a demand.’” *United Food & Com. Workers Union & Participating Food Indus. Emps. Tri-State Pension Fund v. Zuckerberg*, 262 A.3d 1034, 1048 (Del. 2021) (citing *Rales v. Blasband*, 634 A.2d 927, 934 (Del. 1993)).

At the pleading stage, “[t]he well-pleaded factual allegations of the derivative complaint are accepted as true....” *Rales*, 634 A.2d at 931. “Plaintiffs are entitled to all reasonable factual inferences that logically flow from the particularized facts alleged” *Brehm v. Eisner*, 746 A.2d 244, 255 (Del. 2000). The trial court is not entitled “to discredit or weigh the persuasiveness of well-pled allegations.” *United Food & Com. Workers Union v. Zuckerberg*, 250 A.3d 862, 877 (Del. Ch. 2020),

aff'd sub nom. Zuckerberg, 262 A.3d 1034. Dismissal is warranted only “if the defendants’ interpretation is the *only* reasonable construction as a matter of law.” *Kuhn Constr., Inc. v. Diamond State Port Corp.*, 990 A.2d 393, 396 (Del. 2010) (citing *Vanderbilt Income & Growth Assocs., L.L.C. v. Arvida/JMB Managers, Inc.*, 691 A.2d 609, 613 (Del. 1996)).

2. The Trial Court Properly Held that the Four Corners of the Complaint State a Claim

Based solely on the four corners of the Complaint, the trial court found that the Complaint states a Red-Flags Claim and a *Massey* Claim. As to the Red-Flags Claim, the trial court found that the allegations support a pleading-stage inference “that the directors knew that the Company’s existing [control] systems were inadequate and consciously decided not to take any action in response to ... red flags.” Op. at *16. As to the *Massey* Claim, the trial court found that “the allegations support a reasonable inference that the managers and directors acted with the [requisite] intent” Op. at *18. The trial court concluded that, if its analysis stopped there, “the Complaint would survive the motion to dismiss.” Op. at *2.

3. The Trial Court Improperly Relied on the *West Virginia Decision* to Deprive Plaintiffs the Reasonable Inferences to Which They Are Entitled

After articulating and acknowledging the plaintiff-friendly inferences supported by the Complaint, the trial court improperly discredited those plaintiff-friendly inferences based on the factual findings of the *West Virginia Decision*. That was legal error because (i) the *West Virginia Decision* is extrinsic evidence that the trial court was not permitted to credit for the truth of the matter, (ii) the *West Virginia Decision* does not support the inescapable conclusion that the Company complied with the CSA, and (iii) giving dispositive weight to a non-final, bellwether decision creates an unworkable regime where demand futility turns on the timing of when the motion is decided.

a. The Trial Court Erred By Relying on Delaware Rule of Evidence 202 to Consider Extrinsic Evidence

Except for three limited exceptions, post-complaint extrinsic evidence “should not be considered in ruling on a Rule 12(b)(6) motion to dismiss.” *Vanderbilt*, 691 A.2d at 612. The three exceptions are: (1) when an extrinsic document is integral to a plaintiff’s claim and is incorporated into the complaint, *In re Santa Fe Pac. Corp. S’holder Litig.*, 669 A.2d 59, 69 (Del. 1995); (2) when the document, or a portion thereof is properly subject to judicial notice, *Fawcett v. State*, 697 A.2d 385, 388 (Del. 1997); or (3) when the court does not rely upon the

document to establish the truth of its contents, but to examine only what was disclosed, *Santa Fe*, 669 A.2d at 69. The trial court erroneously concluded that the second exception applied.

In its Rule 60(b) Opinion, the trial court explained that it “acted properly by considering the *West Virginia Decision*”¹⁰⁷ because D.R.E. 202(a)(1) permitted it to take judicial notice of a “post-complaint development,”¹⁰⁸ *i.e.*, the *West Virginia Decision*’s finding “that the Company had complied with its anti-diversion obligations.”¹⁰⁹ But, D.R.E. 202(a)(1) authorizes courts to “take judicial notice of the common *law*, case *law* and *statutes* of the United States and every state, territory and jurisdiction of the United States,”¹¹⁰ not findings of fact. As the comments to the rule make clear, D.R.E. 202(a)(1) is intended to apply to “the admissibility of *evidence of law*.”¹¹¹

¹⁰⁷ Rule 60(b) Op. at *10.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.* at *2.

¹¹⁰ D.R.E. 202(a)(1) (emphasis added).

¹¹¹ D.R.E. 202 cmt.s (emphasis added).

In the *West Virginia Decision*, the West Virginia Court divided its opinion into “Findings of Fact” and “Conclusions of Law.”¹¹² The West Virginia Court’s finding that AmerisourceBergen complied with the CSA was among the *West Virginia Decision*’s “Findings of Fact.”¹¹³ As noted above, D.R.E. 202(a)(1) does not permit the trial court to take judicial notice of findings of fact. The trial court’s reliance on D.R.E. 202(a)(1) to take judicial notice of the *West Virginia Decision*’s finding of fact that the Company complied with the CSA was thus legal error.

Nor does D.R.E. 201 permit the trial court to take judicial notice of the *West Virginia Decision*’s findings of fact. D.R.E. 201 permits courts to take judicial notice of an “adjudicative fact” only if it is “a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court’s territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.”¹¹⁴ The *West Virginia Decision*’s factual finding that AmerisourceBergen complied with the CSA meets neither requirement.

¹¹² *West Virginia Decision*, 609 F. Supp. 3d at 413, 471.

¹¹³ *West Virginia Decision*, 609 F. Supp. 3d at 438 (“Plaintiffs did not prove that defendants failed to maintain effective controls against diversion and design and operate sufficient SOM systems to do so. Relatedly, plaintiffs did not prove that defendants’ due diligence with respect to suspicious orders was inadequate.”).

¹¹⁴ D.R.E. 201(b).

First, it is a foreign judicial determination; its findings barely scratch the public consciousness, let alone constitute a fact “generally known within the trial court’s territorial jurisdiction.” *Second*, the accuracy of the factual finding is being challenged on appeal to the Fourth Circuit and is subject to change, and thus cannot be characterized as being from “sources whose accuracy cannot reasonably be questioned.” See *Fawcett*, 697 A.2d at 388 (not proper to take judicial notice “[i]f there is any possibility of dispute”); see also *Santa Fe*, 669 A.2d at 69-70 (proxy statement cannot be used “to establish the truth of the statements therein”).

Neither D.R.E. 201 nor D.R.E. 202 permitted the trial court to take judicial notice of the *West Virginia Decision*’s findings of fact. The trial court thus reversibly erred by taking judicial notice of the *West Virginia Decision*’s factual finding that plaintiffs in that case failed to prove that AmerisourceBergen complied with the CSA in Huntington and Cabell, West Virginia.

b. The Trial Court Erred by Giving Dispositive Weight to the *West Virginia Decision*

The trial court erred for the additional reason that the *West Virginia Decision* does not foreclose the possibility that the Company violated the CSA (in West Virginia or elsewhere) even if its factual findings are accepted for the truth of the

matter. The Complaint includes ample allegations that support a pleading-stage inference that the Company violated the CSA, including:

- The U.S. Senate’s conclusion that in Missouri, AmerisourceBergen “consistently failed to meet [its] reporting obligations” under the CSA, and had “the most egregious record of underreporting among the major distributors”;¹¹⁵
- The U.S. House’s conclusion that AmerisourceBergen failed to comply with the CSA in West Virginia by, among other things, “continu[ing] shipments ... to certain pharmacies despite clear red flags of diversion”;¹¹⁶ and
- AmerisourceBergen’s agreement to pay \$6.4 billion to settle more than 1,800 lawsuits as part of a multidistrict litigation alleging that the Company violated the CSA.¹¹⁷

Additional facts properly before the trial court further support the pleading stage inference that Defendants violated the CSA:

¹¹⁵ A133, ¶237.

¹¹⁶ A133-34, ¶238.

¹¹⁷ A156, ¶270; A162, ¶280.

- Three weeks *after* the *West Virginia Decision*, the Company (and other distributors) agreed to pay \$400 million to settle actions related to AmerisourceBergen’s involvement in the opioid crisis;¹¹⁸ and
- The DOJ Complaint alleging that the Company violated the CSA hundreds of thousands of times.¹¹⁹

Against that backdrop, the bellwether *West Virginia Decision* cannot support the inescapable conclusion that the Company complied with the CSA. Indeed, the *West Virginia Decision* is being challenged on appeal as being premised on an overly narrow interpretation of the CSA with “no basis in law” and in contravention of “the CSA and its regulations as interpreted by the D.C. Circuit in *Masters [Pharmaceuticals, Inc. v. DEA]*, 861 F.3d 206 (D.C. Cir. 2017)”, the [Opioid] MDL court, and DEA.”¹²⁰ As explained in the appellate brief, the district court erred in its interpretation of the CSA in two respects:

First, it construed the duty to prevent diversion under [the CSA] as requiring only that distributors not sell to ‘pharmacies that are essentially acting as adjuncts of the illicit market’....

¹¹⁸ Knauth, *supra* note 83.

¹¹⁹ DOJ Complaint, A531 ¶227; A563-64, ¶443-46.

¹²⁰ A426, *West Virginia Decision Appeal* at 46.

Second, the district court ruled that distributors could be liable only for opioids ‘diverted while in defendants’ control or under their control’ or by their direct pharmacy customers, excusing them from responsibility to guard against ‘diversion that occurred downstream from their pharmacy customers.

Id. As argued on appeal, the CSA requires more. *Id.* (citing *Masters*, 861 F.3d at 218-19; *Southwood Pharms., Inc.*, 72 Fed. Reg. 36,487 (DEA July 3, 2007)).

Even if affirmed, the *West Virginia Decision* does not even support the broad conclusion that the Company complied with the CSA in Huntington and Cabell County, West Virginia. Rather, because of its novel interpretation of the CSA, the West Virginia Court “overlook[ed] [AmerisourceBergen’s] failures to identify and investigate suspicious orders [and] ignore[ed the] DEA’s allegations that [AmerisourceBergen] violated the CSA and [AmerisourceBergen’s] own admissions of wrongdoing.”¹²¹ Having failed even to consider significant evidence demonstrating the Company’s violation of the CSA, the *West Virginia Decision* cannot be said to have “knock[ed] the stuffing out of the plaintiffs’ claim” that the Company violated the CSA (in Huntington and Cabell, West Virginia or elsewhere).
Op. at *17.

¹²¹ A426, *West Virginia Decision Appeal* at 46; see also A442, *Id.* at 62-63.

Moreover, the *West Virginia Decision* by its very nature cannot support the dispositive weight that the trial court gave it because bellwether trials are employed for nonbinding informational purposes and for testing various theories and defenses in a trial setting. Eldon E. Fallon et. al., *Bellwether Trials in Multidistrict Litigation*, 82 Tul. L. Rev. 2323, 2337-38 (2008). A bellwether trial is intended to be a “test case” that is representative of a range of cases and outcomes—it is *not* determinative for the entire MDL or any broader application. See 22.315. Test Cases, Ann. Manual Complex Lit. § 22.315 (4th ed.). To fairly evaluate MDL claims, there must be “a *sufficient number of representative verdicts* and settlements to enable the parties and the court to determine the nature and strength of the claims. *Id.* (emphasis added). Because AmerisourceBergen settled every bellwether case except for the West Virginia trial, there is no representative sample.

Finally, even if the *West Virginia Decision* withstands appeal and even if it supports the inescapable conclusion that the Company complied with the CSA in Huntington and Cabell County, West Virginia, it does not follow that the Company necessarily complied with the CSA elsewhere. To reach that conclusion, the trial court was required to draw an impermissible defendant-friendly inference based on an unsupported syllogism—*i.e.*, if (a) Huntington and Cabell, West Virginia were amongst the worst for opioid abuse and (b) the Company complied with the CSA in

Huntington and Cabell, then (c) the Company complied with the CSA everywhere. That syllogism was particularly unwarranted given the Senate’s conclusion that AmerisourceBergen failed to meet its reporting obligations in *Missouri*.

At most, the Complaint’s well-pled allegations that, *e.g.*, the Company paid \$7 billion to settle opioid litigations premised on the Company’s alleged violations of the CSA, on the one hand, and the *West Virginia Decision*, on the other hand, support competing inferences as to whether the Company complied with the CSA. The trial court was required (but failed) to resolve those competing inferences in Plaintiffs’ favor. *See Inter-Mktg. Grp. USA, Inc. v. Armstrong*, 2020 WL 756965, at *14 (Del. Ch. Jan. 31, 2020) (crediting plaintiff-friendly inference even where defendants’ reasonable interpretation of the facts was “perhaps even the most reasonable”); *Louisiana Mun. Police Emps.’ Ret. Sys. v. Pyott*, 46 A.3d 313, 358 (Del. Ch. 2012), *rev’d on other grounds*, 74 A.3d 612 (Del. 2013) (“It may be that the directors in fact acted in good faith ... but at the pleadings stage I do not believe that I can adopt a defendant-friendly interpretation of the plaintiffs’ allegations.”).

c. Giving Dispositive Weight to the *West Virginia Decision* Creates an Unworkable Regime

The trial court’s decision to give dispositive weight to a post-complaint, non-final, judicial decision from a foreign court is also problematic because it creates a

“floating” assessment of demand futility that may turn on when the decision is issued. While it may make sense to dismiss following a final decision in a foreign court in, for example, a tag-along derivative action that turns on the outcome of a single securities case, dismissal here based on a single decision in a foreign court was problematic because it was possible (if not likely) that the premise of the decision would subsequently be undermined.

Put differently, the outcome of Defendants’ motion to dismiss turned on when it was decided. If the motion was decided before the *West Virginia Decision*, the Complaint presumably would have survived. If the Fourth Circuit reverses and the motion was decided thereafter, the Complaint presumably would have survived. And if the motion was decided after the DOJ Complaint—and the trial court had considered that the DOJ, after a years-long investigation by the DEA, determined that the Company violated the CSA—the Complaint may have survived.

By giving dispositive weight to a single bellwether decision subject to reversal or contradiction, the trial court rendered the outcome of its decision a function of timing rather than the merits. A Rule 23.1 motion should not legally or practically depend a “test case” or the timing of the shifting sands of judicial decisions from foreign courts. The trial court’s decision thus creates chaos from order and is incompatible with the administration of justice.

4. The Complaint’s Well-Pled Allegations That Defendants Opted for *Less* Regulatory Compliance in the Face of Red Flags Establishes Bad Faith Regardless of Whether the Company Violated the CSA

In the face of an avalanche of red flags of potentially illegal conduct, a fiduciary’s decision to pursue *less* regulatory compliance establishes a pleading-stage inference of bad faith regardless of whether the Company is ultimately found to have violated positive law. *See Constr. Indus. Laborers Pension Fund v. Bingle*, 2022 WL 4102492, at *7 (Del. Ch. Sept. 6, 2022) (noting possibility of pleading a *Caremark* claim premised on failure to monitor business risks rather than a violation of positive law).

Directors face a substantial likelihood of liability when they “knew of evidence of corporate misconduct—the proverbial ‘red flag’—yet acted in bad faith by consciously disregarding its duty to address that misconduct.” *Reiter v. Fairbank*, 2016 WL 6081823, at *8 (Del. Ch. Oct. 18, 2016); *accord In re Boeing Co. Derivative Litig.*, 2021 WL 4059934, at *33 (Del. Ch. Sept. 7, 2021). Bad faith may be shown if the directors “ignored either willfully or through inattention obvious danger signs of employee wrongdoing” *Graham v. Allis-Chalmers Mfg. Co.*, 188 A.2d 125, 130 (Del. Ch. 1963). Where, as here, regulations governing “health and safety are at issue,” a board “must actively exercise its oversight duties in order

to properly discharge its duties in good faith.” *Teamsters Loc. 443 Health Servs. & Ins. Plan v. Chou*, 2020 WL 5028065, at *18 (Del. Ch. Aug. 24, 2020).

The Complaint’s well-pled allegations support a pleading stage inference that Defendants consciously chose to approve a system of *downgraded* monitoring in the face of persistent warnings that AmerisourceBergen was fueling the opioid epidemic.¹²² Put differently, when faced with red flags that the Company’s business practices were resulting in massive numbers of drug overdoses, Defendants consciously chose to change the Company’s monitoring system so that it would flag *fewer* suspicious orders and, in turn, *increase* the distribution of opioids for illicit, non-medical use.

Defendants’ “we don’t care about the risks” attitude had severe consequences for stockholders (not to mention the health and safety of the public) regardless of whether the Company is ultimately found to have violated the CSA. *See In re Walt Disney Co. Derivative Litig.*, 825 A.2d 275, 289 (Del. Ch. 2003) (Directors breach their duty of loyalty by taking a “we don’t care about the risks” attitude concerning oversight obligations). The Company paid approximately \$7 billion in settlements,

¹²² Op. at *18 (Defendants adopted the Revised OMP for the “seemingly apparent purpose of driving down the already low numbers of suspicious orders that AmerisourceBergen was reporting”).

\$1 billion in litigation defense costs, and suffered incalculable reputational harm. Those costs continue to rise and, importantly, could have been avoided or minimized if the Company responded to the avalanche of red flags of wrongdoing discussed herein. Accordingly, the Complaint well-pled a *Caremark* claim even assuming *arguendo* that the Complaint failed to adequately plead that the Company violated the CSA.

II. THE TRIAL COURT ERRED BY NOT REVISITING ITS DECISION AFTER THE DOJ COMPLAINT

A. Questions Presented

Whether the trial court erred in concluding that the DOJ Complaint did not constitute “newly discovered evidence” and by otherwise refusing to reconsider its Opinion based on the DOJ Complaint.¹²³

B. Scope of Review

The standard of review of a decision denying a Rule 60(b) motion is *de novo*. *Lenois v. Sommers*, 268 A.3d 220, 232 (Del. 2021) (citing *Unitrin, Inc. v. Am. Gen. Corp.*, 651 A.2d 1361, 1385 (Del. 1995)).

C. Merits of Argument

Rule 60(b)(2) provides that a court “may relieve a party [f]rom a final judgment, order, or proceeding” on the basis of “newly discovered evidence.”¹²⁴ The trial court determined that Plaintiffs failed to meet *Levine* factors 1, 3, and 4 which require that: “[1] the newly discovered evidence has come to [movant’s] knowledge since the [judgment]...[3] that it is so material and relevant that it will

¹²³ Appellants preserved this issue in their Rule 60(b) Motion. A472-91.

¹²⁴ Ct. Ch. R. 60(b)(2).

probably change the result; [and 4] that it is not merely cumulative or impeaching in character.”¹²⁵

In denying Plaintiffs’ Rule 60(b) Motion, the trial court held that, “[t]o the extent the plaintiffs seek to rely on the filing of the DOJ Complaint as evidence of the DOJ’s belief in the strength of its allegations, the DOJ Complaint is ‘new evidence’ that cannot support relief under Rule 60(b)(2).”¹²⁶ After refusing to consider the filing of the DOJ Complaint as evidence of the DOJ’s belief that the Company violated the CSA, the trial court held that the DOJ’s allegations were not “sufficiently material to change the result” and “cumulative.” The premise of the trial court’s Rule 60(b) Opinion is fatally flawed.

First, the trial court erred in holding that the DOJ Complaint was “new evidence” that it was not permitted to consider under Rule 60(b)(2) because the decision to file the DOJ Complaint was extant before the trial court dismissed the action, but only discovered after the dismissal Opinion.¹²⁷ The DOJ Complaint was

¹²⁵ *Levine v. Smith*, 591 A.2d 194, 202 (Del. 1991).

¹²⁶ Rule 60(b) Opinion at *8.

¹²⁷ *See Grobow v. Perot*, 1988 WL 127094, at *2 (Del. Ch. Nov. 25, 1988) (holding that deposition testimony taken in separate action that was first publicly disclosed after litigation had been dismissed provided material basis to reconsider result of demand futility analysis).

the result of three grand jury investigations and followed the DOJ's and DEA's review of internal Company documents.¹²⁸ The DOJ Complaint was not filed in a vacuum, and there can be little doubt that the DOJ and DEA concluded that AmerisourceBergen violated the CSA (and chose to bring suit) long before the trial court issued its Opinion. Indeed, the Company *itself* publicly acknowledged in its August 3, 2022 Form 10-Q that it had been “engaged in discussions” with the DOJ, DEA, and various U.S. Attorney’s Offices “in an attempt to resolve these matters.”¹²⁹ The DOJ’s determination that AmerisourceBergen violated the CSA was therefore “newly discovered” factual evidence subject to consideration under Rule 60(b)(2).

Second, for the same reasons, the trial court erred in concluding that the DOJ Complaint was not “sufficiently material” and “cumulative.” Both holdings were premised on the trial court’s incorrect determination that the DOJ’s conclusion that AmerisourceBergen violated the CSA was “new evidence.”¹³⁰ Had the trial court considered the DOJ Complaint “as evidence of the DOJ’s belief in the strength of its allegations” that the Company violated the CSA, it almost certainly would have

¹²⁸ DOJ Complaint at A499, ¶14; A516-17, ¶121; A521, ¶151, ¶154; A522, ¶157; A522-23, ¶¶161-62; A525, ¶178; A535, ¶253; A535, ¶256 (describing burgeoning DOJ subpoenas and grand jury investigations)).

¹²⁹ See A601-02, AmerisourceBergen August 3, 2022 Form 10-Q at 18-19.

¹³⁰ Rule 60(b) Opinion at *8-10.

changed the result of the motion. The DOJ Complaint reflects the conclusions of the DEA and the DOJ following a years-long investigation and was filed eight-months *after* the issuance of the supposedly dispositive *West Virginia Decision*. The DOJ’s and DEA’s conclusion that the Company violated the CSA, particularly when viewed in combination with the Company’s \$7 billion in settlement payments and the findings of the U.S. House and Senate, rebut the trial court’s determination that the *West Virginia Decision* renders it impossible “to infer that the Company failed to comply with its anti-diversion obligations.”¹³¹

Moreover, to the extent the trial court gave any weight to the fact that the DOJ Complaint sounds in negligence,¹³² that was error as a matter of fact and law. As a matter of fact, the DOJ Complaint alleges more than mere negligence, including, for example, that the Revised OMP was *intentionally* designed by the Company to dramatically *reduce* the number of suspicious orders reported to DEA¹³³—which the trial court acknowledged that the Company’s Audit Committee was told.¹³⁴ As a matter of law, the question is whether the DOJ Complaint supports the inference that

¹³¹ Op. at *17.

¹³² See Rule 60(b) Opinion at *2, *9.

¹³³ A498-99, DOJ Complaint at ¶11.

¹³⁴ Op. at *8.

the Company violated the CSA, not whether it supports the inference that any Defendant breached their duties.

* * *

By crediting the *West Virginia Decision* for the truth of the matter; concluding that the bellwether *West Virginia Decision*—which applied only to Huntington and Cabell, West Virginia—rendered it impossible “to infer that the Company failed to comply with its anti-diversion obligations”; and refusing to credit the DOJ Complaint “as evidence of the DOJ’s belief in the strength of its allegations,” the trial court committed reversible error.

CONCLUSION

For the reasons stated above, the trial court's decision should be reversed and remanded.

Of Counsel:

KESSLER TOPAZ MELTZER &
CHECK, LLP
Eric L. Zagar
Grant D. Goodhart III
280 King of Prussia Road
Radnor, Pennsylvania 19087
(610) 667-7706

*Counsel for Plaintiff Lebanon County
Employees' Retirement Fund*

BERNSTEIN LITOWITZ BERGER &
GROSSMANN LLP
Jeroen van Kwawegen
Eric J. Riedel
1251 Avenue of the Americas
44th Floor
New York, New York 10020
(212) 554-1400

PRICKETT, JONES & ELLIOTT,
P.A.

By: /s/ Samuel L. Closic
Samuel L. Closic (Bar No. 5468)
Eric J. Juray (Bar No. 5765)
Robert B. Lackey (Bar No. 6843)
1310 King Street
Wilmington, Delaware 19801
(302) 888-6500

BERNSTEIN LITOWITZ BERGER &
GROSSMANN LLP
Gregory V. Varallo (Bar No. 2242)
Andrew Blumberg (Bar No. 6744)
500 Delaware Avenue, Suite 901
Wilmington, Delaware 19801
(302) 364-3600

*Counsel for Plaintiffs-
Below/Appellants*

HACH ROSE SCHIRRIPA &
CHEVERIE LLP
Frank R. Schirripa
Daniel B. Rehns
Kurt Hunciker
Hillary Nappi
112 Madison Avenue, 10th Floor
New York, New York 10016
(212) 213-8311

LEVI & KORSINSKY, LLP
Gregory Mark Nespole
Daniel Tepper
55 Broadway, 10th Floor
New York, NY 10006

Additional Counsel for Plaintiffs

ROBBINS LLP
Brian J. Robbins
Craig W. Smith
5040 Shoreham Place
San Diego, CA 92122

Additional Counsel for Plaintiffs

Dated: March 28, 2023

CERTIFICATE OF SERVICE

I, Samuel L. Closic, hereby certify on this 10th day of April, 2023, that I caused a copy of the foregoing *Public Version of Appellants' Opening Brief* to be served by eFiling via File & ServeXpress upon the following counsel of record:

Stephen C. Norman, Esquire
Jennifer C. Wasson, Esquire
Tyler J. Leavengood, Esquire
Christopher D. Renaud, Esquire
POTTER ANDERSON &
CORROON LLP
1313 N. Market Street
Hercules Plaza 6th Floor
Wilmington, Delaware 19801

Gregory V. Varallo, Esquire
Andrew Blumberg, Esquire
BERNSTEIN LITOWITZ BERGER &
GROSSMANN LLP
500 Delaware Avenue, Suite 901
Wilmington, Delaware 19801

/s/ Samuel L. Closic
Samuel L. Closic (#5468)