RECOMMENDED FOR FULL-TEXT PUBLICATION
Pursuant to Sixth Circuit I.O.P. 32.1(b)

File Name: 15a0210p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

JAMES CALLOWAY, individually and as a representative of a class of former Caraco employees,

Plaintiff-Appellee,

v.

CARACO PHARMACEUTICAL LABORATORIES, LTD.,

Defendant-Appellant.

No. 14-2526

Appeal from the United States District Court
for the Eastern District of Michigan at Detroit.
No. 2:11-cv-15465—Mark A. Goldsmith, District Judge.

Argued: July 30, 2015

Decided and Filed: August 26, 2015

Before: COLE, Chief Judge; GIBBONS and STRANCH, Circuit Judges.

COUNSEL

ARGUED: Christopher P. Mazzoli, BODMAN PLC, Troy, Michigan, for Appellant. Alan B. Posner, KELMAN LORIA, PLLC, Southfield, Michigan, for Appellee. **ON BRIEF:** Christopher P. Mazzoli, John C. Cashen, BODMAN PLC, Troy, Michigan, for Appellant. Alan B. Posner, KELMAN LORIA, PLLC, Southfield, Michigan, for Appellee.

OPINION

COLE, Chief Judge. Defendant Caraco Pharmaceutical Laboratories, Ltd. ("Caraco"), appeals the district court's judgment in favor of the plaintiffs, former Caraco employees.

Following a bench trial, the district court found that Caraco violated the Worker Adjustment and Retraining Notification ("WARN") Act, 29 U.S.C. §§ 2101–2109, by failing to comply with the Act's notification provision when it closed its drug manufacturing operation. The sole issue before us is whether the United States Food and Drug Administration's ("FDA") mass seizure of Caraco products was an unforeseeable business circumstance that would excuse Caraco from complying with the WARN Act's requirement to notify employees at least 60 days prior to a mass layoff. We conclude that it was not and therefore affirm the district court's judgment.

I. BACKGROUND

A. Factual Background

Caraco is a Michigan pharmaceutical manufacturer. James Calloway was an employee of Caraco at its Detroit facility from 2006 until he was laid off on June 29, 2009. He is a member and representative of a class of former Caraco employees certified by the district court.

As a drug manufacturer, Caraco was subject to the regulatory authority of the FDA. The FDA enforces its regulations through periodic inspections of facilities under its jurisdiction. After an inspection, the FDA may issue a Form 483, which "is intended for use in notifying the inspected establishment's top management in writing of significant objectionable conditions, relating to products and/or processes . . . which were observed during the inspection." (FDA Invest. Op. Manual at 5.2.3, R. 23-5, PageID 487.) A Form 483 is issued when an investigator believes that a drug has "been adulterated or . . . prepared, packed, or held under conditions whereby [it] may become adulterated or rendered injurious to health." (*Id.*)

More serious than a Form 483, a warning letter is "a correspondence that notifies regulated industry about violations that FDA has documented during its inspections or investigations." (FDA Regulatory Procedures Manual, R. 23-6, PageID 495.) "Warning Letters should only be issued for violations of regulatory significance, i.e., those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected." (*Id.*) Alternatively, an untitled letter may be issued in order to "cite[] violations that do not meet the threshold of a Warning Letter." (*Id.*)

Several years before the mass layoff in question here, the FDA issued two warning letters to Caraco, on July 6, 2000 and October 11, 2002. Both letters stated that the company's failure to correct the violations promptly could result in enforcement action by the FDA without further notice. After the 2000 warning letter, the FDA conducted a follow-up inspection in 2001 and issued a Form 483 with 17 observations of violations. The 2002 warning letter dealt with only a single product.

The FDA issued another Form 483 to Caraco on May 11, 2005. Caraco's new chief executive officer, Daniel Movens, responded on June 10, 2005, stating that the company had "determined that most of the observations presented in the FDA 483 were isolated events and not reflective of overall systemic failures." (6/10/05 Movens Letter, R. 22-6, PageID 215.) On August 5, 2005, Movens again wrote to the FDA to report that the company had taken corrective action on 10 of the 13 observations in the May 2005 Form 483 and to update the FDA on its progress in dealing with the other three observations. Judith Putz, an FDA compliance officer, responded on August 19, 2005, disagreeing with Movens's characterization of most of the observations as isolated and not reflective of systemic failures. On August 10, 2005, the FDA also conducted a meeting with Movens, in which Putz urged Caraco to submit a more definitive timeline for its corrective actions. On September 9, 2005, Movens wrote to the FDA to describe further corrective actions to its handling and packaging procedures that it had taken or planned to take.

On September 16, 2005, the FDA issued a Form 483 with four observations to an independent company, Future Pak, Ltd., whose premises Caraco used as a packaging facility (where it was responsible for FDA compliance). On June 21, 2006, the FDA issued another Form 483 to Caraco with 22 observations. That same month, Caraco issued a recall of Midrin capsules. On July 20, 2006, and again on August 25, 2006, Movens wrote to the FDA to notify it that Caraco was taking additional corrective actions regarding the 22 observations from the June 2005 Form 483.

After an inspection in August 2007, the FDA issued a Form 483 and Caraco again responded. In February 2008, Caraco issued a recall of metformin tablets. The FDA issued another Form 483 on March 6, 2008, noting four significant deviations from current good

manufacturing practices ("cGMPs"), to which Caraco responded on March 31, 2008. On June 11, 2008, the FDA issued another Form 483 detailing 14 significant deviations from cGMP. In his response to this Form 483, Movens admitted that these 14 violations were "not all inclusive and could represent broader issues." (7/10/08 Movens Letter, R. 22-20, PageID 290.)

In 2008, Movens hired Quintiles Consulting to conduct an independent audit of Caraco's facilities. In an email to Movens on July 7, 2008, Maxine Fritz, a vice president at Quintiles, noted that "[i]t is our opinion that the company faces the real possibility of FDA enforcement action. We believe it likely that FDA will initiate some form of seizure action which may target individual products or, conceivably may be a 'mass seizure.'" (7/7/08 Fritz Email, R. 23-10, PageID 523.) Further, Fritz stated that "FDA's recent enforcement strategy has been to favor seizure of product and resolution of such action with a consent decree of permanent injunction. . . . We have been involved in many such actions and I can tell you they are to be avoided at all costs." (*Id.*) Fritz further stated that "[a]t this point, we believe it will be very difficult to dissuade [the] FDA from the enforcement approach we believe it is pursuing," but that if Caraco was "more aggressive and comprehensive in demonstrating to the FDA" that it was willing and able to take significant corrective action, the FDA might be willing to give Caraco another chance. (*Id.*) As part of this strategy, Fritz recommended an in-person meeting with the FDA to outline Caraco's plan and receive feedback on it, and a response to the most recent Form 483 that would include not only specific responses to the most recent observations but also a "Quality Systems Enhancement Plan" with several elements. (*Id.*) These elements included a comprehensive approach to reach cGMPs, specific timelines, an emphasis on Caraco's commitment to quality principles, and offers to the FDA to make periodic progress reports and get feedback. Fritz also wrote that if there was no seizure, a warning letter was still "a virtual certainty." (*Id.* at 524.)

Movens later testified at trial that Fritz's email "startled" Caraco's management because they "hadn't seen seizures happening in the industry as [Fritz] had claimed." (Trial Tr., R. 46, PageID 1470.) Although Movens spoke to Caraco vice presidents Robert Kurkiewicz and Dan Barone, who both thought Fritz was "being an alarmist," Movens testified that Caraco "still went forward with [the] remediation efforts, worked with [Quintiles] to be responsive to the FDA

inquiry and basically started a training program on the steps [Caraco] wanted to remediate." (*Id.* at 1470, 1471.)

After receiving Fritz's email, Movens updated the FDA on its progress approximately every two or three weeks until October 24, 2008. On October 31, 2008, the FDA issued Caraco a formal warning letter based on the June 11, 2008 inspection and associated Form 483, determining that Caraco's drug products were adulterated and that its manufacturing, processing, and holding policies did not conform with cGMP. The warning letter also noted that Caraco's previous responses to earlier Form 483s had been significantly inadequate, and that many current failures of its processes and policies had been previously noted by the FDA and not corrected by Caraco. The letter further stated that the FDA had "serious concerns" regarding the firm's compliance history, the serious nature of the violations, Caraco's plans for expansion despite the serious deficiencies, and the potential product contamination and associated risk to consumers. (10/31/08 Warning Letter, R. 23-11, PageID 531.) Finally, the letter stated that "[f]ailure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction." (*Id.*) Caraco did not dispute the findings in the warning letter, nor had it disputed previous warning letters.

According to Movens, after receiving the warning letter, he did not ask Quintiles whether Caraco would receive any more chances to correct the violations before being subject to an enforcement action. Caraco then hired Kendle International as an outside consultant. In an email to Movens on November 6, 2008, Kendle's senior vice president, Tony Celeste, attached an article he had written advising how to respond to FDA warning letters. The letter stated:

> An FDA "Warning Letter" is considered by the agency to be the first step in the enforcement process. . . . The firm's response to a warning letter may be the last opportunity a firm has, prior to a legal or administrative action, to adequately address a situation that FDA has concluded constitutes a violation . . . . Immediate affirmative action to correct the objectionable conditions and inform the proper office of the action is necessary to satisfy FDA and to prevent further regulatory action.

(11/06/08 Celeste Email, R. 22-24, PageID 322.)

On November 12, 2008, Celeste emailed Movens again with feedback on Movens's draft response to the warning letter. (11/12/08 Celeste Email, R. 22-25, PageID 324.) Celeste's email

noted that Quintiles, Caraco's previous consultant, "ha[d], of late, not had a lot of success with FDA remediation programs," and noted two examples in which Quintiles had not been successful in helping prevent enforcement actions. (11/12/08 Celeste Email, R. 22-25, PageID 324.) Celeste reiterated that the "FDA did not want Caraco to describe specific actions that were already submitted," but instead wanted to be informed about "new information and corrections, especially where the previous responses were deemed inadequate." (*Id.*) He explicitly stated that Kendle "believe[d] that the company is at risk of an enforcement action. This action would probably take the form of a civil injunction . . . ." (*Id.*) Celeste also made four specific suggestions for Caraco to prevent an enforcement action, including (1) recalling certain products; (2) destroying two lots of cross-contaminated products; (3) delaying moving into a new facility until the FDA inspected and agreed that Caraco had achieved compliance; and (4) agreeing not to start production of any newly approved products.

Movens responded to the warning letter on November 24, 2008, reiterating that Caraco recognized the seriousness of the violations and describing the actions Caraco was taking to correct them. In particular, Movens wrote that the goal of its expansion project was not to introduce new products but to "allow[] the consolidation and modernization of [Caraco's] manufacturing activities as well as allowing executive management to be located in the manufacturing facility." (11/24/08 Movens Letter, R. 23-12, PageID 536.) Movens stated that Caraco would "delay moving any production related activities" until after Caraco had successfully implemented its new quality management system. (*Id.*) As Celeste suggested, Caraco also destroyed the two lots of cross-contaminated products.

The FDA replied to Caraco's letter on December 22, 2008, characterizing Caraco's response to the warning letter as "positive." (12/22/08 FDA Letter, R. 23-14, PageID 565.) The letter also raised another issue that Putz had discussed with Caraco management—the varying sizes of the tablets it produced—instructing Caraco to resolve this issue "as it has been going on for quite some time." (*Id.*) On the same day, the FDA issued Caraco another Form 483 with five observations.

On January 21, 2009, Movens responded to each of the observations in the Form 483. The letter claimed that Caraco had "taken immediate action to correct the systems that caused

these lapses." (1/21/09 Movens Letter, R. 23-16, PageID 571.) Movens also insisted that "[i]n spite of the specific lapses found during the inspection, Caraco has no evidence that any product commercially distributed failed to meet its quality, purity, or identity standards[.]" (*Id.*) He also reiterated that Caraco had hired an outside firm for additional training and audits.

On January 29, 2009, Caraco issued a press release reporting results of its net sales. The press release cited the FDA's 2008 warning letter, noting specifically that the FDA had stated that a "failure to promptly correct the deficiencies may result in legal action without further notice, including, without limitation, seizure and injunction." (1/29/09 Press Release, R. 22-31, PageID 361.) The press release included a quote from Movens: "We believe we are substantially compliant with cGMP. We have corrective actions in place and continue to work to improve our quality system." (*Id.*) Movens also stated that "[t]he Company intends to aggressively move forward with the development of new products," and that Caraco was "continu[ing] to add products to our portfolio through Sun Pharma and its affiliates that we will launch into the US." (*Id.* at 360, 361.)

On February 2, 2009, Caraco filed a Form 10-Q with the United States Securities and Exchange Commission ("SEC"), which acknowledged the most recent FDA warning letter. The Form 10-Q noted that the FDA had commented on Caraco's corrective action plans in the wake of the warning letter and had "added that failure to promptly correct the deficiencies may result in legal action without further notice, including, without limitation, seizure and injunction." (2/22/09 SEC Form 10-Q, R. 22-32, PageID 367.)

On February 19, 2009, Movens wrote again to the FDA to update the agency on the steps taken by Caraco in its "corrective action program since [Caraco's] last communication." (2/19/09 Movens Letter, R. 23-17, PageID 625.) One of the actions to be taken was a rolling shut-down of several manufacturing units to re-emphasize quality control.

On March 31, 2009, Caraco issued a nationwide Class I recall[1] of digoxin tablets due to their size variability, which could indicate varying drug dosage levels. On April 16, 2009, the

[1]A Class I recall is the most serious kind of recall, constituting "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." (FDA Enforcement Statistics, R. 23-7, PageID 512.) A Class II recall "is a situation in which use of, or

company issued Class II recalls on Metoprolol and Clonazepam tablets. The recalls were initiated due to concern that the products were defectively manufactured and unsafe for public consumption. Kendle had previously recommended that Caraco begin recalling products in November of 2008.

On April 14 through 17 of 2009, Kendle performed a limited audit on Caraco in which it noted nine observations, eight of which it classified as major, or likely to appear on a future Form 483. Kendle informed Caraco of these results on April 23, 2009.

On May 12, 2009, the FDA issued Caraco another Form 483, citing 18 cGMP deviations. Caraco responded on June 19, 2009, admitting that its quality control systems needed to be revamped and insisting that it "completely underst[ood] the serious nature of the observations." (6/19/09 Movens Letter, R. 23-19, PageID 699.)

On June 24, 2009, the FDA filed a Complaint for Forfeiture of Adulterated Articles of Drug. The following day, the FDA, with the assistance of United States Marshals, served Caraco with the complaint and a warrant for arrest and seized various products manufactured by the company at its Detroit and Farmington Hills facilities. On June 26, 2009, the company began a mass layoff of hourly and salaried workers at those facilities. The company granted no notice to any of the employees until the layoffs began, and eventually issued WARN Act notices on July 6, 2009, 11 days after the layoff began, which stated that the notices were tardy because the company did not "reasonably foresee that the FDA would take the action that it did."

B. Procedural History

On December 14, 2011, the plaintiffs filed a complaint in the United States District Court for the Eastern District of Michigan, alleging that Caraco violated the WARN Act by failing to give a 60-day notice of the mass layoff to the affected employees. On August 17, 2012, the district court certified a proposed class of former Caraco employees. The parties filed cross-motions for summary judgment, and the district court denied both motions. The district court conducted a bench trial on November 21–22, 2013.

---

exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." (*Id.*)

On September 16, 2014, the district court granted judgment for the plaintiffs. The court found that it was reasonably foreseeable in April 2009 that the FDA would execute a large-scale enforcement action against Caraco. The district court cited several facts on which it based its conclusion that Caraco did not meet its burden of proof to show that the mass layoff was caused by unforeseeable business circumstances:

> (1) the tenor of the FDA's October 2008 warning letter which uncovered numerous violations dating back to 2005, (2) the gravity of the concerns raised in this warning letter including the risks to consumers, (3) Caraco's inability to accurately assess its own state of compliance leading up to nearly every FDA inspection, (4) Caraco's refusal to adopt the findings of its independent consultants, both of which warned the Company of the very real possibility of an FDA enforcement action, (5) the FDA's December 22, 2008 directive to correct a long-standing issue with tablet size variation, (6) the number and breadth of Caraco's product recalls, totaling a half million bottles of 29 different products between January and April 2009, (7) Caraco's failure or inability to account for a large quantity of a dangerous substance, digoxin, (8) Caraco's lengthy history of GMP violations, dating back to 2000, and (9) the proximity in time between the FDA's warning letter in October 2008 and Kendles' [sic] post-inspection report, which indicated that, after the passage of approximately six months, Caraco continued to experience significant unresolved compliance issues.

(Order, R. 55, PageID 2072.)

The district court awarded damages to the plaintiffs in the stipulated amount of $491,723.99, as well as prejudgment interest and attorney's fees. Carcaco now seeks reversal of the district court's judgment, entry of judgment in its favor, and an award of attorney's fees and costs.

II. ANALYSIS

A. Standard of Review

Following a bench trial, we review a district court's factual findings for clear error and its legal conclusions de novo. *Foster v. Nationwide Mut. Ins. Co.*, 710 F.3d 640, 643–44 (6th Cir. 2013). In reviewing factual findings for clear error, "the reviewing court must give due regard to the trial court's opportunity to judge the witnesses' credibility." Fed. R. Civ. P. 52(a)(6). "We cannot find that the district court committed clear error where there are two permissible views of

the evidence, even if we would have weighed the evidence differently." *King v. Zamiara*, 680 F.3d 686, 694 (6th Cir. 2012) (internal quotation marks, citations, and brackets omitted).

B. The Unforeseeable Business Circumstances Exception

The WARN Act requires employers to give a 60-day notice to affected employees before a plant closing or mass layoff. 29 U.S.C. § 2102(a).[2] The purpose of the Act is to extend:

> protection to workers, their families and communities by requiring employers to provide notification 60 calendar days in advance of plant closings and mass layoffs. Advance notice provides workers and their families some transition time to adjust to the prospective loss of employment, to seek and obtain alternative jobs and, if necessary, to enter skill training or retraining that will allow these workers to successfully compete in the job market.

20 C.F.R § 639.1(a).

The full 60-day notice period is not required if the closing is "caused by business circumstances that were not reasonably foreseeable as of the time that notice would have been required." 29 U.S.C. § 2102(b)(2)(A). In order to qualify for the exception, the defendant "must prove two elements: (A) that the circumstances complained of were unforeseeable; and (B) that the circumstances complained of actually caused the mass layoff or plant shutdown." *Pearce v. Faurecia Exhaust Sys., Inc.*, 529 F. App'x 454, 457 (6th Cir. 2013). The only issue before us is whether, on the record before it, the district court properly found that the mass seizure was unforeseeable.

Regulations promulgated by the United States Department of Labor have explained that "[a]n important indicator of a business circumstance that is not reasonably foreseeable is that the circumstance is caused by some sudden, dramatic, and unexpected action or condition outside the employer's control." 20 C.F.R. § 639.9(b)(1). A government-ordered closing of an employment site that occurs without prior notice may be an unforeseeable business circumstance. *Id.*

"The test for determining when business circumstances are not reasonably foreseeable focuses on an employer's business judgment." 20 C.F.R. § 639.9(b)(2). "The employer must

[2]The parties do not dispute that Caraco is an employer within the meaning of the Act, that the class members are affected employees, and that the mass layoff was proximately caused by the FDA's seizure.

exercise such commercially reasonable business judgment as would a similarly situated employer in predicting the demands of its particular market." *Id.* Importantly, our court has noted that the "propriety of utilizing the exception in any particular scenario involves a highly factual inquiry to be assessed on a case by case basis." *Watson v. Mich. Indus. Holdings, Inc.*, 311 F.3d 760, 764 (6th Cir. 2002) (internal quotation marks omitted).

We have cautioned that "[i]n making this determination, a reviewing court must be careful to avoid analysis by hindsight and remember that an employer's commercially reasonable business judgment dictates the scope of this exception." *Id.* at 765. "[I]t is the probability of occurrence that makes a business circumstance reasonably foreseeable, rather than the mere possibility of such a circumstance." *Id.* (internal quotation marks omitted). "WARN was not intended to force financially fragile, yet economically viable, employers to provide WARN notice and close its doors when there is a *possibility* that the business may fail at some undetermined time in the future." *Id.* (emphasis in original).

1. The District Court Properly Found that the Enforcement Action was Foreseeable

Caraco argues that both the nature and timing of any possible enforcement action were not foreseeable by April 27, 2009, and that to hold otherwise would be contrary to the WARN Act's intent to protect employees because economically viable employers would be forced to issue WARN notices and close at even a remote possibility of enforcement action. In support of its argument, Caraco contends that seizures are a very infrequent consequence of FDA warning letters, citing FDA enforcement statistics that show that between 2007 and 2009, the agency issued 1,390 warning letters but conducted only 22 seizures. Attempting to analogize its circumstances to several out-of-circuit cases where the unforeseeable business circumstances exception applied, Caraco further insists that it had no reason to believe that the FDA would initiate a mass seizure when, in the past, the agency had not done so after issuing earlier warning letters, and that in any case it would not have been possible to predict the timing of such a seizure. Caraco also contends that the tenor of the 2008 warning letter contained the same "boilerplate warning" of possible enforcement action as all of the previous warning letters the FDA had issued to Caraco, and that there was no indication that this warning letter suggested a higher probability of enforcement action than the prior letters.

We have addressed the unforeseeable business circumstances exception only twice, first in *Watson v. Michigan Industrial Holdings, Inc.*, where we agreed with the district court that the exception applied when an auto-parts supplier had "operated under financial difficulties for years" yet had maintained a consistent relationship with its primary customer, which then closed abruptly, forcing the supplier to shut down. 311 F.3d at 766. Because the customer had previously promised the supplier that it would continue to purchase parts for at least a month past the date that it ultimately shut down, we found that the customer's earlier warning that at some point in the future it planned to begin purchasing at least some parts from another supplier was insufficient to make the shutdown foreseeable absent any other warning. *Id.* at 765–66. In *Pearce v. Faurecia Exhaust Systems, Inc.*, we likewise found that the unforeseeable business circumstances exception applied where employees failed to offer any evidence that an employer had knowledge that the company's primary customer was on the verge of filing for bankruptcy. 529 F. App'x at 458. In both of these cases, a fact-based inquiry revealed that there was no evidence of the employers' advance knowledge of the loss of a major customer.

Several of our sister circuits have examined the unforeseeable business circumstances exception in cases where a government order caused the mass layoff. The facts before us here are similar to those in *Pena v. American Meat Packing Corp.*, where the Seventh Circuit held that a reasonable jury could find that a government agency's multiple citations of a company for regulatory violations over a lengthy period of time would have made an enforcement action foreseeable to a reasonable employer. 362 F.3d 418, 422 (7th Cir. 2004). In *Pena*, the United States Department of Agriculture ("USDA") issued at least 31 noncompliance records ("NRs") documenting sanitation violations to a slaughterhouse over the course of a year and then ordered it to shut down. *Id.* at 419–20. The NRs contained a standard warning that failure to comply with regulatory requirements could result in adverse consequences. *Id.* at 419. After receiving several NRs, the slaughterhouse retained two outside consultants, both of which told the company that its problems could be fixed, and the slaughterhouse maintained frequent communications with the USDA and took several actions to remedy the sanitation violations, including installing additional rodent traps, retaining an expert to identify airflow problems in the facility, soliciting quotes for the cost of testing products for contamination, and forming a crisis

team to identify and correct various deficiencies. *Id.* at 420. The USDA nevertheless ordered the shutdown because "the measures taken up to that point were unsatisfactory." *Id*.

The Seventh Circuit rejected the employer's argument that the shutdown could not have been foreseeable because its experienced top management had never before experienced a shutdown caused by regulatory violations. *Id.* at 422. In support of this conclusion, the court cited new USDA rules for slaughterhouses that it characterized as "results-driven" rather than focusing on the "efforts" of the company. *Id.* Given the ineffective results of the slaughterhouse's attempts to remedy its unsanitary conditions, the court found a genuine issue of material fact about whether it was reasonably foreseeable that a failure to improve such conditions would result in enforcement action, and therefore it reversed the district court's grant of summary judgment to the employer. *Id.*

Caraco attempts to distinguish *Pena* by pointing out that the FDA did not change its enforcement strategy or increase its number of enforcement actions in the months preceding the seizure. But both Caraco and the slaughterhouse in *Pena* faced a similar pattern of escalating violations that culminated in a shutdown despite management's long experience with operating a facility without0 such an enforcement action. If anything, Caraco received more pessimistic feedback from its consultants about the likelihood of an enforcement action than the defendant in *Pena*.

Caraco contends that its mass layoff was no more foreseeable than those in three other out-of-circuit cases in which a government order rendered a layoff unforeseeable. In *Roquet v. Arthur Andersen LLP*, the Seventh Circuit found that the accounting firm Arthur Andersen was entitled to the benefit of the unforeseeable business circumstances exception when it announced mass layoffs after the United States Department of Justice unsealed an indictment of the company for obstruction of an SEC investigation. 398 F.3d 585, 588, 591 (7th Cir. 2005). The court held that the layoffs were not reasonably foreseeable before the indictment was unsealed because "in the past, the government typically went after culpable individuals, not companies as a whole," and therefore "it was not a foregone conclusion that Andersen would be indicted as a company." *Id*. at 589. Because the company continued to negotiate with the government up until the indictment became public, and it was unknown whether or when the government would

indict the firm as a whole, the court found that it would have been "a poor business decision" to conduct a mass layoff before the indictment was unsealed. *Id.*

In *Hotel Employees and Restaurant Employees International Union Local 54 v. Elsinore Shore Associates*, the Third Circuit determined that the unforeseeable business circumstances exception applied when the Atlantis Hotel and Casino was forced to close after its gaming license was not renewed. 173 F.3d 175, 187 (3d Cir. 1999). The court held that it was not reasonably foreseeable if or when the Commission would order the closing of Atlantis because an auditor's determination in early March that Elsinore's finances "raised substantial doubt about [its] ability to continue as a going concern for more than a year . . . [did] not reflect an opinion as to [Elsinore's] ability to operate for any specific period less than one year," especially since the auditors had made such statements for several years in a row. *Id.* at 186–87 (internal quotation marks omitted). The court also noted that the Commission had never before declined to renew a casino license, "even for applicants in serious financial distress." *Id.* at 186. Finally, the court pointed out that when the Commission appointed a conservator who subsequently blocked a proposed sale of the casino, a reasonable employer could have interpreted such an action as *increasing* the likelihood that the casino would remain open, even after the Division of Gaming Enforcement recommended that it be closed. *Id.* at 187.

In *Loehrer v. McDonnell Douglas Corp.*, the United States Navy terminated its contract with the McDonnell Douglas Corporation and another contractor to build the A-12 fighter-bomber, leading to mass layoffs at McDonnell Douglas. 98 F.3d 1056, 1057 (8th Cir. 1996). The Eighth Circuit noted that McDonnell Douglas was certainly aware of a multitude of problems with the contract, including scheduling delays, budgetary overruns, and difficulties with the manufacturing process. *Id.* at 1057–58, 1062. However, due in part to the "rather unique, politically charged area of defense contracts," the court found that the termination of the contract was not reasonably foreseeable. *Id.* at 1062. The court noted that the government had expressed a need for the program, Congress had expressed "ongoing conditional support for the A–12," and five days before the termination announcement, the under-secretary of the Navy had declared that the government had no intention of terminating the contract. *Id.*

The circumstances of *Roquet*, *Elsinore*, and *Loehrer* are distinguishable from those leading up to the shutdown here. In *Roquet*, because it was highly unusual for the government to indict an entire company, Arthur Andersen's decision to continue negotiating with the government without issuing a WARN notice until the indictment was unsealed was reasonable. Caraco, on the other hand, knew that enforcement action could result from product deficiencies and its consultants had told them such action was likely. Moreover, Caraco had already publicly acknowledged the 2008 warning letter in its January 2009 press release and February 2009 SEC filing, so the specter of regulatory action, unlike the sealed indictment in *Roquet*, was not shielded from public view. In *Elsinore*, it was reasonable for the company to believe that the casino's sale might be stopped if a prospective buyer stepped forward, and the company also knew that the Commission had never revoked a casino license and had been aware of the casino's precarious financial situation for years. Here, the FDA had initiated seizures before, and the district court found that Caraco knew as early as July 2008 that an FDA seizure was likely and would be very difficult to avoid. And in *Loehrer*, the company was faced with contradictory news—criticism and serious problems with the contract, but also support from Congress and a statement by the under-secretary of the Navy that the contract would not be terminated. Caraco, on the other hand, while occasionally garnering positive feedback from the FDA regarding its attempts to comply, also received increasingly critical Form 483s, warning letters, and feedback from its consultants that the company was at serious risk of an enforcement action including a mass seizure. The case law militates against the application of the unforeseeable business circumstances exception here.

The district court properly concluded that Caraco's actions in the months leading up to April 27, 2009 demonstrate that the company was aware of serious deficiencies at its facilities that rendered imminent enforcement action foreseeable. Caraco publicly acknowledged the 2008 warning letter in its January 2009 press release even as it stated an intent to move forward with its expansion plans, which the FDA had cautioned against. It issued nationwide recalls of multiple products in late March and early April. Later in April, Kendle's audit revealed multiple outstanding observations that Caraco had failed to address after receiving the 2008 warning letter. Taken together, and combined with the warnings from both of Caraco's consultants and

the FDA's dissatisfaction with Caraco's previous corrective actions, the enforcement action was reasonably foreseeable by April 27, 2009.

Caraco relies on the *Elsinore* court's discussion of the difficulty of predicting the exact timing of a shutdown. But it would make little sense to require that the exact date of an enforcement action be predictable in order for WARN liability to attach, and nothing in the statute or regulations so requires. Caraco argues that premature WARN notices would force employers to lay off employees prematurely and thus hurt the intended beneficiaries of the Act. But the Act mandates notice, not layoffs. Caraco could have issued notice to its employees of (or conditional notice of probable layoffs caused by) an imminent enforcement action without actually conducting the layoffs if the action never occurred. To hold otherwise would all but do away with the WARN Act's requirements because the exact date of a government enforcement action will rarely, if ever, be foreseeable. Therefore, we reject Caraco's argument that based on the factual circumstances here, the timing of the enforcement action was unforeseeable.

2. The District Court Did Not Engage in Analysis by Hindsight

Caraco next contends that the district court ran afoul of *Watson* by viewing the facts through the lens of hindsight rather than asking whether Caraco "exercise[d] such commercially reasonable business judgment as would a similarly situated employer." 20 C.F.R. § 639.9(b)(2); *see also Watson*, 311 F.3d at 765 ("In making this determination, a reviewing court must be careful to avoid analysis by hindsight. . . ."). In particular, Caraco asserts that it would not have been reasonable to issue a WARN notice in April 2009 because the FDA was still conducting an inspection and had not yet issued a follow-up Form 483. However, in an audit conducted from April 14 to 17, 2009, Kendle had made Caraco aware of nine outstanding observations, eight of which the FDA was "likely" to note on a future Form 483 and that Caraco had not resolved since receiving the 2008 warning letter. (Kendle Audit, R. 28-3, PageID 1245, 1246.)

It was not analysis by hindsight for the district court to find that a reasonable, similarly situated employer would have realized—based on the tenor of the 2008 warning letter, the multiple outstanding violations dating back several years of which management was aware, and the advice of the company's consultants—that an enforcement action was imminent. The district court reasonably relied on these factors when it concluded that the audit showed that "Caraco

had seemingly made little, if any, progress during the six months which followed the issuance of the FDA's warning letter," and that therefore an enforcement action was foreseeable at this time even though the FDA did not ultimately issue a Form 483 for these violations until May 2009. (Order, R. 55, PageID 2071.)

Other factors upon which the district court relied in reaching this conclusion included the number and breadth of recalls in early 2009, the missing digoxin, and the FDA's December 22, 2008 order to correct Caraco's longstanding problem of tablet-size variation. None of these factors required the benefit of hindsight to suggest that a significant enforcement action was imminent, and they all implicated consumer safety concerns that a reasonable employer in the pharmaceutical manufacturing industry would understand to be serious.

Although Caraco is correct that FDA enforcement actions are relatively rare, we reject the company's argument that an enforcement action was foreseeable only in hindsight. Caraco did not present any statistical evidence beyond the number of warning letters issued and enforcement actions undertaken in a three-year period; such evidence could just as easily be interpreted to show that enforcement actions were rare not because they were empty threats but because other employers who were issued warning letters promptly corrected their deficiencies or in some other way were not similarly situated to Caraco when the FDA seized its products. Therefore, we find Caraco's reliance on enforcement statistics insufficient to meet its burden to establish the applicability of the exception.

Finally, although previous warning letters to Caraco had not resulted in enforcement action, the district court reasonably concluded that the number of serious and longstanding violations, coupled with the advice of Quintiles and Kendle, among other factors, would have put a reasonable employer on notice that an enforcement action was imminent. *See Blough v. Voisard Mfg., Inc.*, No. 1:14-CV-263, 2015 WL 366934, at *6–7 (N.D. Ohio Jan. 27, 2015) (denying summary judgment to an employer because the record equally lent itself to either of two interpretations: (1) that it was unforeseeable that the employer's bank would freeze its line of credit because in the past the bank had always worked with the company to modify the loan agreement, or (2) that the bank's actions were foreseeable because its previous extensions were

intended to be temporary). We find that the district court did not engage in analysis by hindsight.

3. The District Court Did Not Fail to Consider the Circumstances that Led to the Mass Layoff

Caraco next contends that the district court did not consider the circumstances that led to the mass layoff, including Caraco's history with the FDA and the nature of the pharmaceutical industry. In support of its argument that it maintained a cooperative relationship with the FDA, Caraco argues that it undertook the steps that Kendle recommended in order to avoid an enforcement action, including voluntary recalls of some products, replacing ineffective management personnel, hiring additional consultants to conduct audits and train employees, acquiring additional machinery, and conducting rolling shutdowns of manufacturing units that were the subject of observations from the FDA.

This argument is unavailing. A reasonable drug manufacturer should have known that a positive working relationship with the FDA would not be enough to insulate it from the possibility of regulatory action, just as the multitude of corrective actions taken by the employer in *Pena* were not enough to forestall a shutdown. Moreover, it was not unreasonable for the district court to conclude, based on the record before it, that Caraco was not, in fact, sufficiently cooperative with the FDA based on, for example, the longstanding problem with tablet size variation that it had failed to correct, as well as multiple recalls and the April 14–17 audit, which showed a lack of improvement since the 2008 warning letter. Furthermore, this court "must give due regard to the trial court's opportunity to judge the witnesses' credibility." *Madden v. Chattanooga City Wide Serv. Dep't*, 549 F.3d 666, 674 (6th Cir. 2008) (quoting Fed. R. Civ. P. 52(a)(6)). The district court was entitled to evaluate the credibility of Caraco's executives based on the record and their testimony about their working relationship with the FDA, and nothing Caraco points to suggests that we should doubt its determination. *See In re Flexible Flyer Liquidating Trust*, 511 F. App'x 369, 374 (5th Cir. 2013).

Similarly, the fact that Kurkiewicz had never experienced a mass enforcement action and that such actions were statistically rare are not sufficient, in a fact-intensive, case-by-case inquiry, to settle this question. First, Quintiles had recently worked with two companies against

which the FDA conducted mass seizures, and Quintiles's vice president Fritz also told Movens that Quintiles had worked with many companies that were subject to seizures. Thus, Movens was apprised of the fact that seizures occurred yet disregarded the advice of his consultants. Second, and more importantly, although enforcement actions were rare and outside of the personal experience of Caraco management, the multiple factors cited by the district court show that the district court engaged in a proper case-by-case analysis and relied on the multitude of regulatory issues and actions taken or not taken by Caraco management in issuing its judgment.

Caraco also argues that because the FDA issued a Form 483 with 17 observations in its inspection the year after the 2000 warning letter, a reasonable employer would not have expected an enforcement action to result from a similar inspection with a large number of observations that immediately followed the warning letter in 2008. However, the language of the 2000 warning letter can reasonably be distinguished from that of the 2008 letter. Although the 2000 letter documented several critical deviations from protocol and noted that many deficiencies were repeat violations from the previous year's inspection, the 2008 letter characterized Caraco's responses to the previous Form 483 as "troublesome," and noted "significant inadequacies . . . , including inconsistencies with other explanations you provided previously during the inspection." (2000 Warning Letter, R. 27-8, PageID 912–14; 2008 Warning Letter, R. 23-11, PageID 527.)

4. The District Court's Factual Findings Were Not Clearly Erroneous

Finally, Caraco argues that several of the district court's factual findings were clearly erroneous, including: (1) that Movens repeatedly refused to acknowledge the significance of the FDA's findings; (2) that Caraco refused to adopt the findings of its independent consultants; and (3) that Caraco gave no indication of making changes in its business practices in response to the FDA's warning letters.

There is some evidence that Movens acknowledged that the FDA's observations were "serious" and that Caraco expressed a sense of urgency to address its regulatory violations. And the district court did appear to rely in part on Movens's statement that he believed the FDA's observations were only "isolated," which he wrote on June 10, 2005, well before the key events in question here. (*See* Order, R. 55, PageID 2069.) However, there was also ample evidence in

the record that Movens did not acknowledge the seriousness of the FDA's warnings. For example, Movens credited Kurkiewicz's assurances that an FDA enforcement action was not probable, despite the two independent consultants' warnings to the contrary. Indeed, Movens admitted at trial that it "may be true" that the advice he received from Kurkiewicz and Barone by mid-2008 was unreliable given that the FDA had found several times by then that Caraco was not FDA-compliant, despite Kurkiewicz's and Barone's assurances to the contrary. (Trial Tr., R. 46, PageID 1539–40; *see also id.* at 1522, 1534.) Furthermore, after Fritz's email to Movens on July 7, 2008, in which she opined that an FDA seizure action was "likely," and that "it will be very difficult to dissuade FDA from the enforcement approach we believe it is pursuing," Movens discussed the email with Kurkiewicz, who told Movens he thought Fritz was being "alarmist." (7/7/08 Fritz Email, R. 23-10, PageID 522–24; Trial Tr., R. 49, PageID 1840.) Movens also testified that he credited Kurkiewicz's and Barone's views over Fritz's because "[t]he consultant was new to the company and hadn't created that relationship of trust yet." (Trial Tr., R. 46, PageID 1549.) Additionally, Movens stated that he spoke to Kurkiewicz and Barone about how many additional chances the FDA might give Caraco to fix its compliance problems before resorting to an enforcement action, and he said "[t]hey had no view" on that question. (*Id.* at 1557–58.) Yet he did not attempt to discern the answer by asking Quintiles the same question. (*Id.*) Finally, Movens stated in the January 29, 2009 press release that "[w]e believe we are substantially compliant with cGMP." (1/29/09 Press Release, R. 22-31, PageID 361.) Based on the evidence before it, the district court did not err in concluding that Movens refused to acknowledge the significance of the FDA's findings.

The district court's factual finding that Caraco did not adopt the findings of its independent consultants was also not clearly erroneous. In addition to Quintiles's strongly worded warning to Movens that an enforcement action was likely, Kendle also warned Caraco that the company was "at risk of an enforcement action. This action would probably take the form of a civil injunction." (11/12/08 Celeste Email, R. 23-13, PageID 562.) Movens testified that he thought Celeste, Kendle's vice president, was "overly cautious" or "conservative" in evaluating the FDA's expected response. (Trial Tr., R. 46, PageID 1572.) Moreover, Movens's failure to "tie [] together" Quintiles's warning that the FDA was taking an enforcement approach with Kendle's information that Quintiles had recently worked with two other companies that had

been subjected to FDA enforcement actions was surely unreasonable. (*Id.* at 1573.) Finally, Kendle strongly recommended that Caraco not move forward on the development of new products until it had achieved cGMP compliance, but the January press release indicated that Caraco still planned to do so. Based on these warnings from the consultants and Movens's own admissions that he relied on Kurkiewicz and Barone instead of the consultants on multiple occasions, the district court did not err in inferring that Caraco unreasonably refused to adopt its consultants' recommendations.

It was also reasonable for the district court to conclude that Caraco gave no indication of making changes in its business practices in the wake of the FDA's 2008 warning letter. Although Caraco did take some action in response to the warning letters and Form 483s, the district court did not err in determining that these actions fell short of the kind of significant change that a reasonable employer should have known was necessary to forestall an enforcement action. First, Caraco's January 2009 press release stating that it planned "to aggressively move forward with the development of new products" was not a reasonable strategy in light of the serious regulatory problems Caraco faced at that time and was contradictory to Kendle's advice. (Press Release, R. 22-31, PageID 360.) Second, Kendle's April 14–17, 2009 audit of Caraco, which Kendle characterized as only "a very limited tour during which we did not attempt to conduct a comprehensive evaluation of cGMPs," revealed nine observations, including eight that would be classified as major and thus likely to appear on a subsequent Form 483. (Kendle Audit, R. 28-3, PageID 1245, 1246.) Finally, the district court noted that Caraco's nationwide Class I recall of digoxin tablets due to size variability and the loss of a significant quantity of digoxin at its facility were additional factors that would cause a reasonable employer to expect that an enforcement action was probable.

The district court also noted that the "number and breadth of Caraco's product recalls, totaling a half million bottles of 29 different products between January and April 2009," militated in favor of finding the enforcement action foreseeable. (Order, R. 55, PageID 2072.) It was therefore reasonable for the district court to conclude that Caraco did not make significant changes to its business practices after the issuance of the 2008 warning letter. *See Childress v. Darby Lumber Inc.*, 126 F. Supp. 2d 1310, 1316 (D. Mont. 2001) (holding that a company's

closing was foreseeable because the bank that provided the credit line to the company "notified the company on multiple occasions throughout [the previous year] that the company was in violations [sic] of its covenants, and that the company needed to come into compliance or risk [its] losing credit with the bank"). Accordingly, the district court's factual findings were not clearly erroneous.

III. CONCLUSION

Because it was reasonably foreseeable on April 27, 2009 that an FDA enforcement action was imminent, Caraco was not entitled to the unforeseeable business circumstances exception under the WARN Act. We therefore affirm the judgment of the district court.