NOT FOR PUBLICATION WITHOUT THE
APPROVAL OF THE APPELLATE DIVISION

SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NO. A-4318-10T2

JOEL S. LIPPMAN, M.D.,

Plaintiff-Appellant,

v.

ETHICON, INC. and JOHNSON & JOHNSON, INC.,

Defendants-Respondents.

APPROVED FOR PUBLICATION

September 4, 2013

APPELLATE DIVISION

Argued January 19, 2012 - Decided September 4, 2013

Before Judges Fuentes, Harris, and Koblitz.

On appeal from Superior Court of New Jersey, Law Division, Middlesex County, Docket No. L-9025-06.

Bruce P. McMoran argued the cause for appellant (McMoran, O'Connor & Bramley, attorneys; Mr. McMoran, of counsel; Mr. McMoran and Michael F. O'Connor, on the briefs).

Francis X. Dee argued the cause for respondents (McElroy, Deutsch, Mulvaney & Carpenter L.L.P. and Howard M. Radzely (Morgan, Lewis & Bockius L.L.P.) of the District of Columbia bar, admitted pro hac vice, attorneys for respondents; Mr. Dee and Mr. Radzely, of counsel; Mr. Dee, Mr. Radzely, Stephen F. Payerle, and Elena Chkolnikova, on the brief).

The opinion of the court was delivered by

FUENTES, P.J.A.D.

Plaintiff Joel S. Lippman, M.D., filed a complaint against his former employer, defendant Ethicon, Inc., a subsidiary of defendant Johnson & Johnson, Inc. (J&J), alleging a violation of the protections afforded to whistleblowers by the Legislature under the Conscientious Employee Protection Act (CEPA), N.J.S.A. 34:19-1 to -8. Plaintiff appeals from the order of the Law Division, granting defendants' motion for summary judgment and dismissing the cause of action as a matter of law.

Accepting plaintiff's allegations as true for purposes of deciding the summary judgment motion, the trial court held that plaintiff did not present a prima facie case under CEPA. The motion judge found that "[a]ll evidence indicates that [p]laintiff performed his job by notifying his supervisors of issues and Ethicon responded appropriately." Relying in part on this court's decision in Massarano v. New Jersey Transit, 400 N.J. Super. 474 (App. Div. 2008), the motion judge concluded that plaintiff admitted "it was his job to bring forth issues regarding the safety of drugs and products," thus he "failed to show that he performed a whistle-blowing activity."

On appeal, plaintiff argues that the motion judge's "narrow interpretation of CEPA" runs counter to the Supreme Court's repeated admonitions that, as a remedial statute, CEPA should be construed liberally to effectuate its social goal of protecting

employees who report workplace misconduct from retaliation. Battaglia v. United Parcel Service, ____ N.J. ____, ____ (2013) (slip op. at 45-46) (citing Dzwonar v. McDevitt, 177 N.J. 451, 461-62 (2003)). According to plaintiff, the trial court misread our dictum in Massarano to create a class of employees who, as a matter of law, fall outside CEPA's protection merely because they were hired to monitor and express an opinion about the employer's compliance with relevant laws and regulations.

Defendants argue that "[t]he trial court correctly held that plaintiff did not engage in whistle-blowing under CEPA when," in the course of performing his regular core job functions, he expressed an opinion about the safety of a product. According to defendants, the evidence shows that plaintiff's opinions were considered by his employer through an established deliberative process, that his colleagues and supervisors followed his opinions and recommendations in most cases, and that, in those cases where plaintiff's opinions did not prevail, his suggestions were given due consideration before they were rejected in accordance with established internal protocols. Stated differently, defendants argue that it is not a CEPA violation for an employer to disagree with or, in some cases, even disregard an employee's opinion about the safety of

a particular drug or medical device as long as the employer does not retaliate against the employee for expressing such opinions.

As an alternative basis for affirming the trial court's final judgment,[1] defendants argue that: (1) the evidence shows that plaintiff was terminated from his position because he had an inappropriate sexual relationship with a subordinate employee; (2) plaintiff did not establish a prima facie causal nexus between his alleged whistle-blowing activities and his termination; and (3) plaintiff did not rebut the facially business-based, non-retaliatory reasons presented by defendants to justify plaintiff's termination.

In our view, the parties' polarized positions are primarily predicated on the motion court's incorrect legal assumption that an employee's job title or employment responsibilities should be considered outcome determinative in deciding whether the employee has presented a cognizable cause of action under CEPA. We disagree that this notion is consistent with the legal principles established by our Supreme Court in construing the protections afforded to whistleblowers under CEPA. Furthermore, to the extent that such a notion was approvingly expressed or

[1] As respondents, defendants can raise alternative arguments in support of the trial court's judgment without filing a cross-appeal. Chimes v. Oritani Motor Hotel, Inc., 195 N.J. Super. 435, 443 (App. Div. 1984).

implicitly adopted by the panel in Massarano, supra, 400 N.J. Super. 474, we explicitly decline to endorse it here.[2]

After conducting our own de novo review of the record, Town of Kearny v. Brandt, 214 N.J. 76, 91 (2013), viewing the factual record presented in the light most favorable to plaintiff, Brill v. Guardian Life Ins. Co. of Am., 142 N.J. 520, 540 (1995); R. 4:46-2(c), and applying the standards established by the Supreme Court in Dzwonar, supra, 177 N.J. at 462, we reverse the trial court's decision to grant defendants' motion for summary judgment. We conclude that there are sufficient material issues of fact in dispute that can only be resolved by a trier of fact.

I

Plaintiff received his degree as a medical doctor from New York Medical College and has a master's degree in public health from Harvard University School of Public Health. From 1983 to 1987, plaintiff had a private medical practice specializing in obstetrics and gynecology. He also served as a clinical assistant professor of obstetrics and gynecology at Tufts

[2] We reach this conclusion mindful of Judge Stern's perspicacious admonition that "an appeal to this court should not turn on the Part or judges to which the matter is assigned. . . . However, each judge must decide an issue as he or she believes appropriate after giving due deference to any precedent available." Hellwig v. J.F. Rast & Co., Inc., 215 N.J. Super. 247, 254 (App. Div.) (Stern, J.A.D., concurring) certif. granted, 107 N.J. 636, (1987), aff'd, 110 N.J. 37 (1988).

University School of Medicine in Boston, Massachusetts during the last year of his private practice. Plaintiff left the private practice of medicine to work at Wyeth-Ayerst Laboratories as an associate director of medical affairs and eventually as a director in the clinical development division of medical affairs.

Plaintiff began his employment association with defendants in 1990, when J&J's subsidiary Ortho-McNeil Pharmaceutical (OMP) hired him to serve as their director of medical services. OMP was, at the time, a manufacturer of pharmaceutical products. Plaintiff received a number of promotions during his ten-year tenure at OMP. He was first promoted to senior director of clinical affairs, then to executive director for clinical affairs, and in 1998 to vice-president of clinical trials.

According to plaintiff, his function at OMP with respect to new products was,

> [t]o work with the folks in PRI[3] that were . . . developing these products. To work with the folks at Ortho-McNeil in the group

[3] PRI stands for "Pharmacological Research Institute." PRI is the entity responsible for the development of pharmaceutical products for companies affiliated with J&J. In his May 5, 2010, deposition, plaintiff testified that PRI changed its name at one point to "Pharmaceutical Research and Development" (PRD). According to plaintiff, PRD was the name used by the research and development branch of J&J at the time it "was actually developing the drugs and then giving them to the operating companies like Ortho-McNeil."

> that was called New Product Development as they were looking to launch the product bringing it to market.
>
> So really it was twofold. I had a responsibility to work with the folks actually developing the product and then I had a responsibility to work with the folks who were actually going to market and sell the product once it became available and launched.

ORTHO-PREFEST®

Plaintiff alleges that his first "whistle-blowing" activity occurred between 1998 and 1999 while he was employed at OMP as the vice-president of clinical trials. It is undisputed that plaintiff's position gave him direct responsibility over product quality and safety. Plaintiff alleges that, in 1999, he expressed concerns about the safety of a hormone replacement product developed by PRI called Ortho-Prefest®.

Based on data received from clinical trials in which patients participated in a control study to assess the drug's efficacy and potential risks and side effects, Ortho-Prefest® was shown to cause a higher rate of endometrial hyperplasia, a precursor to endometrial cancer. Plaintiff was concerned about the safety of this drug and made his opinion known to his supervisor Michael Kafrissen. Plaintiff also shared his views with the Ortho-Prefest® team as well as Robert Wills, the vice-president of PRI, and Clair Peterson, PRI's chairperson.

At the time, plaintiff objected to launching Ortho-Prefest® because he believed that marketing the product would violate both the Food, Drug and Cosmetic Act (FDCA) regulations and New Jersey's products liability laws and was "incompatible with the clear mandate of public policy against marketing defective products that present a reasonably foreseeable risk of injury" to the public. Although plaintiff claims that he was reprimanded for expressing this opinion, the record does not support his assertion.

When specifically asked at his deposition to describe the reaction he received from OMP or PRI management for expressing his safety concerns about Ortho-Prefest®, plaintiff responded as follows:

> A. I remember feeling pretty bad when I heard what they were saying.
>
> Q. What did they say?
>
> A. They said they didn't agree with it. That this is going to prevent progression of the product. That, you know, to evaluate this it would involve doing a whole new study. This could effect [sic] FDA approval. I don't remember specific comments, but I know it was long [sic] those lines, yes.
>
> Q. Who said that?
>
> A. I don't remember who said it . . . .
>
> Q. You don't remember?

> A. I don't remember exactly, no. It was 12 years ago.[4]

The only other evidence of an ostensible "reprimand" concerns an email sent by Wills to six people, including plaintiff. In the email, Wills stated: "All of you created this issue and all of you will fix it." According to plaintiff, although he was not the only one at OMP who had these concerns[5] about Ortho-Prefest®, he was "the one that raised" them. OMP eventually ceased marketing the drug and began a new study. Plaintiff was not demoted, reassigned, or otherwise adversely affected for expressing his opinion about the safety of Ortho-Prefest®.

ORTHO-EVRA®

In late 1999, while serving as vice-president of clinical trials, plaintiff began reviewing data concerning the efficacy and safety of the ORTHO-EVRA® Contraceptive Patch, a transdermal patch that delivered contraceptive agents. As plaintiff explained in response to defendants' interrogatories:

> At the time, OMP was a market leader in oral contraceptives. However, many of its

[4] Given that plaintiff was deposed on June 22, 2010, we deduce that the event occurred in 1998.

[5] Plaintiff identified, by name, three individuals that shared his specific concerns about Ortho-Prefest®, including Kafrissen, his direct supervisor.

> oral contraceptive products were going off patent and needed to be replaced with new products or OMP's revenue and market share would decrease.
>
> PRI was developing a new oral contraceptive regimen to replace the older products that were going off patent. [ORTHO-EVRA®] was also in development at this time. [ORTHO-EVRA®] was intended to be a secondary option for consumers that had compliance problems, i.e., they forgot to take their pill each day. It was not intended to be the product of choice.

In his certification submitted in opposition to defendants' motion for summary judgment, plaintiff indicated that he objected to the launching and marketing of the ORTHO-EVRA® patch because "[t]he data showed that patients were experiencing increased [deep venous thrombosis (DVT) a/k/a blood clots] due to the estrogen dosage in the patch." Plaintiff certified that DVTs "can travel through the bloodstream to different parts of the body and cause emboli, strokes, heart attacks[,] or blindness." In lieu of launching the patch at that time, plaintiff suggested that PRI conduct additional research on these potentially negative side effects. Plaintiff opined that, as originally proposed, the patch presented "an unreasonable risk of substantial harm in violation of the FDCA and applicable regulations and the public policy they reflect."

Defendants note, and the record reflects, that OMP heeded plaintiff's recommendations. As plaintiff acknowledged in his

deposition, after discussing the problems with an advisory board comprised of scientists employed by PRI, external experts, and plaintiff, it was mutually decided to stop the launching and marketing of ORTHO-EVRA® pending the results of a clinical study to examine the DVT issue as well as the other known risk factors. When asked specifically if he thought this was an acceptable outcome, plaintiff answered: "I was okay with it at the time." Plaintiff clarified that, although the study was started, it stopped after he left OMP sometime after 2000 because the company "stopped selling the product."

In response to defendants' interrogatories, plaintiff claimed that OMP launched ORTHO-EVRA® in 2002 despite insufficient information about "how much estrogen was getting into the patient." Although he left OMP in June 2000, plaintiff claimed that "[i]n late 2003 and 2004, OMP began receiving reports of deaths caused by pulmonary emboli, heart attacks[,] and strokes." Because these alleged developments occurred after plaintiff's separation from OMP, their relevance to his claims of retaliation is, at best, tangential. The veracity and probative value of these claims are further undermined by plaintiff's own deposition testimony, in which, in response to the question: "But do you know whether - - how it got on the market or what happened in terms of looking at this issue that

you raise?," plaintiff answers, in relevant part: "I only know that after I saw from [sic] the information in the media that the product was on the market I think in 2002 . . . ."

II

EMPLOYMENT AT ETHICON

Plaintiff characterizes his employment at Ethicon as a "transfer," which he implicitly attributes to the concerns he expressed about ORTHO-EVRA®.[6] Plaintiff elaborated on this point in an answer he gave to defendants' interrogatories:

> In the spring of 2000, at the same time plaintiff was raising his complaints about the safety and efficacy of [ORTHO-EVRA®], he received a call from Cliff Holland, the [p]resident of Ethicon. [Holland] offered plaintiff the position of [vice-president of] [m]edical [a]ffairs for Ethicon. Plaintiff did not go through any formal interviews other than his conversation with [Holland]. He joined Ethicon in July 2000, approximately one and a half months later even though there was a hiring freeze at the time.

[6] Defendants argue in a footnote that plaintiff's position at Ethicon "was obviously not an adverse employment action." To the extent that plaintiff deems it as such, defendants further argue that a claim based on an event that occurred in 2000 is time barred under CEPA's one-year statute of limitations. N.J.S.A. 34:19-5. Although we need not address the issue to decide this appeal, we take this opportunity to reaffirm Judge Pressler's condemnation of the practice of raising legal arguments in footnotes as "wholly inappropriate" and in clear violation of Rule 2:6-2(a)(5). Almog v. Isr. Travel Advisory Serv., Inc., 298 N.J. Super. 145, 155 (App. Div. 1997), appeal dismissed, 152 N.J. 361 (1998).

In an effort to rebut plaintiff's characterization of his move to Ethicon as a "transfer," defendants emphasize that at all times relevant to this case, OMP and Ethicon were separate corporate entities with their own presidents and management structures, notwithstanding their subsidiary affiliation to J&J. Whether these assertions are technically correct is not germane to the issues before us.

The record shows that major decisions at both OMP and Ethicon were made and implemented only after they were discussed with and approved by J&J's senior management liaison. Paraphrased in the vernacular used by Ethicon's senior management: "we need to run it by and get approval from corporate in New Brunswick." And with respect to governmental oversight, both OMP and Ethicon were subject to the FDCA, 21 U.S.C.A. §§ 301-399f, and its Medical Device Amendments, 21 U.S.C.A. §§ 360c-360m, and regulated by the Food and Drug Administration (FDA).

In the interest of balance, the record also shows that plaintiff received a significant increase in salary as a result of his new position at Ethicon. When plaintiff separated from OMP in June 2000, his annual salary was $228,000; six months later, plaintiff's annual salary at Ethicon was $242,000. Finally, to dispel any lingering doubts, plaintiff specifically

stated in his May 5, 2010 deposition that, at the time, he viewed his new position at Ethicon as "better for [his] career."

Dorothy A. Donnelly-Brienza was Ethicon's vice-president of human resources when plaintiff began working for the company. According to Donnelly-Brienza, plaintiff's direct superior and the person to whom he reported was Dennis Longstreet, Ethicon's company group chairperson. Longstreet, who served in this capacity until July 2005, reported to Michael J. Dormer, J&J's chairperson for the medical devices and diagnostic group.

Donnelly-Brienza explained that, as the vice-president of Ethicon's medical affairs, plaintiff was "responsible for safety, ensuring that safe medical practices occurred in clinical trials of [Ethicon's] products; . . . medical reviews, information from a medical standpoint; [and] medical writing." By virtue of these responsibilities, plaintiff was required to serve on a number of internal review boards designed to provide an environment for senior management and policy makers to express their views and suggestions within their particular areas of expertise.

The first of these boards was Ethicon's global management board (GMB). Plaintiff testified that Longstreet created the GMB sometime between 2001 and 2002. Plaintiff's role as a member of the GMB was "to work with the other [GMB] members[,]

[s]trategically make decisions, evaluate the pipeline, make decisions regarding business opportunities[,] [t]hings of that nature."

Sherilyn S. McCoy replaced Longstreet as Ethicon's company group chairperson in July 2005. According to McCoy, the GMB,

> evaluate[d] situations where if there was an increase in customer complaints or if there was concern about a product or anything that we were manufacturing or selling, [the board] would convene a group that was a cross-functional group that had expertise in medical, safety, manufacturing, and they would look at whether there was any concern about the product itself or the frequency of events that were occurring and decide what they wanted to do moving forward.

However different the parties may have perceived the role of the GMB, it is clear to us that the GMB was intended to create an internal deliberative process through which senior management could evaluate a variety of important matters, and if necessary, solicit opinions or insights from external experts.

Plaintiff was also a member of Ethicon's products board, a group headed by Holland, Ethicon's president. The products board was comprised of senior, high-level policy decision makers. In addition to plaintiff, the products board's membership included the company's chief financial officer (CFO), the vice-president of international market development, the head of marketing for Europe, the vice-president of marketing and

sales, and the vice-president of research and development. Plaintiff described his responsibilities as a member of the products board as an advisor in his field of expertise, "[t]o provide the medical/clinical/health economics input into the Ethicon products strategic activities."

The quality board was created to assess the health risks posed by Ethicon's products and to provide "medical input" in determining whether the company needed to take corrective measures with respect to their products in the field. According to plaintiff, in addition to himself, the quality board's membership included Catherine Beath, Ethicon's vice-president of quality and regulatory affairs, the head of research and development, the CFO, and "the head of operations."

The particular action required from these various boards, but in particular from the quality board, obviously depended on the situation. Always looming was the possibility that a recall of a product would be necessary to conform to the requirements of the particular regulatory agency with jurisdiction, internal policy directives, and/or to protect the health and safety of the patient who would be most affected by the defective or malfunctioning product. As plaintiff explained in his deposition testimony, consistent with Ethicon's internal policy,

the quality board "would have the final say," even in the absence of a directive from a governmental agency.

Quality board members were expected to express their view points from their particular perspective or area of expertise. When asked at his deposition whether "for the most part, everybody at these quality board meetings expressed their viewpoint forcefully?" plaintiff responded: "It happens at times, yes . . . I wouldn't say a lot of times."

As part of this cause of action, plaintiff claims the quality board's final decision-making authority was improperly usurped when McCoy, the chairperson of Ethicon and Beath, Ethicon's vice-president of quality and regulatory affairs, overruled the board's decision to recall a defective "life sustaining" medical device. We will describe the particulars of this incident at length during our discussion of a medical product called DFK-24.

Plaintiff also served on Ethicon's products board. As plaintiff explained, his function as a member of these various internal review or self-critical analysis boards was,

> [t]o provide medical and clinical expertise and opinion to issues that came in front of the quality boards.
>
> Q. And what do you mean by issues?
>
> A. Things would come to quality boards if there were reports of adverse events or any

> other reason that might require a field action.
>
> Q. And so at these quality board meetings, your job was to provide your medical input as to what the decision would be?
>
> A. That was my job.

Plaintiff's career at Ethicon was initially prosperous. He was promoted in 2002 to be the worldwide vice-president of medical affairs and chief medical officer. In this capacity, plaintiff oversaw three medically related areas: clinical affairs, health economics and reimbursement, and medical affairs. In this role, plaintiff was responsible for reviewing product safety data to determine when a new product should be marketed. He considered his general professional responsibilities at Ethicon to be similar to those that he had at OMP - to candidly and forthrightly express his opinions and concerns about the safety of a product.

III

WHISTLE-BLOWING ACTIVITIES

CORLINK™

CorLink™ was a medical device, licensed by the FDA, to be used in cardiac bypass surgery in lieu of sutures. As plaintiff explained:

> In traditional bypass surgeries, the heart is stopped, and the patient is put on a pump while the diseased tissue is excised

> and the healthy tissue is sutured back together. The more time the patient spends on the pump, the greater the risk for neurologic sequelae.
>
> [CorLink™] was essentially a coupler that would be used to attach the healthy tissue after the diseased tissue had been excised. It was intended to take the role of sutures. [CorLink™] was intended to be a platform product for [CardioVations], Ethicon's heart division. It was supposed to put [CardioVations] on the map.

The actual medical procedure is called anastomosis, which "means bringing two ends together." Using the CorLink™ device, the physician would introduce a coupler that would bring "the two ends of the arteries together without a suture." CorLink™ was intended to produce a "sutureless anastomosis."

CorLink™ was developed by an Israeli company called ByPass, Ltd. In 2001, plaintiff objected to the marketing of CorLink™ by Ethicon, which had acquired the license to market the device in the United States. According to plaintiff, one of ByPass's "major investors" was a man named Lewis Pell, who was also at the time J&J's "single largest" individual shareholder.

Plaintiff testified that he reviewed the data gathered from an animal study that compared the results achieved using a traditional suture anastomosis and those using CorLink™. He found the results were the same. However, when he examined the results of the study more carefully, he determined that in both

scenarios (suture anastomosis and CorLink™) the animals died. Ethicon was relying on the consistency of the results to show that the device was safe. In this case, as plaintiff explained, "yeah, they were the same, but equally bad."

Based on the results of the animal study, ByPass proceeded to human trials. Plaintiff testified that when he evaluated the human study, he determined that "it was a very poorly designed and run study." He thus concluded that the "device had not been adequately tested." Plaintiff claims that he "voiced" his concerns to Longstreet, his direct supervisor at Ethicon, and other senior management members, including, Holland, Jim Lenehan, and Dormer as well as ByPass's leadership team. Plaintiff does not dispute that the research he conducted to determine the efficacy and safety of CorLink™ and the action he took thereafter expressing his opinion to senior management, was exactly what he was hired to do as Ethicon's worldwide vice-president of medical affairs and chief medical officer.

Plaintiff testified that his opinion was not universally shared. He claims that a recently hired cardiologist, the veterinarians who conducted the animal studies, the head of research and development, and "the medical directors in [his] group" all agreed with his assessment of the product's safety. However, and most importantly, as it relates to this case,

Longstreet, Dormer, Pell, Ron Guido,[7] and other senior decision makers at Ethicon disagreed with plaintiff's opinion. In plaintiff's words, these individual "were with ByPass." According to plaintiff, Longstreet left him a voicemail saying "if you don't corporate [sic] with bringing this to market, it will affect your bonus and possibly your standing in the company."

Plaintiff claims that from 2002 through 2003, he continued to be pressured by Longstreet and other members of Ethicon's senior management to cooperate in their efforts to bring CorLink™ to market. Despite this, plaintiff held true to his convictions and professional judgment. Although a second human study was commissioned, the research did not continue after six patients demonstrated recurring safety and efficacy issues. Ultimately, Ethicon did not bring CorLink™ to market. According to plaintiff, this decision was due to his efforts. In his own words: "They did listen to my opinion."

PANACRYL®

According to Beath, Ethicon's vice-president of quality and regulatory affairs, in terms of gross sales, sutures are the

[7] Guido, at the time, was the vice-president and general manager of Ethicon's business unit, CardioVations. Plaintiff testified that Guido believed that the tests were done properly and was particularly in favor of bringing the product to market.

biggest product line that the company markets. Most of the sutures manufactured by Ethicon are absorbable. This means that they do not have to be physically removed by a medical professional. Most absorbable sutures dissolve within ninety days. PANACRYL® is a suture that dissolves outside of this ninety-day window. In fact, Beath testified that PANACRYL® "was the longest absorbable suture at the time." Its "absorption profile" indicated that "[i]t could stay in the body for one and a half to two years."

Starting in 2001, Ethicon began to receive reports of "adverse events" regarding PANACRYL®. A quality control group, initially headed by John Pawson, collected these reports. Beath took over the group sometime during that year. Plaintiff testified that, at his direction, the quality control group consisted of three surgeons and medical directors. He asked the group to investigate the reports of adverse events[8] involving PANACRYL® while working "with the quality assurance folks." Under the direction of both plaintiff and Beath, the

[8] Plaintiff testified that the adverse events consisted of "inflammatory reaction from the suture," including "suture spitting" which happens when "portions of the suture start getting extruded through the skin." There were also reports of "suture granulomas," which plaintiff defined as an "inflammatory reaction where people would have [their] sutures applied." These suture granulomas would sometimes require surgery to remove both the suture and the granuloma, "and sometime[s] actual wound infections."

investigation proceeded over a period of months. The results were inconclusive.

At a quality board meeting held in February 2002, which plaintiff attended, the members decided that they did not have a sufficient basis to recall the product. They opted instead for the investigation to continue and to update the warning in the package insert and send what are referred to in the industry as "Dear Doctor" letters, alerting surgeons of the problem.

Thereafter Ethicon decided not to continue selling PANACRYL®. As part of this legal action, plaintiff claims that when he learned that Ethicon had stopped selling the product, he told Beath that the company should also "recall the stuff that's out there." When asked by defense counsel whether he asked Beath or anyone else at Ethicon to reconvene the quality board for the purpose of formally raising this issue, plaintiff answered:

> I spoke to [Beath] about it. I can't sit here and say I said you have to have a quality board, but I told her that was my recommendation, that we need to recall the rest of the product, which would involve the quality board.
>
> Q. But if you didn't insist upon having a quality board meeting to discuss the recall issue --
>
> A. Say again.

Q. You said that when it was -- when a decision was made not to sell [PANACRYL®] anymore.

A. Yes.

Q. You thought what was out on the market should be recalled?

A. Yes.

Q. Did you ask that a quality board meeting be held to discuss that feeling that you had, that it should be recalled?

A. I don't remember specifically asking for a quality board meeting.

Q. But you could have, couldn't you?

A. I could have.

. . . .

Q. Well, if you felt strongly that this was a risk to patients, an unacceptable risk that required a recall, can you explain why you wouldn't raise a bigger fuss about it?

A. Yes.

Q. Why?

A. I felt strongly that it required a recall. I didn't feel it was [an] []acceptable risk because of the enhanced warning.

Q. And you didn't go over [Beath]'s head to insist on a recall?

A. I don't remember specifically doing that. I did go to other people and I assumed [Beath] would tell her management, as she always reported things that were

> going on of this nature, but I did not specifically go to somebody else.

At the time, unbeknownst to plaintiff, Ethicon did not send the surgeon alert (i.e., the so-called "Dear Doctor" letter) as directed by the quality board. Plaintiff discovered this in 2006. He does not know who made this decision or the reasons that supported it.

INTERGEL®

INTERGEL® was a gel product sold by Ethicon, but actually manufactured by Lifecore Biomedical, Inc. According to plaintiff, INTERGEL® is used "intraoperatively," in the course of surgery, to prevent the onset of adhesions from surgical procedures. Adhesions are "fibrous bands of tissue that occur secondary to trauma associated with surgery." Adhesions "can cause organs to cling together or [cause] pain." Dr. Martin Weisberg, who was the medical director of Gynecare in 2002, a division of Ethicon, and reported directly to plaintiff, described INTERGEL® as "a compound made of hyaluronic acid and iron," used "to prevent or diminish the incidents of adhesions following open, conservative gynecological surgery."

In 2002 and early 2003, Ethicon began receiving adverse incident reports "mostly from [its] internal event reporting" system, which, according to plaintiff, were "[v]ery similar" to what Ethicon experienced with PANACRYL®. In August 2002, the

quality board decided not to recall INTERGEL®, opting instead to issue "Dear Doctor" letters to surgeons and revise the product labeling. Although plaintiff conceded that he "signed off" on the decision not to recall INTERGEL®, he testified that he did not agree with the decision to send the "Dear Doctor" letters. When asked if there were any contemporaneous notes or minutes of the meeting reflecting his dissent, he answered: "I didn't sign it and I would typically sign those letters, but I don't know if anything else is in writing."

When pressed by defense counsel on this issue, plaintiff said he told Beath that he would not sign the physician alert letters. He did not remember when he told her or if there was anyone else present. He told her he would not sign the letters to the doctors because: "I don't agree with the recommendation to surgeons not to operate on people who are having this problem because I'm concerned they will have a bowel injury and infection and die." The only direct evidence of plaintiff's alleged contemporaneous concerns and desire for a recall of INTERGEL® is a memorandum written by plaintiff dated March 14, 2003. In this document, produced in response to defendants' discovery requests, plaintiff allegedly memorialized his "increasing concerns throughout 2002 and 2003 and called for a [q]uality [b]oard meeting and a recall."

The quality board met again when a second patient died as a result of INTERGEL®. The board decided to voluntarily recall the product. Plaintiff claims that in April 2003, within weeks of the quality board's decision to voluntarily recall INTERGEL®, Dormer, J&J's chairperson of its medical devices and diagnostic group, summoned all of the high-level decision makers at Ethicon, including plaintiff, to discuss the problems with INTERGEL®. The meeting was prompted by the circumstances surrounding the second death.

Describing what allegedly occurred at this meeting entirely from plaintiff's perspective, as required under Rule 4:46-2(c) given the procedural posture of this case, Dormer was steadfast against a voluntary recall of the product, at one point dismissively saying that "all devices have risks." Dr. Weisberg was among the senior staff in attendance at the meeting. As part of his duties as the medical director of Gynecare, Dr. Weisberg prepared a health hazard evaluation (H.H.E.) of INTERGEL®. The H.H.E. revealed that the physician who treated the second patient admitted that, when the patient reported post-operative pain, he assumed it was due to the INTERGEL®, and, as a result, he did not operate on her. When he eventually operated on her, she died two days after the surgery. The cause of death was "from sepsis . . . secondary to bowel perforation."

According to plaintiff, to the best of his recollection, all of the senior staff at the meeting who expressed an opinion were in favor of a voluntary recall. It is undisputed that Ethicon voluntarily recalled INTERGEL® "immediately after the second death." As of 2010, the year of plaintiff's deposition, Ethicon had not remarketed INTERGEL®.

PROCEED™

Manufactured by Ethicon and introduced into the United States between 2003 and 2004, PROCEED™ is a "mesh product used to bring tissue together and close wounds after surgery." The mesh is used to provide support filled space, decrease tension, and promote wound healing. Ethicon was a market leader in manufacturing these types of mesh devices, and Beath characterized the market sales of PROCEED™ as "good."

In September 2004, Ethicon started receiving "complaints of delamination[9] of the mesh." The complaints "spiked" in August 2005. It is undisputed that complaints escalated from this point on. By October 2005, the complaint rate was ten times greater than the mean complaint rate. The quality board initially focused its investigation on determining the root cause of the problems. According to Beath, Ethicon's vice-

[9] Delamination occurs when a product comes apart or separates into its constituent elements. Webster's Third New International Dictionary 595 (1981).

president of quality and regulatory affairs, Ethicon "expect[ed] some delamination in this product" because it was identified in the design. However, the rate and severity of the delamination complaints far exceeded the reasonably anticipated rate.

The consequences for patients who experienced the delamination of a PROCEED™ mesh were very serious. Ethicon's own internal documents indicated that "patients could develop severe adhesions and possibly bowel fistulization resulting in [the] need for a second surgical procedure to remove the mesh." As explained by Beath, who, despite her title and responsibilities at Ethicon, is not a physician, bowel fistulization occurs "[w]hen adhesions form and create, I believe, an opening from the bowel into the abdomen."[10]

The parties strongly dispute what position plaintiff advocated at the quality board's meetings. Beath unequivocally denied that plaintiff "pushed for" or was a driving force behind the decision to have more quality board meetings to discuss and decide on a plan of action to effectively respond to this burgeoning PROCEED™ problem. In her words: "The [board]

[10] Beath's description of the possible health hazards from the delamination associated with PROCEED™ precisely matched the language in a power-point presentation attached to an email sent on November 1, 2005, by Mark Yale to the members of the quality board. The documents attached were to be presented at a board meeting, which was scheduled that day at 3:30 pm.

meetings were scheduled by me based on the data I was getting, and there were a lot of inputs, not just Dr. Lippman." Plaintiff claims he was instrumental in getting the board to meet and discuss the problem.

Giving plaintiff the benefit of the presumption of credibility he is entitled to receive at this juncture of the case, a jury may find that the quality board met on November 12, 2005, December 12, 2005, and December 15, 2005, to discuss the PROCEED™ problem, principally due to his conscientious persistence. Plaintiff testified that at the December 12, 2005 meeting, the board agreed "[t]o not proactively tell the FDA [that they were] going to recall the product, but to present the information to the FDA and get their input about a recall." When asked if he agreed with the board's decision, plaintiff responded: "Yes. I think I suggested it."

Plaintiff explained that his concurrence with a material part of Ethicon's response to this serious product-defect problem was merely a strategic decision on his part "to move the process forward." He was frustrated with the length of the board meetings (one lasted over two days) and by how much time had elapsed without any form of concrete action. Plaintiff emphasized, however, that he remained adamant that the data showed "an increase[d] risk of events" and believed that the

product should be recalled. Plaintiff also conceded that there were other board members who were equally adamant in their convictions that a recall was not warranted.

Plaintiff testified that the board was completely polarized on this issue. He was getting "a lot of push back, and it was not very pleasant." Plaintiff claimed he was called by one board member either "obstinate or destructive." He thus made this suggestion to "proactively" give the data to the FDA, confident that once the agency reviewed the data, it would order or strongly suggest that the product be recalled.

Considering the evidence in the light most favorable to plaintiff, the record indicates that plaintiff's position was vindicated. In a memorandum to the quality board dated December 20, 2005, Beath confirmed that, pursuant to the board's December 12, 2005 decision, Ethicon contacted the FDA's recall coordinator for New Jersey and informed them about the complaints that Ethicon had received from surgeons about the "varying degrees of delamination . . . from [PROCEED™] during some hernia repair procedures." Beath emphasized that "[t]o date, no adverse events related to delamination of recalled products lots of [PROCEED™] have been reported."

Despite these efforts to mitigate or, as plaintiff may argue, minimize the magnitude of the problem, Beath confirmed in the memorandum that the FDA recall coordinator,

> believe[d] [Ethicon] should treat this like a recall. She believe[d] that [PROCEED™] is violative and while [Ethicon] ha[s] no reported [adverse events] to date, there is still a likelihood.
>
> . . . .
>
> Based on input from [the] FDA, [Ethicon] will move forward with this as a recall in accordance with internal procedure.

The recall of PROCEED™ occurred during McCoy's first year as Ethicon's company group chairperson. As noted earlier, she replaced Longstreet in July 2005. McCoy indicated in her deposition that the cost incurred by Ethicon to recall PROCEED™ "was greater than 10 million [dollars] and probably less than 100 million [dollars]. So it was somewhere in that range, is my guess."

DFK-24

According to plaintiff, DFK-24 is an arterial cannula device that "returns arterialized blood from the cardio pulmonary bypass (CPB) machine to a patient's systemic circulation via the aorta during [CPB] surgery." The device returns the external oxygenated blood to the patient's circulatory system through the aorta. In short, "DFK-24 is life

sustaining during use." (Emphasis added). DFK-24 was marketed by CardioVations, the cardiology division of Ethicon.

Because DFK-24 literally sustains the patient's life while in use, plaintiff opined "a recurrence presented a risk of serious interoperative injury or death to the patient. Since the cannula was inserted through a small surgical incision, in most cases a malfunctioning cannula could not be swapped out and replaced quickly enough to prevent injury or death." Beath, who headed the quality board despite not being a physician, testified that the board found that "if the particular malfunction [with DFK-24] occurred and was not noticed by the physician and the physician could not correct for it, the patient could die."

In April 2006, Ethicon received its first report that the device had "fallen apart during a cardiac procedure." Although not certain if the incident occurred in Germany or Italy, plaintiff was certain it did not occur in the United States. The incident proved uneventful to the patient, however, because the surgeon had completed the procedure when the mishap occurred, and the patient was relying on his own circulatory system.

According to plaintiff, because "the distal tip of the canula fell apart" it could have caused the patient who was

attached to the machine to "have disrupted . . . circulation," which could lead to "a catastrophic event for the patient." Plaintiff reported the incident to Beath and expressed his great concern "about the potential risk if another device falls apart." He also told Beath that he believed that the quality board needed to discuss this issue "as soon as possible because the health hazard [was] so severe."

Plaintiff testified that Beath disagreed with his suggestion for an immediate recall of DFK-24 pending the outcome of a quality board investigation. Plaintiff claims Beath believed that, before convening a quality board meeting, Ethicon "needed to get the device back and check it out for root cause[s]." Despite plaintiff's opinion, suggesting a different approach, Beath exercised her prerogative as head of the quality board, and took a different course of action.

Ethicon received two more DFK-24 related complaints in April 2006. Dr. James Hart, who was, at the time, the vice-president of medical affairs and reported directly to plaintiff, sent plaintiff a series of emails documenting his concern for the safety of DFK-24. The main concern centered on the cannula coming apart while the patient was still connected to external circulation. By email dated April 11, 2006, Dr. Hart informed plaintiff that he had "just received word of a third complaint

for the [DFK-24] arterial cannula." All of the incidents occurred in Italy and "involve[d] parts of the device becoming disconnected." After reviewing the limited information available at the time about the particular details of each incident, Dr. Hart concluded: "If these descriptions are all accurate[,] then the devices seem to have become apart at three different connection points?? None of these events resulted in patient injury."

In light of these reports, plaintiff claims that he repeatedly asked Beath to convene the quality board to review the results of the investigation, and if necessary recall the product. Beath testified that, in her view, quality board involvement was not warranted at the time. She grounded her position on the product's five-year safety history. Before convening the board, Beath wanted the investigators to review the surgeons' reports of the events, to determine whether the incidents had been caused by surgeon misuse as opposed to a product defect.

Beath remained undaunted in her position that a quality board review was premature until the device was returned, even after she was confronted at her deposition with evidence showing that Dr. Hart had interviewed the team of surgeons who had reported the problem and found them to be physicians with

experience using the device. When asked if she still believed that plaintiff's request for a quality board review was unreasonable, Beath answered: "I thought it was too early for one. But in [plaintiff]'s position he had the right to ask for it, so we scheduled a quality board."

The quality board convened on April 14, 2006. After a free and presumably lively exchange of views, plaintiff's opinion prevailed. Ethicon issued an order implementing a global hold on the use and sale of DFK-24. On April 18, 2006, recall teams were created to prepare drafts of notices to customers and to officially notify the FDA. In the meantime, Ethicon continued to investigate the root causes of the reported product failures. Beath informed McCoy, her superior and the company group chairperson, of the quality board's decision to recall the product.

Beath testified that she may have told McCoy that she believed the decision to recall at the time was conservative, but nevertheless reasonable, in light of the potential life threatening consequences for the patients. Beath denied, however, that McCoy asked her to delay implementing the recall until she had the opportunity to discuss it with Dormer, her superior at J&J. Beath explained there was no need for McCoy to have asked for a delay because, depending on the product, on

average, the recall process "can take anywhere from two days to two weeks."

As is the case with a number of material facts in this case, plaintiff strongly disputes Beath's account of events. Plaintiff claims that on April 19, 2006, Beath told him that despite the quality board's decision, she and McCoy both believed that a recall of the product was unnecessary. On April 21, 2006, plaintiff claims he left a voicemail for McCoy complaining that the recall of DFK-24 had not occurred as directed by the quality board. Plaintiff further claims that he had attempted to raise the recall issue with McCoy at a board meeting held April 24, 2006, but was rebuffed. He left another voicemail for McCoy the following day, April 25, 2006, once again objecting to Ethicon's failure to adhere to the quality board's decision to recall DFK-24.

On April 26, 2006, plaintiff claims McCoy called him and told him she had been trying to reach Dormer to inform him of the recall decision. Plaintiff received an email from McCoy later that same day confirming that Dormer had approved the recall. Plaintiff argues that this documents Ethicon's upper management's improper interference with the quality board's decisions. According to plaintiff, this type of interference by J&J's upper management is expressly prohibited by Ethicon's

policy because it nullifies the quality board's autonomy to make decisions and recommendations about a product's efficacy and safety guided only by the professional opinions of its members.

IV

CORPORATE REORGANIZATION

On January 20, 2006, Donnelly-Brienza, Ethicon's vice-president of human resources, informed the GMB that McCoy had reorganized the senior management structure. Part of this reorganization included the newly created position of vice-president of clinical operations and health economics and reimbursement. Plaintiff claims that this was done in retaliation for the position he advocated concerning the recall of PROCEED™ one month earlier. Defendants point out that under these organizational revisions, plaintiff continued to have responsibility and authority over decisions regarding the recall of a product. Furthermore, McCoy discussed with plaintiff her plans concerning this newly created position as early as September 2005, long before the recall of PROCEED™.

Relevant to the determination of whether the reorganization plan constituted an adverse employment action, defendants note that plaintiff continued to have voting rights in the quality board and other internal boards. He also received a $10,000 raise in salary on February 27, 2006, making his gross annual

salary $304,000. Thus, when compared with the $228,000 original annual salary when he started at Ethicon in June 2000, plaintiff's final salary of $304,000 translates into a 33.33% increase over his six-year tenure.

Plaintiff claims corporate business interests at J&J pressured McCoy to conduct a so-called "headcount" of senior management at Ethicon and identify "non-essential" areas. He argues that McCoy's alleged reorganization plan was merely a subterfuge to strip plaintiff's authority and responsibility in retaliation for his unyielding positions, as a physician and as an employee charged with monitoring product safety, to adhere to his professional ethics and to follow relevant FDA guidelines.

TERMINATION

Plaintiff was terminated from his employment at Ethicon on May 16, 2006. The reason for plaintiff's termination was emphatically and succinctly stated by McCoy as follows: "Dr. Lippman was terminated because he had a relationship, an inappropriate relationship, with someone who worked directly for him."

For purposes of this appeal, we will consider the following factual items all in the light most favorable to plaintiff: (1) the person allegedly involved in this consensual romantic relationship with plaintiff is a competent adult; (2) this

person was an employee in a department under plaintiff's authority during part of the time the alleged relationship existed; (3) she did not directly report to plaintiff at any time; (4) she did not, at any time, allege that the relationship was unwelcomed or non-consensual; (5) to this date, she has not filed any complaint against or alleged any impropriety by plaintiff, including but not limited to sexual harassment, intimidation, or ill-treatment of any kind; (6) the alleged relationship came to McCoy's attention when an employee, who was unsatisfied with the performance rating he believed plaintiff had given him, mentioned it to McCoy as a possible explanation or motive for plaintiff's alleged unfair assessment of his work performance; (7) the person allegedly romantically involved with plaintiff worked, at one point, directly for and reported to the person who believed that he had received an unfair performance rating from plaintiff; (8) McCoy does not know of any prior case in which an Ethicon or J&J employee was terminated (or even disciplined) for having a consensual romantic relationship with an alleged subordinate; and (9) J&J does not have a policy prohibiting the type of consensual romantic relationship that allegedly occurred between plaintiff and the female employee.

V

Against this record, we will now address the legal issues raised. Although we have made this point clear, we reaffirm that because the motion judge dismissed plaintiff's complaint as a matter of law, our review of his decision to grant defendants' motion for summary judgment is de novo. Brandt, supra, 214 N.J. at 91 (citing Coyne v. State, Dep't of Transp., 182 N.J. 481, 491 (2005)). Pursuant to Rule 4:46-2(c), summary judgment,

> shall be rendered forthwith if the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to a judgment or order as a matter of law. An issue of fact is genuine only if, considering the burden of persuasion at trial, the evidence submitted by the parties on the motion, together with all legitimate inferences therefrom favoring the non-moving party, would require submission of the issue to the trier of fact.
>
> [R. 4:46-2(c) (emphasis added).]

As part of our de novo review, we must decide whether "the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational factfinder to resolve the alleged disputed issue in favor of the non-moving party." Brill, supra, 142 N.J.

at 540. We are satisfied that the dispute before us cannot be resolved through summary judgment.

As a starting point, plaintiff argues that he was terminated from his position at Ethicon because he consistently advocated positions that favored the recall of products that, in his professional opinion, were dangerous to the public. He believed that he zealously discharged his responsibilities in his role as Ethicon's worldwide vice-president of medical affairs and chief medical officer in good faith, and mindful of legal and public policy considerations.

Plaintiff argues that his superiors and other key decision makers at Ethicon perceived the way he performed his duties and the positions he advocated as either needlessly conservative or naively insensitive to Ethicon's business and corporate interests. Thus, plaintiff argues, he was terminated from his job because he engaged in CEPA-protected activities, not because he allegedly violated a nonexistent policy that prohibited consensual adults employed by J&J, or one of its subsidiaries, from engaging in romantic relationships but because his penchant for recalling dangerously defective products was economically unfeasible.

Defendants, relying in large measure on our decision in Massarano, supra, 400 N.J. Super. 474, argue that plaintiff's

acts do not constitute whistle-blowing activities because they fall within the sphere of his job-related duties. Defendants maintain that plaintiff was given multiple opportunities to express his opinion, freely and openly, in a variety of deliberative forums, including board meetings, and one-to-one and small-group discussions with key decision makers. Defendants emphasize that the record shows plaintiff's views were almost always universally accepted. Paraphrasing the views expressed by our colleagues in Massarano, defendants argue that "plaintiff was merely doing [his] job . . . by reporting [his] findings and [his] opinion[s] to [Ethicon's quality board]." See id. at 491. Under this line of reasoning, a plaintiff who reports conduct as part of his or her job is not entitled to the whistle-blowing protections afforded under CEPA. See ibid.

We respectfully disagree that this outcome is consistent with CEPA's broad remedial purposes and, most importantly, correctly applies our Supreme Court's construction of the protections afforded under CEPA. We thus decline to endorse it. Indeed, the facts of this case illustrate the gaping holes this line of reasoning creates in the wall erected by the Legislature to protect whistleblowers from retaliation. "Watchdog" employees, like plaintiff, are the most vulnerable to retaliation because they are uniquely positioned to know where

the problem areas are and to speak out when corporate profits are put ahead of consumer safety.[11]

The Legislature defined an "employee" in CEPA as "any individual who performs services for and under the control and direction of an employer for wages or other remuneration." N.J.S.A. 34:19-2(b). Even a cursory reading of this statutory language reveals that this definition is not based on the employee's title or the "core functions" the employee performs for the employer. In deciding a motion to dismiss a case brought under CEPA, the court's analysis must be guided by the elements established by the Supreme Court in Dzwonar.[12]

> A plaintiff who brings a cause of action pursuant to N.J.S.A. 34:19-3(c) must demonstrate that: (1) he or she reasonably believed that his or her employer's conduct was violating either a law, rule, or regulation promulgated pursuant to law, or a clear mandate of public policy; (2) he or she performed a "whistle-blowing" activity described in N.J.S.A. 34:19-3(c); (3) an

[11] Plaintiff also argues that the motion judge was free to disregard the language in Massarano as mere dictum. We disagree. As our Supreme Court has recently made clear, lower courts should consider themselves bound by a higher court's dicta. State v. Dabas, ____ N.J. ____, _____ (2013) (slip op. at 29) (citing State v. Breitweiser, 373 N.J. Super. 271, 282-83 (App. Div. 2004), certif. denied, 182 N.J. 628 (2005)).

[12] Defendants do not argue that plaintiff falls under the exemption recognized by the Supreme Court in D'Annunzio v. Prudential Insurance Co. of America, 192 N.J. 110 (2007), Stomel v. City of Camden, 192 N.J. 137 (2007), and Feldman v. Hunterdon Radiological Associates, 187 N.J. 228 (2006).

> adverse employment action was taken against him or her; and (4) a causal connection exists between the whistle-blowing activity and the adverse employment action.
>
> [Dzwonar, supra, 177 N.J. at 462 (citations omitted).]

Under CEPA, an employee engages in a "whistle-blowing activity" if the employee:

> Objects to, or refuses to participate in any activity, policy or practice which the employee reasonably believes:
>
> (1) is in violation of a law, or a rule or regulation promulgated pursuant to law, including any violation involving deception of, or misrepresentation to, any shareholder, investor, client, patient, customer, employee, former employee, retiree or pensioner of the employer or any governmental entity, or, if the employee is a licensed or certified health care professional, constitutes improper quality of patient care;
>
> (2) is fraudulent or criminal, including any activity, policy or practice of deception or misrepresentation which the employee reasonably believes may defraud any shareholder, investor, client, patient, customer, employee, former employee, retiree or pensioner of the employer or any governmental entity; or
>
> (3) is incompatible with a clear mandate of public policy concerning the public health, safety or welfare or protection of the environment.
>
> [N.J.S.A. 34:19-3(c) (Emphasis added).]

Here, applying the four elements in Dzwonar, supra, 177 N.J. at 462, we are satisfied that there is sufficient evidence in the record for a rational jury to find that plaintiff engaged in whistle-blowing when he objected to his employer's tactic of delaying the recall of dangerous defective medical products and insisted that his employer take a patient-centered approach when deciding whether or not to recall a medical device. A jury can rationally find that plaintiff's superiors considered his opinions to be medically sound and in furtherance of public policy favoring a cautious, patient-centered approach, but yet needlessly conservative and against the company's pecuniary interest.

Based on this record, a jury can find that Beath, McCoy, and Dormer worked in concert to circumvent, undermine, "push back," and intentionally delay the decision of the quality board to recall DFK-24 because they were concerned that a recall would negatively affect CardioVations's bottom line. Plaintiff presented sufficient evidence to demonstrate that he objected to this course of action because he in good faith believed it was in violation of FDCA regulations, this State's products liability laws, otherwise "incompatible with the clear mandate of public policy against marketing defective products that

present a reasonably foreseeable risk of injury" to the public. N.J.S.A. 34:19-3(c)(3).

The record shows that Ethicon created the quality board to function as an autonomous, deliberative forum, where professionals could freely and openly discuss how best to address serious questions concerning the safety of pharmaceutical and medical products. If plaintiff's testimony is accepted as credible, a jury could find that McCoy and Dormer's concerns were not only callously indifferent to product safety considerations but also that their conduct breached the wall created by Ethicon to keep the business side of the company segregated and unable to influence the product safety side. Plaintiff could argue that McCoy and Dormer sought to undermine the vital roles these internal boards played, as a business strategy to maximize corporate profits by avoiding or delaying the high cost and commercial stigma involved in recalling a medical product.

Because plaintiff would not yield to the pressure or moderate his patient-centric approach, a jury could find that defendants retaliated against him by seizing upon a specious claim of impropriety to fire him. Viewed from plaintiff's perspective, the evidence shows that when McCoy learned that one of plaintiff's subordinates believed plaintiff had given him an

unfair performance evaluation because plaintiff had an alleged consensual relationship with another subordinate, McCoy seized upon this as an opportunity to rid herself and the company of this meddlesome, and in her view, uncooperative and fiscally irresponsible employee. These facts establish a prima facie case that defendants' actions violated the legislative protections afforded under CEPA to employees like plaintiff. This evidence squarely addresses all four of the elements identified in Dzwonar, supra, 177 N.J. 451.

Our Supreme Court has recognized that "at the time of its enactment" CEPA was "the most far reaching 'whistleblower statute' in the nation." Mehlman v. Mobil Oil Corp., 153 N.J. 163, 179 (1998). Those in the highest level of corporate governance at times might be inclined to decide on a monetary basis the cost of recalling a defective product outweighs the potential cost of compensating those who may be injured by it. These decision makers must also consider that CEPA will protect from retaliation those employees whose core function and duty is to monitor the employer's compliance with the relevant laws, regulations, or other expressions of a clear mandate of public policy.

When using the term "watchdog" employee, we are referring to the employee who, by virtue of his or her duties and

responsibilities, is in the best position to: (1) know the relevant standard of care; and (2) know when an employer's proposed plan or course of action would violate or materially deviate from that standard of care. In our view, it would be a sad irony indeed if such a "watchdog" employee, like plaintiff, would be deemed by a court to fall outside the wall of protection created by the Legislature to whistleblowers. If an individual's job is to protect the public from exposure to dangerous defective medical products, CEPA does not permit the employer to retaliate against that individual because of his or her performance of duties in good faith, and consistent with the job description.

In the interest of assisting both the trial courts and the attorneys who practice in this field, we will distill our holding in this case to the following Dzwonar-guided paradigm. To establish a prima facie cause of action under CEPA, employees who perform "watchdog" activities as their employment function must demonstrate the following. First, the employee must establish that he or she reasonably believed that the employer's conduct was violating either a law, government regulation, or a clear mandate of public policy. Second, the employee must establish that he or she refused to participate or objected to this unlawful conduct, and advocated compliance with the

relevant legal standards to the employer or to those designated by the employer with the authority and responsibility to comply. To be clear, this second element requires a plaintiff to show he or she either (a) pursued and exhausted all internal means of securing compliance; or (b) refused to participate in the objectionable conduct. Third, the employee must establish that he or she suffered an adverse employment action. And fourth, the employee must establish a causal connection between these activities and the adverse employment action. We are satisfied that this paradigm tracks and adheres to the four elements established by the Court in Dzwonar, supra, 177 N.J. at 462.

The evidence in this case has given us only a mere glimpse into the pharmaceutical and medical products industry. From this flash of light, we have seen that this important sector of our economy is both highly regulated and highly competitive. The profit window created by patents is also a ticking clock, reminding research and development departments that the search for the next breakthrough drug or medical device is never ending. This highly competitive industry creates enormous pressure on those entrusted to monitor, and when necessary enforce the process and procedures created to ensure that safety rules are followed. We are firmly convinced that these "watchdog" employees are entitled to the protections against

retaliation that the Legislature intended to apply to all employees. Here, a jury will determine whether defendants' actions violated the protections afforded by the Legislature under CEPA to employees like plaintiff. See N.J.S.A. 34:19-5.

Reversed and remanded. We do not retain jurisdiction.