EFiled: Nov 21 2018 04:47PM EST
Filing ID 62691685
Case Number 535,2018

IN THE SUPREME COURT OF THE STATE OF DELAWARE

AKORN, INC., Plaintiff and Counterclaim Defendant Below, Appellant. v. FRESENIUS KABI AG, QUERCUS ACQUISITION, INC. AND FRESENIUS SE & CO. KGAA, Defendants and Counterclaim Plaintiffs Below, Appellees.	No. 535, 2018 Case Below: Court of Chancery of the State of Delaware C.A. No. 2018-0300-JTL

APPELLEES' ANSWERING BRIEF ON APPEAL

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NATURE OF PROCEEDINGS

The Court of Chancery's ruling that Fresenius rightfully terminated the Agreement correctly applied well-established Delaware law to an extraordinary factual record of complete and unexpected financial collapse; blatant, severe and systemic violations of Akorn's responsibilities to the FDA and the public that breached contractual representations and warranties; and post-signing misconduct and deceit in breach of Akorn's ordinary course covenant.[1]

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[1] *See* Frankel, *MAC Wall Has Been Breached!*, REUTERS (Oct. 2, 2018) (law professor: "this case is so far over the line that if it weren't a MAC you should not even write the provision into agreements."); Gibson Dunn, *M&A Report* (Oct. 2, 2018) (decision "not surprising given the facts"); Sullivan & Cromwell, *Delaware Chancery Court Upholds Termination of Merger* (Oct. 4, 2018) ("*Akorn* presented a perfect storm of dramatic post-signing performance decline … plus shocking regulatory misbehavior that combined to create an MAE record that will be difficult to replicate."); Practical Law, *Akorn v. Fresenius Kabi* (Oct. 5, 2018) ("hewing closely to the court's own precedent, particularly *IBP* and *Hexion*," "the decision simply represents the first time that a target company's financial performance and regulatory compliance fell so short … to be egregious enough to qualify as an MAE"); Simpson Thacher, *Delaware Chancery Court Finds a MAE for the First Time* (Oct. 8, 2018) ("*Akorn* … does not represent a sea of change in Delaware law … it is a decision specific to the facts"); Wachtell Lipton, *The MAC Is Back* (Oct. 9, 2018) (decision "confirms that all contract provisions—including MAE provisions—will be enforced by their terms upon an appropriate evidentiary record"); Morrison & Foerster, *Delaware Court of Chancery Finds a MAE* (Oct. 9, 2018) ("the high burden for establishing an MAE did not change as a result of this decision," which "turned on its facts"); McLaughlin & McGovern, *'Akorn v. Fresenius'*, NEW YORK LAW JOURNAL (Oct. 10, 2018) (court "applied longstanding precedents" to "extraordinary facts"); Leinwand, Langston & McDonald, *What Akorn Teaches Us About Delaware MAC Clauses*, LAW360 (Oct. 12, 2018) (emphasizing "particularly unhappy facts"); Fenwick & West, *Akorn* v. *Fresenius* (Oct. 24,

During four and a half trial days, the Court of Chancery heard 16 witnesses, including both parties' CEOs. The factual and credibility findings in the trial court's comprehensive and detailed opinion establish that Fresenius properly terminated the Agreement for at least three independent reasons:

First, Akorn's catastrophic post-signing financial collapse gave rise to an MAE. As a condition of signing in April 2017, Akorn publicly reaffirmed its 2017 earnings guidance. But because of a series of unexpected events, its financial performance "fell off a cliff" as 2017 unfolded. Op.2. Unlike previous MAE cases where acquirers failed to show significant and sustained impact on the seller, here every essential fact was unchallenged: By the end of 2017, Akorn had missed its EBITDA guidance by almost 85%, substantially underperforming on every relevant metric. That performance was far worse than Akorn's peers—the same peer group used by Akorn's investment banker and presented as comparable companies in Akorn's complaint. Akorn's CEO testified at trial that the events that caused this astonishing collapse were "unexpected" even to him. Op.155. Akorn did not dispute these facts below and does not do so now. Since the Court of Chancery's opinion, Akorn's shares have not traded above $7.52, less than a third of the $25.22 pre-announcement price and under a quarter of the $34 deal price.

2018) ("result was driven by specific—and oftentimes egregious—facts rather than any drastic re-interpretation of MAE clauses").

Second, Fresenius validly terminated because of what the trial court found was "overwhelming evidence of widespread regulatory violations and pervasive compliance problems," Op.163, amounting to blatant breaches of Akorn's representations that it was complying with critical FDA requirements.

The testimony of witness after witness—including Akorn's consultants and employees—showed Akorn to be "a company in persistent, serious violation of FDA requirements with a disastrous culture of noncompliance." Op.178. The Company's violations were so fundamental that Akorn's own data integrity ("DI") consultant testified he would not expect to see them "at a company that made Styrofoam cups, much less a sterile drug" company, and so serious that they "call[] into question … all of the test data, all of the production data, all of the raw material specifications" at Akorn, as well as "'literally … every released product they've done for however many years it's been this way."' Op.24. He ranked Akorn in the "'top three worst"' of the roughly 125 companies with DI problems he had audited. Op.26. Even Akorn's testifying expert, Kaufman, conceded that she "had never before encountered some of the [DI] problems that Akorn exhibited, including a senior quality officer who made misrepresentations to the FDA, company-wide computer access issues that allowed any employee to make changes to files without any traceability or accountability and the pervasive backdating of lab entries." Op.175.

The record provides overwhelming support for the trial court's finding that Akorn's egregious violations would reasonably be expected to result in an MAE. Qualitatively, as the trial court found, compliance with FDA requirements "is an essential part of Akorn's business" and Akorn "cannot meet its burden to prove to the FDA" that its data is accurate and reliable. Op.163,178. As expert testimony showed, nothing is more important for a drug company than compliance with FDA requirements and dealing honestly with the agency.

Quantitatively, after reviewing a detailed and "credible" analysis by experienced Fresenius personnel and hearing the testimony of top Fresenius executives, the Court of Chancery found that remediation of Akorn's crippling problems and verification or reproduction of its data would reduce Akorn's value by at least $900 million. Op.181-84. Tellingly, Akorn did not present a comparable remediation plan. Instead, it proffered a patently unrealistic estimate that falsely assumed its data was fully reliable. Akorn's own DI investigator, NSF (among others), has repeatedly shown that premise to be untrue.

Third, Fresenius validly terminated based on Akorn's material—and bad faith—breaches of its ordinary course covenant. Akorn conceded it had an obligation to investigate and remediate DI problems in the ordinary course. But it intentionally did the opposite after signing—ignoring serious DI and

manufacturing problems and taking extraordinary steps to conceal its violations in the hope that Fresenius would not discover them until after the transaction closed.

Once the Agreement was signed, Akorn cancelled numerous audits to avoid detecting "any more [DI] gaps that could jeopardize their efforts to sell the Company"; ordered employees to stop all DI work; and, at the direction of its head of quality, Mark Silverberg, submitted fraudulent test data to the FDA "to avoid inviting any scrutiny of Akorn's [DI] deficiencies until after the Merger closed, when it would be Fresenius's problem." Op.19,26. When Akorn was eventually forced to meet with the FDA, Akorn and its representatives again attempted to cover up its fraud and deceive the FDA about the state of Akorn's DI compliance. Even Kaufman conceded that Akorn was "'not fully transparent'" with the FDA. Op.4.

These egregious ordinary course breaches were material under any standard. Because of Akorn's wrongdoing, it lost an entire year in which it could have made meaningful remediation; exacerbated its problems by continuing to produce and use unreliable data that will have to be redone; repeatedly deceived its regulator; and has already been subject to intensive FDA inspections at key facilities that have identified serious violations, halted product approvals and forced product recalls. Indeed, Akorn made great efforts to hide its violations precisely because it knew how material they were and feared Fresenius' reaction if

it learned the truth. Akorn's deceptive scheme—in which its CEO, Head of Quality, General Counsel and outside counsel participated—would be material to any acquirer.

As the Court of Chancery wrote, the parties were not "committing themselves to merge at all costs and on any terms"—"they were committing themselves to fulfill the contract they had signed." Op.224-25. The ruling below appropriately holds Akorn to the bargain it struck. Any other result, we submit, would allow Akorn to evade its contractual responsibilities and reward its willful misconduct. The trial court's decision should be affirmed in all respects.

SUMMARY OF ARGUMENT

1. DENIED. The trial court correctly held that Akorn's post-signing financial collapse constituted a General MAE. Op.117-56. Akorn conceded the key issues: "Akorn … do[es] not contest that Akorn suffered a General MAE on a standalone basis," Op.142,n.600; did not dispute its disproportionately poor performance compared with self-selected peers, Appellant's Opening Brief ("Br.") 39-40; and admitted its collapse was "unexpected," Op.155,n.634. (Arg.§I.)

2. DENIED. As the trial court found, Akorn's representations that it was complying with FDA rules were blatantly false. That the court found Fresenius' remediation plan "credible" but did not credit its full amount is a discretionary factual finding, not, as Akorn contends, a "failure of proof." Akorn's contention that Fresenius knew Akorn was lying and could not rely on Akorn's representations is false and misstates Delaware law. (Arg.§II.)

3. DENIED. The trial court correctly found that Akorn incurably violated its ordinary course covenant. Far from having "no evidentiary support," as Akorn claims, this finding was based on a detailed evidentiary record of Akorn's breaches, including extraordinary efforts to hide its serious regulatory violations in the "hope[] that Fresenius would not get the full story until after the deal closed." Op.229. The trial court correctly defined "material" using its

ordinary meaning. Moreover, Akorn's brazen ordinary course breaches were material even under Akorn's incorrect standard. (Arg.§III.)

4. DENIED. Akorn's reasonable best efforts claim reduces to the argument that Fresenius had no right to investigate and act upon Akorn's blatant and intentional breaches of the Agreement. The trial court correctly found that Fresenius complied in good faith with the reasonable best efforts covenant. Indeed, as Akorn conceded, when suit was brought, "all closing conditions [were] satisfied," aside from FTC clearance, which was "close at hand." A57,65-66/¶¶8,26. The closing conditions ultimately were not met, but only because of Akorn's financial implosion and misconduct—not any act of Fresenius. (Arg.§IV.)

COUNTER-STATEMENT OF FACTS

I. The Merger

Beginning in February 2017, Fresenius engaged in "detailed" due diligence regarding Akorn. Op.40. Contrary to Akorn's suggestions, Br.6-8, the Court of Chancery found that diligence "did not identify any [DI] issues." Op.35-45,200. As Akorn notes, Fresenius learned of an FDA Form 483 issued to Decatur in mid-2016, Br.7-8, but this "identified manufacturing issues, not [DI] concerns," Op.41,44-45,200.[2] Fresenius also believed that Akorn's Regulatory Affairs Department was "under-resourced" and identified the need for quality enhancements, Br.8, but none of these topics involved DI. Op.41,44-45.

During negotiations, Akorn reassured Fresenius that it was "'on track to meet [its 2017] full year expectations"' of $1,010-$1,060 million in revenue and $363-$401 million in EBITDA. Op.42,48. Before signing, Fresenius insisted on waiting for Akorn's Q1 2017 results, which suggested that Akorn was indeed on track. A4610/1175:17-1177:5-13. Fresenius also required, as a condition of signing, that Akorn publicly reaffirm its 2017 guidance. Op.47-48. On April 24, 2017, Akorn publicly reaffirmed its guidance and Fresenius agreed to buy Akorn for $4.3 billion. Op.48;A4706-4778.

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[2] Fresenius' James Bauersmith testified that only one of "many" observations in the 483 "could become a precursor" to DI issues, and that he had "low to zero" concerns about Akorn's DI. A4398/592:10-594:9; *cf.* Br.7-8.

Recognizing the importance of Akorn's compliance with regulatory requirements, that due diligence was necessarily limited, and that many DI issues are difficult to discover, Fresenius bargained for extensive representations and warranties regarding regulatory compliance. Op.45,163-64;A4515/938:14-22; A4537,4539/1025:1-14,1032:13-1033:10. Akorn represented, among other things, that it was in "'compliance with … all applicable laws … relating to or promulgated by the"' FDA as well as "'current good manufacturing practices'" ("cGMP") and had not "'made an untrue statement of a material fact or a fraudulent statement to the FDA.'" Op.45;A4729-31/§3.18.

As an "additional level of protection," Fresenius required Akorn to "'use … commercially reasonable efforts to carry on its business in all material respects in the ordinary course"' until closing. Op.46,206;A4736-37/§5.01(a).

II. Akorn's 2017 Performance

Contrary to Akorn's expectations and assurances, after signing, Akorn's business declined "dramatically." Op.53. In late July 2017, after Akorn's Q2 results showed year-over-year declines of 84% in operating income and 96% in EPS, Fresenius CEO Stephan Sturm and Fresenius Kabi CEO Mats Henriksson flew to Illinois to meet with Raj Rai, Akorn's CEO. Op.2,53-56. Sturm tasked Henriksson and others "with finding new synergies and developing a business plan that would offset Akorn's problems." Op.56.

Akorn's decline continued in August and September. Op.57-58. Akorn asserts Fresenius then developed "buyer's remorse" and decided to "manufacture" a basis for termination. Op.59;Br.11-13. The trial court disagreed, finding that "Fresenius appropriately began evaluating its contractual rights" while "working hard to figure out how the deal could still work." Op.6,56,n.260,227. By mid-September, Fresenius had engaged Paul, Weiss to evaluate its rights. Op.57. The trial court found that Sturm "would seek to terminate [the Agreement] if Akorn's performance continued to deteriorate, but Fresenius also would live up to its obligations." Op.59. Akorn's Q3 results, released in late October, were even worse—year-over-year declines of 89% in operating income and 105% in EPS. Op.61.

III. Fresenius Learns Of Egregious DI Violations

Fresenius was continuing to assess Akorn's financial condition in October and November 2017 when it received anonymous letters alleging serious DI violations at Akorn. Op.6,66. Fresenius immediately hired leading FDA experts at Sidley Austin and the Lachman consulting firm to investigate. Op.68-73.

Sidley and Lachman visited three Akorn sites, discovering "'serious fundamental flaws in the way [Akorn] managed their data such that there was no [DI], essentially.'" Op.171. "'[M]ajor, systemic [DI] gaps' … 'call[ed] into

serious question'" Akorn's data, its FDA submissions and "'the safety and efficacy of Akorn's products.'" Op.171-72. Lachman team leader Ron George—a 40-year DI expert—testified he had never before seen such serious issues and ranked Akorn "'with the worst."' Op.172-73.

Fresenius' investigation and once this case commenced, discovery—particularly after the trial court ordered Akorn to produce materials withheld as privileged—uncovered proof of regulatory violations on an unprecedented scale and outrageous misconduct. The record showed that Akorn had consciously ignored DI violations for years, and after signing, had actively concealed them in the "hope[] that Fresenius would not get the full story until after the deal closed." Op.229. The opinion details much of Akorn's misconduct, including:

Cerulean: In 2016, Akorn engaged Cerulean, a highly regarded DI consulting firm, to inspect its Decatur, Somerset and Amityville facilities. A4213/31:14-32:3.

In December 2016, Cerulean reported seven "critical" deficiencies—which "'[h]istorically … have consistently resulted in public enforcement actions"'—at Decatur. Op.22-23. For example, Cerulean found serious violations relating to access controls—which restrict who may access electronic data—and audit trails—which document how that data is accessed. Akorn permitted completely uncontrolled, company-wide access to vital computer test records,

meaning that "any employee could make changes 'willy-nilly with no traceability or accountability[.]'" Op.164,n.652.

Cerulean reported that these violations undermined "'all of the test data [and] all of the production data'"; '"call[ed] into serious question the identity, strength, quality, safety, purity, and sterility of Akorn's drug products"'; and "'rais[ed] questions over the integrity of the laboratory's data since initial usage of the instruments.'" Op.24.

In May 2017, Cerulean reported three "critical" violations at Somerset, one of which—failure of senior management "'to ensure an effective quality system"'—was so severe that Cerulean warned Akorn's senior management about their own criminal liability. Op.25. As at Decatur, Cerulean identified deficiencies raising "'serious questions about the reliability of any [DI] controls and thus the trustworthiness of any electronic information used throughout Akorn to make safety, efficacy and quality decisions.'" Op.25.

John Avellanet, Cerulean's principal, testified that:

- Akorn was among the "'top three worst'" of the 120+ pharmaceutical companies with DI problems he has assessed.
- "Some of Akorn's [DI] failures were so fundamental that [Avellanet] would not even expect to see them 'at a company that made Styrofoam cups,' let alone a pharmaceutical company manufacturing sterile injectable drugs."
- "Akorn's lack of [DI] … 'literally calls into question every released [Akorn] product … for however many years it's been this way.'"

Op.26-27. Despite the seriousness of these issues, "Akorn did not do anything meaningful to address the[m]." Op.28. A March 2018 report from Akorn's own Global Quality Compliance ("GQC") internal audit team confirmed that Cerulean's "critical" findings were "valid" and concluded that Somerset did "absolutely nothing to address its deficiencies." Op.166;A10077-78,10157-73. Decatur likewise "failed to appropriately investigate and remediate," having "only completed '32% of the [necessary] corrective actions.'" Op.166;A10078.

Even worse, after the Agreement was signed, Akorn senior management took steps to ensure Cerulean did not "identify any more [DI] gaps that could jeopardize [management's] efforts to sell the Company." Op.26. Akorn "cancelled" Cerulean's scheduled assessment at Amityville. Op.26. Akorn made "'no effort'" to complete the Somerset assessment, which had been suspended because Akorn's IT Department refused even to cooperate. Op.24,26. The "only interest that Akorn's executives showed" in that assessment was a request from Akorn's General Counsel Joseph Bonaccorsi and GQC head Jaspreet Gill that "Cerulean remove the reference to potential criminal liability for Akorn's executives." Op.26. Avellanet was stunned that Akorn ignored critical findings, testifying that "it's as if my entire interim report for Somerset consisted of one paragraph … the [criminal liability] paragraph." A731/204:22-206:2.

GQC: GQC reports carried the same dire message. For example:

- Lake Forest: An April 2016 audit found audit trail deficiencies relating to "'data deletion"' and "'data manipulation.'" These problems remained unremediated even in December 2017.

- Vernon Hills: A June 2016 audit found a "critical" access control failure. Laboratory equipment was "'unable to record audit trails.'" These problems remained unremediated at the time of trial.

- Somerset: An April 2017 audit identified "critical" access control and audit trail deficiencies, still unremediated in December 2017.

- In 2017, GQC identified 42 other serious DI violations across Akorn's sites.

Op.167-68.

Akorn's disastrous state of compliance was specifically highlighted to Akorn senior management, who ignored it. For example, in June 2016, Akorn board member Ron Johnson admonished Mark Silverberg, Akorn's Head of Quality, for "'tolerat[ing] … non-compliance'" and warned that "'[w]e have dogged [sic] a bullet a number of times, but at some point, our number will be up[.]'" Op.21. Silverberg responded "'I think we should communicate live (on the phone).'" Op.21. In December 2016, as Fresenius and Akorn were negotiating, Johnson repeated to Silverberg and Rai '"his concern around the repetitiveness of [quality] issues between sites and across sites identified during audits and external inspections[.]'" Op.22. Silverberg and Rai did nothing.

After the Agreement was signed, desperate to avoid further critical GQC findings—and hoping to head off potential "difficulties for the Merger,"

Op.50—Akorn replaced GQC audits with "verification" audits that would not identify new DI violations but rather focus only on progress against previously identified violations. Op.49-50,216.

DI Freeze: After signing, Akorn management directed that employees cease DI initiatives, particularly those relating to IT, to avoid "identifying any new problems" that could threaten the Merger. Op.49-53,217. IT systems are critical for DI. Op.14,164. Yet Akorn Head of IT Kathy Pramik "prevented any [DI] work that required IT resources from getting off the ground in 2017 and early 2018." Op.51,n.234. An Akorn Quality Director explained in August 2017: "'[e]xecutive leadership have discussed and aligned that [DI] changes are not actionable in 2017[.]'" Op.52; *see id.* (collecting documents). Silverberg reassured others that a Decatur DI plan was acceptable only because it was a sham: it "'serve[d] to represent to outside authorities our cognizance of the subject, without committing IT to any near term work or responsibility.'" Op.28.

Defrauding FDA: To conceal Akorn's DI problems from Fresenius, in August 2017, Silverberg submitted fabricated data to the FDA in reply to an FDA "Complete Response Letter" ("CRL"). Op.19. "Silverberg knew that the CRL relied on fabricated data and submitted it anyway because the only alternative would have been to withdraw the [Abbreviated New Drug Application ("ANDA")] and start an investigation. That would have been a red flag for Fresenius."

Op.217. The trial court opinion describes in detail Silverberg's knowing submission and attempted concealment of fabricated data. Op.77-81.

Well before this incident, Akorn executives knew Silverberg was deceitful. In January 2016, a headquarters employee anonymously reported to Rai and senior management that Silverberg "'provided misleading information to regulatory bodies including the US FDA"' and "'counselled his staff to not speak to [GQC]."' Op.20. Akorn did not investigate. Op.20. Nor did Akorn investigate an incident in which Silverberg "instructed the head of quality at Akorn's Swiss site not to open an investigation into a quality issue he reported, not to put Silverberg's response in any file relating to the matter, and not to put FDA sensitive subjects in emails." Op.20-21.

Akorn's contempt for regulatory obligations went right to the top. The trial court "evaluated [Rai's] demeanor while he was being cross-examined about his commitment to quality" and was "forced to conclude that [Rai] does not regard it as a priority." Op.30. "Another plausible and more alarming inference is that Rai consciously disregarded Akorn's quality issues, including its [DI] problems." Op.30,n.112.

"Eat It" Incident: In December 2017, Cravath—Akorn's deal, investigatory and litigation counsel—stumbled upon the azithromycin fraud while preparing employees to meet with Sidley.

Silverberg then tried to destroy evidence of the fraud. On December 20, Akorn quality official Sherwani informed a Cravath associate that Silverberg had asked Sherwani to coordinate stories and destroy evidence. The associate emailed Cravath lead partner David Stuart that Sherwani was:

> uncomfortable being in the same room with [Silverberg] right now because he is telling her to do things with respect to opening a [T]rackwise investigation that she is seriously concerned about (including inaccurate justifications for why an investigation was not opened earlier and telling her he will "eat" the drafts of the language about that).

Op.77-78. After speaking with Silverberg and Sherwani, Stuart claimed he "very quickly" dismissed this as a "fleeting issue" involving a miscommunication. Op.78. The trial court, however, discredited that claim and found that the associate's email was a "fairly obvious reference to coordinating stories, documenting the coordinated story in Trackwise, the software Akorn uses to track quality issues and investigations, then concealing the evidence of the coordination." Op.78.

A month after this incident, Stuart met with Sidley, supposedly to provide a comprehensive report on the azithromycin events. Stuart said nothing about the incident, and a binder of almost 70 documents Cravath gave Sidley omitted the email quoted above. A4542/1044:23-1046:22.

Defrauding FDA Again: In March 2018, Akorn belatedly met with the FDA about azithromycin. Rather than speak truthfully, Akorn misled the FDA.

Akorn's presentation, given by Stuart, "[e]ndorsed as valid Silverberg's claimed justification for signing" the fraudulent CRL. Op.93. In an "Investigative Finding," Akorn's presentation stated that Silverberg signed the CRL "*without knowing*" fabricated data would be submitted. Op.93. Yet Stuart had previously told Sidley he did not believe Silverberg's story and would not defend it. Op.82-83.

In an internal email initially withheld as privileged, Stuart concluded that if the "document trail" were shown to the FDA, there was "'a high likelihood that [the agency] would conclude … [Silverberg] did act with intent.'" Op.83,94. The solution was simple: Stuart concealed the document trail. Even Kaufman opined that by calling Silverberg's explanation an "investigative finding" and not providing the document trail, Akorn was "'not fully transparent"' with the FDA. Op.92,169,219.

Akorn also misled the FDA about its quality controls. Ignoring its devastating audit reports, Akorn claimed it had "'improv[ed] [DI] controls in the last few years'" when Akorn had ignored its DI violations. Op.94.

NSF: Under impending FDA scrutiny, Akorn finally hired its own DI investigator, NSF, in March 2018. Op.28,98,169. NSF discovered the same types of pervasive DI violations identified by Cerulean, GQC, Sidley and Lachman, together with multiple additional fraudulent submissions to the FDA.

First, NSF found *dozens* of "major" DI violations across six Akorn facilities. Op.100-01,169. Akorn's lawyers were immediately concerned that "'[i]f audit reports make it look like there are similar issues across the company, FDA might see need to get the whole company under decree"' and the "'[s]heer number of issues across all sites … could raise concern."' Op.170,n.683. They concluded that "the longer NSF is on site, the more likely it is that employees are going to raise issues." B47.

Second, by trial, NSF had reviewed eight ANDAs and found data manipulation in *half* of them. Op.103-04. Two ANDAs had "critical deficiencies involv[ing] data fabrication," one of which involved "'deliberate"' falsification by a manager. Op.104-05. Two others contained "manipulate[d]" data. A11571,11633. Shortly after trial, NSF discovered that the same manager falsified data for numerous other products. Op.107.

Third, NSF found "extensive evidence" of trial injections "used in FDA submissions over a five-year period," which "had major regulatory significance." Op.105,170-71. The FDA forbids "trial injections" of product samples, which can allow an analyst to manipulate tests by discarding failing results. A4251/181:14-182:9;Op.105.

IV. Fresenius Terminates

The Agreement's initial Outside Date was April 24, 2018. Op.1,47. As that date approached, Fresenius did not know the full extent of the DI violations discussed above, but even what it had uncovered easily satisfied the MAE standard.

At the same time, Akorn's financial collapse had continued. Akorn's 2017 EBITDA was $64 million, an 86% year-over-year decline and 85% below guidance (issued after Q1). Op.89. Q1 2018 results showed operating income of negative $25 million, a 134% year-over-year decline. Op.99.

Akorn, however, took the position that Fresenius was obliged to close. In mid-April 2018, Fresenius offered to extend the Outside Date to allow Akorn more time to investigate DI issues and attempt to demonstrate that they were not sufficiently severe to violate representations and warranties. Op.98-99. Akorn refused and Fresenius terminated the Agreement on April 22. Op.99. Akorn sued on April 23. The case was tried in July.

V. Akorn's Situation Further Deteriorates After Trial

After trial, "Akorn's situation [grew] even worse." Op.112. On August 9, the FDA formally classified Decatur as Official Action Indicated ("OAI") because it was "in an unacceptable state of compliance," meaning Decatur

will not receive any product approvals. Op.101-03,108,177. Approval is now overdue for 17 ANDAs at Akorn, including 8 at Decatur. B29-44;Op.177.[3]

On August 30, the FDA issued a scathing, 22-page Form 483 following a lengthy inspection at Somerset. Op.107-09. It identified many deficiencies that "echoed the evidence presented at trial," Op.108:

- Trial injections were a "'widespread practice' dating back to 2015." Akorn had not conducted *any* remediation until May 2018. Moreover, Akorn's investigation was inadequate, meaning that "'there is limited assurance in the reliability of data submitted to the [FDA] and generated for commercial batches."'
- Akorn failed to maintain "'[a]ppropriate controls … over computers or related systems[.]"'
- "Akorn delayed investigating quality issues for months 'without adequate justification.'"
- "Akorn distributed batches of adulterated sterile eye drops that failed four separate stability tests" and "Akorn employees retrospectively modif[ied] the relevant laboratory notebooks."

Op.108-09. Akorn's response to the Form 483 further "evidences the deep and pervasive nature of Akorn's quality problems[.]" Op.111. It shows Akorn has been forced to fire its own quality personnel at Somerset and outsource virtually

[3] Akorn states it recently received two approvals. Br.27-28. The trial court denied Akorn's motion to supplement the record with the first approval, finding it was immaterial and did not "change the extensive factual record[.]" A17003-04. Akorn waived any appeal of that decision by not including "arguments and supporting authorities" in its opening brief. *Tumlinson* v. *Advanced Micro Devices, Inc.*, 106 A.3d 983, 988 (Del. 2013). Every ANDA approval Akorn received in the last six months involved a single site—Amityville—which the FDA has not inspected recently.

every facet of its laboratory and DI operations to consultants, essentially conceding that it had no effective quality controls. Op.111; *cf.* A10678-79.

Shortly thereafter, Akorn reported that during the FDA's Somerset inspection, a database containing "all of Somerset's data" for critical safety testing was "deleted intentionally." Op.110. The trial court found it "reasonable to infer that the perpetrator may have been trying to hide information from the FDA[.]" Op.110. The perpetrator is the *fifth* Akorn employee known to be involved in data fraud. Op. 105. Akorn received a DOJ subpoena (which it has refused to disclose) relating to the destruction.

Since trial, Akorn has also released its Q2 and Q3 2018 financial results. As of November 20, Akorn's stock traded at under $7 per share.

ARGUMENT

I. THE COURT OF CHANCERY CORRECTLY FOUND A GENERAL MAE

A. Question Presented

Did the Court of Chancery clearly err in holding that Akorn suffered a General MAE given that Akorn's performance indisputably collapsed on every metric disproportionately to its self-selected peers and that Akorn itself attributed its collapse to unexpected events? A15877-85,15892-94,16105-110.

B. Scope Of Review

Factual findings of the trial court will not be set aside unless they are clearly erroneous. *CDX Holdings, Inc.* v. *Fox*, 141 A.3d 1037, 1041 (Del. 2016). "That deferential standard applies not only to historical facts that are based upon credibility determinations but also to findings of historical fact that are based on physical or documentary evidence or inferences from other facts." *Id.* "When factual findings are based on determinations regarding the credibility of witnesses, the deference already required by the clearly erroneous standard of appellate review is enhanced." *Id.* Legal conclusions are reviewed de novo.

C. Merits

The key factual issues contested in other MAE cases such as *IBP* and *Hexion* are not disputed here. There is no disagreement that Akorn's financial collapse was material; the collapse resulted from "company-specific problems

rather than industry-wide conditions," or at least industry-wide conditions disproportionately affecting Akorn compared with its self-selected peers; and "[n]either Akorn nor Fresenius knew about the events that caused Akorn's problems, which were unforeseen." Op.156.

1. Akorn's Post-Signing Collapse Was Material

Akorn does not dispute its "dramatic underperformance" and "do[es] not contest that Akorn suffered a General MAE on a standalone basis." Op.142,n.600,147. Nor could it.

Akorn wrongly argues that the trial court erred by considering standalone value, instead of making a subjective determination of Akorn's synergistic value to Fresenius. Br.40-42. But as the trial court observed, "the plain language of the definition of an MAE makes clear that any MAE must be evaluated on a standalone basis." Op.139. The Agreement defines an MAE in terms of the value of Akorn without regard to Fresenius or potential synergies—it focuses on the "financial condition of [Akorn] and its Subsidiaries, taken as a whole." A4767-68/§8.12;Op.139-40. Indeed, the MAE definition specifically *carves out* effects of the Merger such as synergies. Op.127;A4767-68/§8.12 ("no effect … arising out of, or resulting from," the "execution … performance … or the consummation of the Transactions" "shall … be taken into account").

Akorn's synergy argument therefore seeks to "introduce a different, non-contractual standard." Op.140. That standard would be unprecedented—"every prior decision has looked at changes in value relative to the seller as a standalone company." Op.140. Akorn cites *IBP*'s statement that courts should consider "the longer-term perspective of a reasonable acquirer," Br.40—but this confirms the test is objective, not specific to Fresenius. Indeed, *IBP* explicitly considered the target's value without reference to synergies. Op.140,n.593. Akorn also cites *Hexion*, but that decision analyzed the target's EBITDA without reference to synergies. Op.140,n.593 (citing *Hexion Specialty Chems., Inc.* v. *Huntsman Corp.*, 965 A.2d 715, 740-42 (Del. Ch. 2008)). Akorn's only other authority is an unreported New York case quoting, in dicta, a fact witness's reference to synergies. Br.40 (citing *RUS, Inc.* v. *Bay Indus., Inc.*, 2004 WL 1240578, at *19 n.22 (S.D.N.Y.)).

Akorn cites *IBP*'s observation that there may not be an MAE if a deal is "still within the range of fairness and a great long-term value." Br.41. That statement—which simply focuses on durational significance—has no application here: Akorn's financial performance is disastrous on every metric. Since the trial court's ruling, Akorn's shares are trading nearly *80%* below the deal price.

Akorn is wrong in claiming (contrary to its buyer's remorse argument) that Fresenius "still thinks [the deal is] profitable." Br.41,68-70. Akorn ignores

the effects of Akorn's devastating DI violations, valued at almost $1 billion by the trial court and $1.9 billion by Fresenius. Op.184. Even excluding those amounts, the Merger would still generate meaningful losses in the first three years (B254/L202-204,M202-204,N202-204)), yielding a return barely higher than Fresenius' cost of capital (B251-52/H76,V73)) despite the deal's immense risks and opportunity costs. Op.141.

Finally, Akorn ignores the contractual standard: whether, since signing, there has been "any effect, change, event or occurrence that, individually *or in the aggregate*," causes an MAE. A4756,4767-68/§§6.02(c),8.12. Although Akorn's financial implosion alone establishes an MAE, the existence of an MAE is made even more evident here when considered with the huge quantitative and qualitative impact of Akorn's ordinary course violations.

2. Akorn's Collapse Was Caused By Company-Specific Problems Or Industry Problems Disproportionately Affecting Akorn

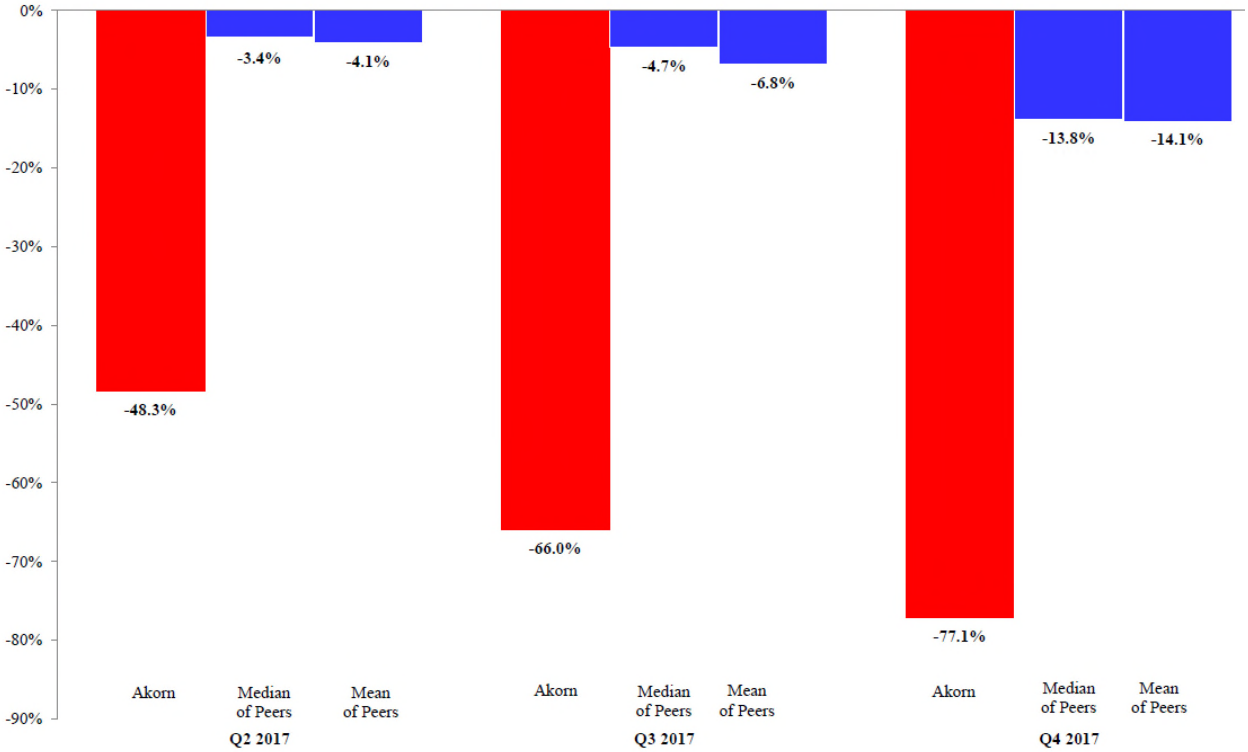
The trial court correctly found that Akorn's collapse was caused by Akorn-specific factors. Op.142-49. Akorn claims that its collapse was caused by industry-wide "systemic risks," Br.37-39—unexpected competition—but ignores the trial court's findings that Akorn's unique problem was a "product mix" unusually susceptible to competition. Op.144. Under Akorn's flawed reasoning, company-specific factors could always be "transform[ed]" into industry factors "by describing them at a greater level of generality." Op.144.

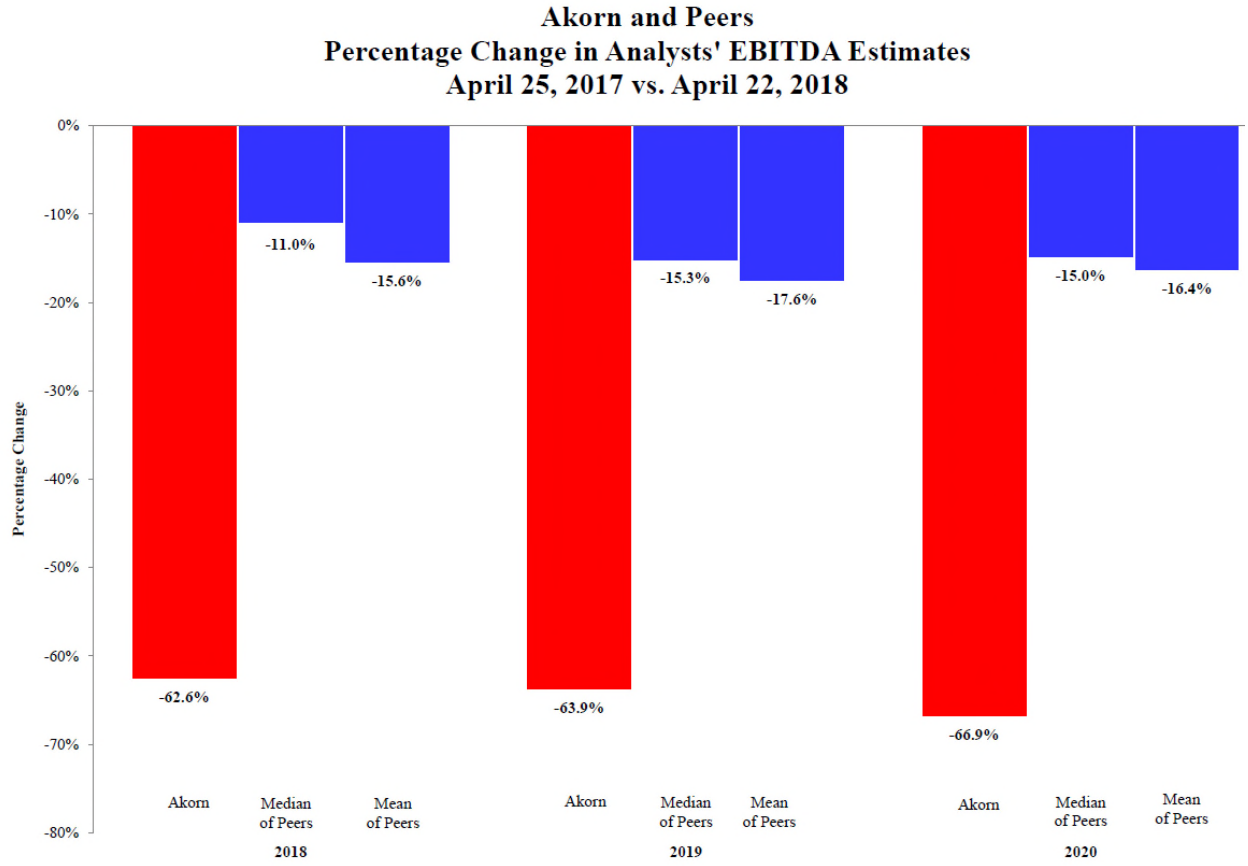
Moreover, this point is moot: the Court of Chancery determined that even if industry factors caused Akorn's collapse, Akorn was disproportionately affected. Akorn does not contest the court's holding that it *conceded* the disproportionality issue. Op.145. Akorn still does not argue that its collapse was proportionate to the industry—nor could it, given the overwhelming numbers.

Akorn argues for the first time on appeal that the trial court erred by not analyzing whether the "*incremental* disproportionate impact" on Akorn was an MAE. Br.39. Akorn waived this argument by not raising it below. Sup. Ct. R. 8; *RockTenn CP, LLC* v. *BE & K Eng'g Co., LLC*, 103 A.3d 512 (Del. 2014). Akorn's briefs below never even used the word "incremental." A3907,15911,16365.

Moreover, Akorn does not argue that the incremental disproportionate impact was not an MAE, nor could it, given Akorn's overwhelmingly poor performance compared to self-selected peers. That is demonstrated by the following exhibits from Fresenius' expert Daniel Fischel:

Akorn and Peers
Actual EBITDA Relative to Analysts' Estimates as of April 25, 2017
Q2 2017 - Q4 2017





A12990-95; *e.g.*, Op.145-46 (performance "*substantially worse* than … peers"); Op.147 ("*vastly underperformed* … comparable firms").

Akorn notes that a "failure to meet" forecasts does not constitute an MAE, Br.39-40, but the trial court did not find that failures to meet forecasts themselves constituted an MAE. Rather, Akorn's wide misses were *reflective of* its financial collapse; nothing in the MAE definition precludes consideration of that. Indeed, the second chart above does not address a failure to meet forecasts; its point is that the reduction in forward-looking estimates evidences Akorn's financial collapse relative to peers.

Akorn's half-baked policy argument—that courts should not consider analyst estimates because of the potential for "[i]rrationally optimistic analysts [who] could create an MAE even where the seller's underlying fundamentals remain sound," Br.40—is equally unavailing. Akorn has never argued—much less shown—that the forecasts used here were irrational. Nor has it argued that its fundamentals remain sound.

3. The Events Causing Akorn's Collapse Need Not Be Unknown But Were Unknown

As the Court of Chancery correctly held, the events giving rise to an MAE need not be unknown. The MAE definition contains a detailed set of exceptions and exclusions delineating the contours of an MAE. Op.150-53. Nothing in the definition excludes the unexpected effects of anticipated events. Implying such an exclusion would be inconsistent with the contractual scheme—which, as the trial court noted, is far more comprehensive than in cases like *IBP*. Op.153-54. Indeed, a recent survey found "28% of deals valued at $1 billion or more involved an MAE carve-out for developments arising from facts disclosed to the buyer or in public filings"; this Agreement did not. Op.152,n.628.

But this does not matter—"the evidence shows that the events that resulted in a General MAE at Akorn were unexpected." Op.153. The trial court found, based on extensive evidence, that "[n]either Akorn nor Fresenius knew about the events that caused Akorn's problems, which were unforeseen." Op.156.

The record overwhelmingly supported this finding: Rai conceded that Akorn's collapse was caused by "unanticipated" factors such as "'unexpected"' new competitors for Akorn's products ("'way more than what [Akorn] had potentially projected"'); "'price erosion … that we had not factored in'"; and a lost contract from which Akorn had "projected … [it] would get additional business." Op.54,60-61,137-38,155,n.634;A4386/546:9-547:12. Akorn gave similar explanations in securities filings. Op.155,n.634 ("'lower than expected"' pricing due to "'unfavorable customer/contract mix and price erosion [that was] not considered,'" and "'unanticipated supply interruptions.'"). Akorn did not know which competitors might be marketing its products until those competitors' ANDAs were approved. A1565/43:24-44:5; *see* Akorn 11/16/18 Confidentiality Motion 2,n.1 (pending ANDAs are competitively sensitive).

Akorn fell short of the low end of its 2017 guidance—reaffirmed the day of the Agreement—by almost 85% for EBITDA. C-SOF§I. "If Akorn management had anticipated the competition and price erosion that was on the horizon, they would not have reaffirmed their guidance." Op.155. Akorn also fell far short of Fresenius' expectations—"Fresenius expected that Akorn would not meet its internal projections and adopted lower forecasts of its own, but Akorn dramatically underperformed Fresenius's less optimistic estimates." Op.155-56.

Although every relevant precedent speaks in terms of unknown *events*, Akorn attempts to change the subject and argue that certain *risks* were known to Fresenius. But "Akorn goes too far by transforming 'unknown events' into 'known or potentially contemplated risks.'" Op.150.

Every time Akorn quotes a precedent, it is forced to speak of "unknown events," Br.29-31, but Akorn then wrongly argues that the MAE test considers unknown "risks." As the trial court noted, *IBP* and *Hexion* "speak in terms of 'unknown events,' not contemplated risks." Op.154; *e.g.*, *In re IBP, Inc. S'Holders Litig.*, 798 A.2d 14, 66 (Del. Ch. 2001) ("Tyson would have to show that the *event* had the required materiality of effect."); *id.* at 68 (MAE provision "protect[s] the acquiror from the occurrence of unknown *events*"); *Hexion* 965 A.2d at 738-39 (following *IBP*).

Indeed, in *IBP*, the buyer was "fully aware of the risks that attended the cyclical nature of IBP's business" (*IBP*, 798 A.2d at 22, 45), but that did not preclude an MAE. Instead, the court found no MAE on quantitative materiality grounds, reasoning that IBP's earnings "would not be out of line" with historical performance during "troughs in the beef cycle" and IBP was projected to "return to historically healthy earnings." *Id.* at 70-71. Similarly, in *Hexion*, the buyers were "familiar with the cyclicality that [the titanium] business is known to face." *Hexion*, 965 A.2d at 745. But that did not preclude an MAE either—instead, there

was no MAE because Huntsman suffered only modest EBITDA decreases. *Id.* at 742-43.

The same result is supported by the Agreement here. "The contractual language is forward-looking and focuses on events. It does not look backwards at the due diligence process and focus on risks." Op.153. Nothing in the MAE definition, for example, excludes risks disclosed during due diligence or known to Fresenius. Op.152. If no event related to a conceivable risk could cause an MAE, MAE provisions would effectively mean nothing—only the rarest of events could not somehow be linked to a conceivable risk. Indeed, the Agreement specifically contemplates that an MAE may result from industry factors—which will always be known risks on some level—disproportionately affecting Akorn.

Akorn points to no evidence suggesting that Fresenius expected the events precipitating Akorn's collapse. It cherry-picks low ephedrine projections from a presentation from Fresenius' financial advisor Moelis (Br.6), but those projections were a "downside case"—the same presentation projected an ephedrine "upside case"; estimated 2017 revenue of $1.15 billion and EPS of $2.33 (compared with actual revenue of $841 million and *negative* EPS of $0.20); and had price targets for Akorn of $31-$42 a share. A5040,5044-45. To the extent accepted by Fresenius, Moelis' estimates were incorporated in Fresenius' financial projections, of which Akorn fell far short. There is therefore no basis to exclude,

as Akorn argues, revenue decline from ephedrine from the MAE analysis—especially given that the MAE definition requires an analysis of Akorn "taken as a whole," not product-by-product. *Cf.* Br.32. Moreover, Akorn focuses on revenue, ignoring its even worse performance on other metrics discussed by the trial court. Op.135-48.

Citing Fresenius' rejected proposal to include revenue-based CVRs, Akorn argues that finding an MAE would give Fresenius "non-bargained-for insurance" against revenue declines, Br.7,32, supposedly making the MAE clause "a non-bargained-for warranty of financial projections." Br.37. To the contrary, the MAE provision is independent of the contractual warranties and protects only against "a sustained decline in business performance that is durationally significant and which would be material to a reasonable buyer." Op.142. Fresenius' proposed CVR was quite different and far more sensitive—it would have applied if Akorn's net sales fell just 6% below expectations. A5779-80;B24.

II. THE COURT OF CHANCERY CORRECTLY FOUND A REGULATORY MAE

A. Question Presented

Did the Court of Chancery clearly err in holding that Fresenius validly terminated based on Akorn's pervasive regulatory violations that could reasonably be expected to give rise to an MAE? A15887,16090.

B. Scope Of Review

See §I.B.

C. Merits

As the trial court found, "[t]here is overwhelming evidence of widespread regulatory violations and pervasive compliance problems at Akorn." Op.163. Akorn does not and cannot disagree. Br.43-52. Instead, Akorn argues that (i) its violations are not sufficiently egregious to constitute an MAE, and (ii) Fresenius should have known that Akorn's representations were false and was never entitled to rely on them.

1. The Court Correctly Found An MAE

The trial court correctly found that Akorn's regulatory violations amounted to an MAE both qualitatively and quantitatively.

The court found that Akorn's DI violations were qualitatively significant because they prevent Akorn from being able to prove its data is reliable—a fundamental requirement. Op.163-64. As Akorn concedes, the FDA's

DI requirements "place the burden on the pharmaceutical company to 'prove … that data is what it is purported to be."' Op.13. Without that proof, drug companies cannot file new product applications or sell manufactured products. Companies submitting ANDAs must certify under penalty of criminal liability that data is "true and accurate," and Akorn's product release form requires certification that testing complies with cGMP. B4-5,502.

The trial court found that "Akorn has pervasive [DI] and compliance problems that prevent Akorn from being able to meet these standards." Op.164; *see* Op.112 (trial court "did not have any confidence that Akorn would be able to support its data."). George, a 40-year DI expert, testified that "'the reliability of all [Akorn] data should be questioned."' Op.173. Avellanet testified that Akorn's problems "'literally call[] into question every released product.'" Op.27. Even Kaufman conceded that Akorn's "incredibly serious" computer violations "undermined the security of Akorn's data." Op.175;A4288/332:20-22.

Compliance with regulatory requirements "is no small thing; it is an essential part of Akorn's business. It was also essential to Fresenius." Op.163. Nothing could be more material to an acquirer than the reliability of a drug company's test data, products and quality systems. As Sturm testified, "we thought we'd buy a house. We're buying a renovation project, including the foundation." A4615/1196:10-15. The trial court was not faulting Akorn for falling

short of "absolute compliance," Br.50, but for being "a company in persistent, serious violation of FDA requirements with a disastrous culture of noncompliance" and unreliable data imperiling its entire business, Op.178. These problems were enormously significant—requiring Akorn to revamp systems, retrain employees and verify its data.

Moreover, the qualitative significance of Akorn's wrongdoing was heightened by its repeated misrepresentations to the FDA. A drug company's relationship with the FDA is of critical importance and Akorn's repeated frauds struck at the heart of that relationship. Akorn must now remediate under intense scrutiny from the FDA and a significantly heightened risk of regulatory sanctions.

The Court of Chancery also correctly found that Akorn's violations were quantitatively significant on an enormous scale. Fresenius presented a detailed plan showing that remediating Akorn's violations would require $254 million in direct costs and cause $1.6 billion in "lost value from suspending sales of existing products and delaying production of pipeline products until data could be verified." Op.97. Fresenius' plan was supported by: detailed trial testimony of Henriksson, Op.181-83;A4521-23/961:19-967:15; a comprehensive presentation to Fresenius' Supervisory Board, A10676-707; hundreds of related documents produced in discovery; and at least five depositions of relevant Fresenius employees, A1686-95,1811-14,2282-84,2388-92,2609-2610. And it is supported

by Akorn's own actions—at trial, Akorn criticized the plan's assumptions that many quality employees would be fired (*e.g.*, A15922), but has now conceded that virtually its entire quality function at Somerset must be replaced with consultants. C-SOF§V.

Tellingly, Akorn submitted no remediation plan of its own addressing these issues. Op.179-82. Instead, Akorn submitted a $44 million estimate that was "not credible" because it falsely assumed that Akorn "would not uncover any additional problems with Akorn's data." Op.179-80. "Given Akorn's pervasive [DI] issues and its obligation to prove the reliability of its data to the FDA, this seems highly unlikely." Op.180. Akorn declined to provide trial testimony supporting its estimate. Op.179-80. Its main DI witness, Wasserkrug, had "no idea" whether the "number is correct or incorrect." Op.179. Kaufman "admitted that she did not have the expertise to determine what the amounts should be" and was not "an expert in data remediation plans." Op.176,180;A3162/136:17-19,4278-79/292:12-293:10,4291/341:18-343:3.

The trial court determined that Fresenius' $1.9 billion estimate was "credible" and "much closer" to the actual remediation cost than Akorn's patently unrealistic estimate. Op.182-83. The court concluded that a conservative estimate would be $900 million over 3-4 years, Op.184, representing a "valuation hit" of 21%. Op.184. Akorn's six criticisms of this finding are baseless:

First, Akorn argues that the court "rejected" Fresenius' $1.9 billion estimate and found a "failure of proof." Br.44. But after careful consideration, the court found that "the evidence persuades me that a responsible remediation plan would be much closer to" Fresenius' analysis than to Akorn's plan, repeatedly describing Fresenius' analysis as "credible." Op.181-83. That the court acted conservatively and did not accept Fresenius' full estimate does not mean Fresenius somehow failed to meet its burden. Akorn's argument would mean that any litigant fails entirely if a court fails to endorse every cent of a damages claim—a startling proposition.

Akorn tries to minimize its violations by pointing to certain DI issues at Fresenius, Br.50, but that comparison is quite unfavorable to Akorn. Fresenius' issues affected one of more than 70 Fresenius sites, accounting for less than 0.5% of Fresenius Kabi's revenue. A4538/1027:2-1028:18. Fresenius' experience at that site—which was crippled for years—was the model for the remediation plan presented to the court, Op.181, so Fresenius personnel did not need third-party consultants or "case studies." *Cf.* Br.26.

Akorn also claims that "[n]ot one expert opined that [Fresenius' remediation plan] assumptions are reasonable." Br.26. Not true. A4642/1303:9-1304:12,12883-84/¶¶61-64,13740-42/¶76 (industry expert Klener

agreeing that Akorn must verify its data); A9810 (FDA expert Chesney "fundamentally agree[ing] with" Fresenius' plan).

Akorn claims that Fresenius' plan was "made-for-litigation." Br.26. In fact, it was made for Fresenius' Supervisory Board. And it was initially withheld, produced in discovery only after Akorn demanded its production because it was "central to this litigation." A14467;Br.67-68. Displeased with the content, Akorn now wants it ignored.

Second, Akorn wrongly criticizes the trial court for not agreeing with experts Nicholson and Gompers, neither of whom were remediation experts or called at trial. Br.44-45. They purported to model hypothetical revenue impacts associated with a handful of drugs (A12109-110/¶59) and facilities (A12016,12044/¶¶6,100), ignoring that "the systemic failures at Akorn raise questions about the accuracy and reliability of all of its data, regardless of site or product." Op.178,182.

Akorn's contention that Fresenius needed to "identify[] products to be withdrawn or facilities that would suffer delays," Br.45, is misplaced for the same reason—overwhelming evidence showed that Akorn has systemic violations calling into question "all of the test data" and "literally … every released product." C-SOF§III.

Third, Akorn recycles its first argument above to contend that the trial court's determination was speculative—but as discussed above, the finding that a $900 million impact "is the most credible outcome," Op.184, was based on substantial evidence, including careful consideration of both parties' positions. This is nothing like *DFC Global Corp.* v. *Muirfield Value Partners, L.P.*, where a court's analysis was not "grounded in the record," "unexplained," and "in tension with [its] own findings." 172 A.3d 346, 388 (Del. 2017). It is unlike *Nixon* v. *Blackwell*, where a court did not supply "the bases for [its] decision," 626 A.2d 1366, 1377-78 (Del. 1993)—the trial court's 246-page decision does that in meticulous detail. No more comparable is *Frontier Oil* v. *Holly Corp.*, where the terminating party did not "demonstrate[] (or even seriously tr[y] to demonstrate) the likelihood" of a liability causing an MAE. 2005 WL 1039027, at *36 (Del. Ch.) (contrasting case where a party "come[s] forward with factual and opinion testimony").

As the trial court noted, Gokhale's report corroborated its analysis. Op.183-84; *cf.* Br.47. Gokhale relied on different assumptions—he modeled a two-year delay in each pipeline product but did not account for remediation of systems or on-market products. A13257-58/¶5. Nevertheless, Gokhale found an $808 million impact to Akorn's value—similar to the Court of Chancery's $900 million finding.

Fourth, Akorn quibbles with the denominator chosen by the trial court, noting that if Akorn's debt were included, the court "would have derived a decline of 19%" rather than 21%—as though that would make all the difference. The trial court did not clearly err by determining that Akorn's value was $4.3 billion, based on the $34 per share deal price (A7287-90)—Akorn and its financial advisor JPMorgan valued the transaction on that basis. A7474,7480-81. Although Akorn contends that the court should have used Akorn's synergistic value to Fresenius, that ignores the MAE definition. *See* §I.C.1. Moreover, the court found that remediation costs of "approximately" or "in the vicinity" of 20% of Akorn's value represented an MAE and emphasized that "[n]o one should fixate on a particular percentage as establishing a bright-line test." Op.184,185,n.740.

Fifth and *sixth*, Akorn complains that the trial court selected a roughly 20% materiality threshold without Fresenius submitting evidence on that topic, Br.48—but Akorn never suggested that the financial impact shown by Fresenius' plan was not material, so Fresenius could not have been expected to respond to that argument. Moreover, the trial court's threshold was based not only on its analysis of this transaction, but also on a detailed comparison of widely used market-driven concepts of materiality. Op.186-90. It was entirely appropriate for the court to refer to these alternative "indicators" of materiality as "cross-checks," even though they were not "directly on point." Op.191. Tellingly, nowhere does Akorn

contend that a roughly 20% valuation drop would *not* be considered an MAE—particularly when combined with the immense qualitative effects of its violations.

2. The Court Correctly Held That Fresenius Did Not Know Of Akorn's DI Violations And Knowledge Was Irrelevant

Akorn claims its DI violations were "identified in diligence." Br.51. In fact, the trial court found that Fresenius did not identify Akorn's DI violations—and certainly "did not know about the [DI] issues that would reasonably be expected to result in a Regulatory MAE." Op.200. That is not surprising—Akorn went to extraordinary lengths to conceal those issues from Fresenius. Fresenius obtained representations from Akorn precisely because it could not fully diligence these issues. Knowledge of potential *risks* also does not mean that Fresenius expected Akorn's DI violations. *See* §I.C.

Knowledge is also irrelevant. "By obtaining the representations it did, [Fresenius] placed the risk that [those representations] were false and that [Akorn] was operating in an illegal manner on [Akorn]." *Cobalt Operating, LLC* v. *James Crystal Enters., LLC*, 2007 WL 2142926, at *28 (Del. Ch.). Akorn cannot distinguish *Cobalt* because it involved a provision "consciously shifting long-term risk to the seller," Br.51—that is precisely the effect of the representations here. Imposing a lack of knowledge requirement would also wrongly impose "an expansive knowledge-based exception framed in terms of everything the buyer knew or should have known … that reading is not consistent with the plain

language of the Merger Agreement." Op.199. This does not give Fresenius a "unilateral termination right," Br.51—Fresenius could only terminate if Akorn's breaches rose to the level of an MAE. If Akorn wanted to avoid that outcome, it should not have made numerous false representations.

III. THE COURT OF CHANCERY CORRECTLY FOUND THAT AKORN BREACHED ITS ORDINARY COURSE COVENANT

A. Questions Presented

(1) Did the Court of Chancery clearly err in finding that Akorn incurably breached its ordinary course covenant by ignoring and concealing DI violations and misleading Fresenius and the FDA, and (2) was it correct to define materiality based on its ordinary meaning? A15885-87,16074-90.

B. Scope Of Review

See §I.B.

C. Merits

1. The Court Correctly Found Ordinary Course Violations

There is no dispute that Akorn was obliged to operate in the ordinary course after signing and to investigate and remediate DI violations. Fresenius explicitly reminded Akorn of that obligation. B46 (Fresenius email to Rai: "Akorn should continue to plan and run your business on a stand-alone basis"). Rai testified that there was "no doubt" that Akorn was required to "investigate and remediate [DI] problems." A4382/525:1-10; *see* A7349 (Akorn presentation recognizing obligation); A4327/371:14-372:7,4736-41/§§5.01(a),(c);Op.49.

Yet as the trial court held, Akorn deliberately violated its obligations, with dire consequences. In a brazen attempt to prevent Fresenius from learning of severe DI violations—which would have jeopardized the Merger—Akorn

consciously ignored its responsibilities, cancelled audits, stopped all DI projects, repeatedly defrauded the FDA and failed to investigate serious DI issues. Akorn's violations delayed by at least a year necessary remediation work, caused a significant amount of untrustworthy data to be generated and severely damaged its vital relationship with the FDA. Op.216-22. It is extraordinary that Akorn argues that its scheme to defraud Fresenius and the FDA—directed by its highest executives—should be dismissed as wholly immaterial.

After a week-long trial in which the Court of Chancery carefully considered the evidence and weighed witnesses' credibility, the court firmly rejected Akorn's position that it did not breach its ordinary course covenant. Rather than attempt to show clear error, Akorn asserts the same factual arguments that failed below:

Failure To Remediate: The trial court found that Akorn did virtually nothing after signing to remediate known, long-standing and pervasive DI violations. C-SOF§III. Akorn responds with a self-serving document, "[DI] Chronological Overview February 20, 2018," A9391-450;Br.57,59, which the trial court refused to credit. It was authored in part by Silverberg—who was fired days later for defrauding the FDA—and is no more reliable than Akorn's azithromycin test results. A1500/215:2-17;B45,86/142:12-144:20. And contrary to the claims in this document that Cerulean's findings were remediated, Br.59, after the document

was prepared, Akorn's *own GQC experts* concluded that Akorn "essentially ignored" the "vast majority of the deficiencies" identified by Cerulean. Op.29-30,166; *e.g.*, A8602 (November 2017 email from Decatur DI Manager stating that Akorn was "making 0 progress on our DI remediation efforts" due to "the culture and message from management").

Cancelling Audits: The trial court also found that Akorn cancelled Cerulean audits and replaced internal audits with verification audits to avoid identifying "more [DI] gaps that could jeopardize their efforts to sell the Company." Op.26,50. Fresenius' industry expert Klener "[could not] think of any reason why this would have been appropriate," A13734/¶52, and Akorn concedes that "FDA guidance recommends that firms conduct internal audits," Br.59,n.296.

Far from disputing the point, Akorn's witnesses admitted that audits were cancelled "because of the merger." A4238/132:11-22; *see* A4382/525:11-528:8. Akorn argued below that it "switch[ed to verification audits] so that Akorn could give Fresenius a short document summarizing open audit findings." Op.50,n.229. The trial court rejected this argument, observing that no such document was ever produced. Op.50,n.229;A15818. Akorn now attributes audit cancellations to other factors, including a "scheduling conflict." Br.60. This too is false. The court correctly found that Akorn moved to verification audits to head off any potential "difficulties for the Merger." Op.50,n.229.

DI Freeze: Akorn implemented a company-wide freeze on DI work, citing "'implications of the pending Fresenius Kabi transaction."' Op.49.

Akorn claims it was allocating "finite resources," Br.57-59, but the trial court properly rejected this claim. Akorn identifies no evidence that it considered allocating resources to fix its severe DI violations—to the contrary, "senior management instructed its IT department not to devote any resources to [DI] projects." Op.217; *e.g.*, A9349 (February 2018 email discussing imperative "from executive leadership … to align all sites that we are not launching [DI] remediation"); A5830 (February 2017 email: "no actions/projects are to launch in the area of [DI]."). Akorn further claims that it only stopped projects "not approved by [its] PRB," Br.57, but no proposal to fix its DI issues was ever presented to the PRB.

Akorn challenges the trial court's finding that Fresenius "[n]ever gave approval for Akorn to stop working on [DI] projects," Op.53, asserting that "there was quite strong evidence" that Fresenius did so (a proposition difficult to reconcile with Akorn's claim that it did not stop DI projects), Br.57-58. Akorn cites Pramik's testimony. But as the trial court found, Pramik's testimony supported Fresenius. A4268/249:7-23 ("Q. No one at Fresenius ever instructed you to cease work … A. Correct"); A1920/260:25-261:22;Op.53,n.238. And the

trial court gave Pramik's testimony "diminished weight" given her lack of credibility. Op.51-52,n.234.

Azithromycin Fraud: Akorn does not dispute that in August 2017, "Silverberg submitted the false [azithromycin] CRL in an effort to avoid inviting any scrutiny of Akorn's [DI] deficiencies until after the Merger closed, when it would be Fresenius's problem." Op.19. Akorn criticizes the trial court for "reach[ing] its own view of Silverberg's mental state" because Silverberg did not testify at trial. Br.64. But Akorn chose not to call Silverberg, despite employing him as a consultant whose only job is to testify in litigation. A1979/82:3-85:13.

Failure To Investigate: Akorn decided "not to conduct its own investigation into" issues raised in the anonymous letters because "Akorn feared a broad investigation of its own would uncover widespread problems." Op.69-70,218. Indeed, Akorn's Board Chairman testified that the letters were "very worrisome"—not because of the compliance issues they raised, but because it would "throw a wrench" into closing the Merger. B221/115:6-19.

Akorn contests the trial court's finding that it retained its deal counsel at Cravath—unqualified in DI or FDA issues—to "front run" and "monitor Fresenius's investigation and head off any problems." Op.70,218. Akorn points to Cravath's investigation of the azithromycin fraud, Br.62, but this is a clear example of Cravath "heading off" problems. Cravath only learned of the fraud because it

was preparing Akorn employees to speak with Sidley (something Stuart falsely denied doing in his trial testimony, Op.71,n.326,77) and realized that Sidley was about to discover the fraud. Op.218;A4541/1041:20-1042:12. Akorn then concealed critical information, such as Silverberg's threats to destroy evidence. Op.83. That this was the "only investigatory work that [Cravath] did on its own" speaks volumes. Op.78.

Akorn also claims Fresenius instructed it not to investigate, and attacks the trial court for not crediting Bonaccorsi's "unrebutted" testimony that Fresenius' General Counsel, Jack Silhavy, provided that instruction. Br.14,61 ("Silhavy did not testify otherwise"). In fact, Bonaccorsi was conclusively rebutted by both Silhavy's testimony, A3037/58:25-59:7 ("I remember making clear to [Bonaccorsi] that, of course, they should do whatever investigation they wanted to undertake"), and contemporaneous emails, Op.70,n.321 (citing A8427-34,8405-14).

Misleading The FDA: Akorn's March 2018 presentation to the FDA was intentionally misleading (Op.4):

First, Akorn falsely touted its DI systems and failed to mention devastating audit findings. Op.94. Akorn claims that this "overly sunny depiction" was appropriate in the "ordinary course activity of advocating for

positive regulatory outcomes." Br.62;Op.94. Intentionally misleading a federal agency is not ordinary course advocacy.

Second, Akorn represented to the FDA as an investigative finding that Silverberg did not know he was submitting fraudulent data even though Akorn knew that was untrue. Op.93-94. Akorn offers the same baseless arguments rejected below. Br.62-65. Conspicuously absent is any justification for why Akorn endorsed Silverberg's explanation despite Stuart believing that it was not "satisfactory" and did not "hang together"—meaning, in Stuart's words, that "I was not going to use his explanation in an attempt to defend the company before the FDA." A4425-26/700:12-701:3;Op.94. That was precisely what Stuart did. Indeed, Stuart concluded that if the FDA had the "'document trail,'" there was a "'high likelihood that [the FDA] would conclude … [Silverberg] did act with intent,'" yet he decided not to disclose those documents. Op.83,94;A16087.

The trial court found that "[i]n the pressure of the moment, Stuart went along" with giving a "misleading" presentation to the FDA. Op.93. Akorn and its advisors were concerned that if the FDA knew of the azithromycin fraud, it would take drastic regulatory action. Op.83-84,105,168-70.

Even Kaufman admitted that Akorn's presentation to the FDA was "'not fully transparent."' Op.92. Akorn asserts that she was not "prepared to assess" Akorn's transparency. Br.65. But Kaufman opined on this topic at length

in her opening report, rebuttal report, deposition, and direct and re-direct examinations at trial. A12206/¶¶171-72,13539-40¶¶45-47,3131/11:11-13:21,4279-80/295:23-297:18,4335/401:9-404:3.

Akorn argues that this mountain of evidence should be ignored in favor of Kaufman's "empirical" analysis of Forms 483 and Warning Letters. Br.56. But the trial court found both Kaufman and her methodology unpersuasive. Op.175-76. Further, Kaufman's analysis only examined which DI problems existed at certain companies, not what those companies did or should have done to remediate them.

Finally, Akorn argues that the Court of Chancery should have considered whether Akorn acted "consistent[ly] or inconsistent[ly] with industry practices" in determining its obligations under the ordinary course covenant, Br.60, but this makes no sense: Akorn *conceded* it was obliged to investigate and remediate DI violations and blatantly failed to do so. Moreover, as discussed above, the court did consider Akorn's violations of industry practices and its own historical practices, and Akorn cannot show that its misconduct—including defrauding the FDA—was consistent with industry practices.

2. The Court Applied The Correct Materiality Standard

Akorn tries to immunize its intentional misconduct by arguing that it was not "material" enough to afford Fresenius the remedy provided by the

Agreement—refusing to close. The trial court properly found that Akorn's wrongdoing was highly material and seriously jeopardized its business and its relationship with the FDA.

The court correctly held that Akorn did not comply with its ordinary course covenant "in all material respects" if there was a "substantial likelihood that the … fact [of breach] would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information." Op.211 (citing *Frontier Oil*, 2005 WL 1039027, at *38).

This standard properly expresses the plain meaning of "material." "[M]aterial" means "important," Cambridge English Dictionary, "having real importance," Merriam-Webster Dictionary, or "of such a nature that knowledge of the item would affect a person's decision-making," Black's Law Dictionary (10th ed. 2014). *See Air Prods. & Chems., Inc.* v. *Wiesemann*, 237 F. Supp. 3d 192, 213 (D. Del. 2017) (for purposes of "in all material respects" qualification, [material means, "'[o]f such a nature that knowledge of the item would affect a person's decision-making process.'") (citation omitted).

Akorn argues that it was free to act outside the ordinary course if its breaches did not constitute a common law material breach. Under that common law doctrine, a contract breach going "'to the root or essence of the agreement'" or "'defeat[ing] the object of the parties,'" Br.53-54, excuses the counterparty from

performance. Akorn cites no authority applying this standard to "in all material respects" language.

Akorn's standard would do violence to the Agreement:

First, it would practically equate "in all material respects" with an MAE, although the former imposes a lower standard. *Frontier Oil*, 2005 WL 1039027, at *38. Indeed, the M&A treatises Akorn cites (Br.54) confirm that "in all material respects" is a lower standard than MAE. Kling & Nugent § 14.02[3],[7]; *see* ABA MERGERS AND ACQUISITIONS COMMITTEE, Model Merger Agreement for the Acquisition of a Public Company, art. 2 cmt. (MAE standard requires "substantially greater deviation" than "all material respects"). The Agreement distinguishes between the two—for example, certain representations must be true "in all material respects" as a condition to closing, while other representations are MAE-qualified. A4756/§6.02(a)(i),(ii).

Second, the "in all material respects" language is used where it could not possibly mean a common law material breach. *E.g.*, A4720/§3.05 (SEC filings must comply with forms "in all material respects").

Third, where the parties wanted the "material breach" standard, they used that term. A4757-58/§7.01(c)(i),(d)(i).

Fourth, the parties' views of materiality are reflected in the interim operating covenants. Akorn was prohibited from hiring employees earning more

than $250,000 or making capital expenditures exceeding $10 million. A4737-39/§5.01(b)(iii)(iv),(vi). These limits are consistent with the standard used by the trial court and far below Akorn's standard.

In any event, Akorn's brazen and intentional breaches are material even under its proposed standard. Akorn lost an entire year in which it otherwise could have made substantial remediation progress; generated a significant amount of unreliable data during that period which will now need to be verified and likely redone at enormous cost and delay, A4641/1299:9-1300:13,12883-84/¶¶161-65; and seriously damaged its relationship with its primary regulator, A4328-29/374:22-378:7,4545-46/1058:15-1060:12,4627-28/1244:20-1248:9.

Experts on both sides agreed that Akorn's intentional misconduct would increase the likelihood and severity of regulatory action. A4328/374:22-375:15,4545-46/1058:15-1059:14,4627/1244:20-1245:6,4640/1296:24-1297:21. Akorn's experience proves that. After belatedly admitting some of its fraudulent activity to the FDA, Akorn is now under intense scrutiny. It must report monthly to the FDA and has already been subject to frequent and intense inspections that have identified significant regulatory violations and precluded product approvals. C-SOF§V;A11581. Akorn is now severely handicapped in fulfilling its primary purpose—developing and bringing to market new drug products. Op.163-64,178.

Akorn's senior-most management—including its CEO, Quality Head, General Counsel, and outside counsel—were actively engaged in attempting to cover up egregious regulatory violations and ordinary course breaches. These actions severely damaged Akorn's business and reputation and greatly increased the risk of severe regulatory action. They demonstrate that Akorn management—and, therefore, the most significant operations of the Company—cannot be trusted and undermine the root of the parties' Agreement. Indeed, Akorn management went to great lengths to deceive Fresenius precisely because they knew how material Akorn's ordinary course violations were.

Akorn's misconduct therefore amounts to a material breach, rendering remand unnecessary even if this Court determines that is the applicable materiality standard. *E.g.*, *In re Peierls Family Testamentary Trs.*, 77 A.3d 223, 231 (Del. 2013). The scope and extent of Akorn's deceptive conduct alone make its breaches material. We submit that any holding excusing Akorn's conduct would encourage such deception.

None of Akorn's breaches could be cured by the Outside Date just because, Akorn asserts, it supposedly "start[ed] acting like a generic pharmaceutical company operating in the ordinary course of business" only in March 2018. Br.66. Akorn cannot ever regain the entire year of remediation it lost.

Moreover, Akorn has yet to make meaningful progress. Even "[b]y the time of trial, Akorn still did not have a remediation plan because it was still in the process of figuring out all of the deficiencies that the Company needed to address." Op.30. The few remediation steps it claims it was taking were meaningless—for example, Kaufman conceded that Akorn's planned remediation "consist[s] predominantly of either revising existing policies or procedures or drafting new such documents." A12209/¶180; *e.g.*, A1595/162:25,4384/533:17-534:19. Akorn still is not comprehensively investigating data generated when Akorn was far out of compliance with DI requirements, which Kaufman agreed was necessary. A4286/324:7-21. Nor is Akorn reviewing FDA submissions involving Silverberg. Akorn's excuse—that Silverberg did not directly make submissions to the FDA—is baseless given that Silverberg oversaw Akorn's entire quality organization, personally submitted the fraudulent azithromycin data, and knowingly allowed other false submissions. Even Kaufman conceded that Akorn must review submissions involving Silverberg. A3330-31/384:16-386:1.

IV. THE COURT OF CHANCERY CORRECTLY FOUND THAT FRESENIUS' EFFORTS COVENANT DOES NOT PRECLUDE TERMINATION

A. Question Presented

Did the Court of Chancery clearly err in finding that Fresenius could terminate where any breach of the reasonable best efforts covenant had no effect on the Merger and the closing conditions were not satisfied solely because of Akorn's blatant misconduct? A15900-906,16112-18.

B. Scope Of Review

See §I.B.

C. Merits

The Court of Chancery correctly recognized that "Fresenius was entitled to investigate" Akorn's misconduct "and assert good faith positions based on its contractual rights." Op.225-29. At the same time, Fresenius "remained committed to fulfilling its obligations under the Merger Agreement" and was "working hard to figure out how the deal could still work." Op.227.

"[H]aving weighed the evidence and evaluated the credibility of the witnesses," the trial court rejected Akorn's arguments that alleged acts by Fresenius were taken in bad faith. *E.g.*, Op.5,230-32. Rather than attempt to show clear error, Akorn recycles the same meritless factual arguments. Br.67-69.

- Akorn complains that Fresenius executed a common interest agreement while assessing its rights against Akorn, but Akorn "certainly knew" Fresenius was doing that. The trial court did "not

credit" Stuart's testimony to the contrary. In fact, Fresenius demanded a change to the two-page common interest agreement to "state[] that 'either party shall be free to use … any and all information learned … in any dispute between them.'" Op.71,n.326,75-76,231-32.

- Akorn complains that Fresenius refused to waive a conflict to allow a firm that represented Fresenius before the FDA to represent Akorn, but the trial court held that Fresenius was "legitimate[ly] concern[ed]" that Akorn would "whitewash" its fraud before the FDA, as Akorn in fact did. Op.90.

- Akorn complains that Sidley wrote letters to Akorn complaining about its misleading presentation to the FDA, Br.23-24,68, but Sidley's criticisms were "fair." Op.95. "Fresenius had good reason to be concerned that Akorn … present[ed] a misleading picture of its situation to the FDA in an effort to get to closing and stick Fresenius with [its] regulatory problems." Op.231. Kaufman testified that Akorn only rectified its "'not fully transparent'" FDA presentation by providing those very letters, as well as Cerulean's reports, to the FDA. Op.169. (Kaufman was wrong—"Akorn never provided the FDA with Cerulean's reports" and "Akorn's regulatory counsel primed the FDA to discount anything Sidley said." Op.169; *see* Op.91,n.425.)

Akorn also argues that "[t]he Court did not consider whether Fresenius" complied with certain contractual obligations, Br.68-69, but that was precisely what the court considered. Op.224-33. Akorn criticizes the court for not "shifting the burden to Fresenius to prove that its breaches did not materially contribute" to the failure of closing conditions, Br.69, but this makes no sense—the court held that Fresenius complied with its obligations. According to the trial court, Fresenius only breached its Hell-or-High-Water Covenant, and only "for approximately a one-week period," Op.6, that was inconsequential and fully cured.

Indeed, Akorn effectively conceded in its Verified Complaint that any such breach was immaterial because FTC approval was "close at hand" at the time of termination and all other closing conditions were supposedly met. Op.242-43. Regardless of where burdens are placed, the evidence demonstrates there was no actionable breach by Fresenius.

Akorn fails to identify any action by Fresenius that could have caused the failure of closing conditions. Fresenius terminated because of Akorn's breaches of its representations and ordinary course covenant and its catastrophic financial performance. These are products of Akorn's wrongdoing and financial underperformance—not any alleged action or inaction of Fresenius. *Cf. Hexion*, 965 A.2d at 730 (buyer intentionally and "effectively kill[ed] the [deal's] financing"). As a result, Fresenius had every right to terminate. *See* A4756-57/§§6.02(a)-(b),7.01(b)(i) (precluding termination only if a party's breach "has been a principal cause of or resulted in" the Outside Date passing without closing conditions being met).

CONCLUSION

The Court of Chancery's orders should be affirmed.

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Dated: November 21, 2018