SYLLABUS

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Mirian Rivera v. The Valley Hospital, Inc.
(A-25/26/27-21) (085992) (085993) (085994)

Argued March 15, 2022 -- Decided August 25, 2022

PIERRE-LOUIS, J., writing for a unanimous Court.

In this matter, the Court considers whether plaintiffs' punitive damages claim -- which requires a showing by clear and convincing evidence that the defendant medical providers' acts or omissions reflected actual malice or wanton and willful disregard for their patient -- should have been dismissed.

Plaintiffs, the heirs and executor of the estate of Viviana Ruscitto, filed complaints seeking compensatory and punitive damages on numerous counts after Ruscitto's death from leiomyosarcoma, a rare cancer that cannot be reliably diagnosed preoperatively, following the hysterectomy she underwent at defendant Valley Hospital with the use of a power morcellation device. Ruscitto sought treatment for uterine fibroids from defendant Howard Jones, a gynecologic surgeon at the hospital with whom Ruscitto met four times before she underwent surgery.

At their second meeting, Dr. Jones informed Ruscitto that the endometrial biopsy conducted at their first appointment revealed noncancerous tissue, and he discussed all treatment options. At their third appointment, Ruscitto decided to proceed with surgical management of her fibroids. Dr. Jones advised Ruscitto that one particular surgical option for removal of the fibroids would result in a significantly longer recovery time and greater postoperative pain, and that the better option was laparoscopic hysterectomy. The laparoscopic hysterectomy would be performed with the use of a power morcellator -- a device used to cut tissue into smaller pieces to facilitate removal. In an update letter to Ruscitto's endocrinologist, Dr. Jones noted he "counsel[ed] her about the risk of morcellation including morcellation of a malignancy."

At their fourth appointment, Ruscitto signed a consent form agreeing to a laparoscopic hysterectomy. The form described the procedure in simple terms and did not mention the use of a power morcellation device. Ruscitto later testified at her deposition that Dr. Jones never mentioned the use of a power morcellator but she conceded that Dr. Jones told her that he would "chop up" her uterus. After the procedure, tissue from Ruscitto's uterus revealed Stage 4 leiomyosarcoma. Ruscitto began cancer treatment and passed away less than one year later.

Approximately six months before Ruscitto's surgery, the FDA issued a Safety Communication discouraging the use of power morcellation. The communication "estimated that 1 in 350 women undergoing [surgery] for the treatment of fibroids is found to have an unsuspected uterine sarcoma, a type of uterine cancer that includes leiomyosarcoma." It stated that, "[i]f laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma, there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient's likelihood of long-term survival." The FDA also provided specific recommendations for health care providers, including informing patients.

Valley Hospital administrators and Dr. Jones exchanged emails about the continued use of power morcellation. They considered factors including that "without the morcellator these cases would be open instead of laparoscopic, which "increases morbidity"; the fact that "the numbers at Valley" did not support the "1 sarcoma in 350 operations" number suggested by the FDA; and the role of informed consent. A "power morcellation group" was convened to draft an informed consent form. A form was prepared and approved by the legal department but was never implemented or used prior to Ruscitto's surgery.

One month after her surgery, the FDA issued an updated communication explicitly warning against the use of power morcellators in the majority of cases. Valley Hospital then discontinued use of the power morcellation device.

Plaintiffs brought claims against several defendants, including Dr. Jones and the Valley Hospital administrators, and defendants sought partial summary judgment dismissing the punitive damages claim. The trial court denied the motions, and the Appellate Division denied leave to appeal. The Court granted leave to appeal. 248 N.J. 552 (2021); 248 N.J. 557 (2021).

HELD: As a matter of law, the evidence presented, even affording plaintiffs all favorable inferences, does not establish that defendants' acts or omissions were motivated by actual malice or accompanied by wanton and willful disregard for Ruscitto's health and safety. A reasonable jury could not find by clear and convincing evidence that punitive damages are warranted based on the facts of this case, and partial summary judgment should have been granted.

1. The Punitive Damages Act (PDA) provides that "[p]unitive damages may be awarded . . . only if plaintiff proves, by clear and convincing evidence," both "that the harm suffered was the result of defendant's acts or omissions," and that defendant's acts or omissions were either "actuated by actual malice" or were "accompanied by wanton and willful disregard of persons who foreseeably might be harmed." N.J.S.A. 2A:15-5.15(a). The PDA explicitly states that "[t]his burden of proof may not be satisfied by proof of any degree of negligence including gross

negligence." Ibid. "Actual malice" is defined as "intentional wrongdoing in the sense of an evil-minded act." N.J.S.A. 2A:15-5.10. "Wanton and willful disregard" is defined as "a deliberate act or omission with knowledge of a high degree of probability of harm to another and reckless indifference to the consequences of such act or omission." Ibid. The PDA codified the common law principle that punitive damages were limited to only exceptional cases; its purpose was to establish more restrictive standards in awarding punitive damages. (pp. 21-24)

2. The Court explains why plaintiffs' claims do not meet the standard for punitive damages. First, the FDA Communication was purely advisory in nature, so the use of the power morcellator after that communication does not constitute per se evidence of wanton and willful disregard for Ruscitto's safety. With regard to Dr. Jones, nothing in the facts before the Court suggests that he acted with actual malice or with wanton and willful disregard of Ruscitto's health as those terms are defined in N.J.S.A. 2A:15-5.10. Dr. Jones noted the complications that can occur with open surgeries as opposed to non-invasive laparoscopic procedures. The FDA Communication noted that there was less than a one percent risk that a woman would have unsuspected uterine sarcoma, and leiomyosarcoma unfortunately cannot be reliably diagnosed preoperatively. Dr. Jones performed the morcellation on Ruscitto after meeting with her four times and conducting tests. As several defendants have conceded, the facts of this case thus far present genuine issues regarding whether defendants were negligent and deviated from accepted standards of care. But plaintiffs cannot recover damages here by recasting their negligence claims as wanton and willful actions based on the same alleged conduct. (pp. 24-28)

3. Plaintiffs' punitive damages claim against the Valley Hospital defendants is even less compelling than the claim against Dr. Jones. The numerous emails among administrators and physicians illustrate that the Valley Hospital defendants took proactive steps, shortly after the issuance of the FDA Communication, to respond to the advised risks of power morcellation. Although the draft consent form was never fully adopted and implemented, plaintiffs' arguments regarding the lack of informed consent for the power morcellation procedure after the FDA Communication sound in ordinary negligence, not in actions taken with an "evil mind." Partial summary judgment should have been granted. The evidence proffered by the plaintiffs may establish defendants' negligence, but it does not constitute conduct that can be characterized as wanton and willful. Punitive damages are available only in exceptional cases, and this matter does not qualify as such. (pp. 28-31)

REVERSED and REMANDED to the trial court.

CHIEF JUSTICE RABNER; JUSTICES PATTERSON and SOLOMON; and JUDGE FUENTES (temporarily assigned) join in JUSTICE PIERRE-LOUIS's opinion.

SUPREME COURT OF NEW JERSEY

A-25/26/27 September Term 2021

085992/085993/085994

Mirian Rivera, as Executrix of the Estate of Viviana Ruscitto, et al.,

Plaintiffs-Respondents,

v.

The Valley Hospital, Inc., et al.,

Defendants-Appellants.

On appeal from the Superior Court, Appellate Division.

Argued	Decided
March 15, 2022	August 25, 2022

Rowena M. Durán argued the cause for appellants Howard H. Jones, M.D. and Valley Physician Services, Inc., d/b/a Valley Medical Group P.A. (Vasios, Kelly & Strollo, attorneys; Rowena M. Durán, of counsel and on the briefs).

William G. Theroux argued the cause for appellant Linda Malkin (Buckley Theroux Kline & Cooley, attorneys; William G. Theroux and Sean C. Garrett, on the briefs).

Evelyn Cadorin Farkas argued the cause for appellants The Valley Hospital, Inc., Valley Health System, and Audrey Meyers (Farkas & Donohue, attorneys; Evelyn Cadorin Farkas, of counsel and on the briefs, and Eileen M. Kavanagh, on the briefs).

Michael Gunzburg, a member of the New York bar, admitted pro hac vice, argued the cause for respondent Mirian Rivera, as Executrix of the Estate of Viviana Ruscitto (Michael Gunzberg and Ruta, Soulios & Stratis, attorneys; Michael Gunzberg, and Demetrios K. Stratis, of counsel and on the briefs).

Rayna E. Kessler argued the cause for respondent Nicholas Roche, Individually and as the Guardian of Maximo Valentino Ruscitto-Roche (Robins Kaplan, attorneys; Rayna E. Kessler, and Ian S. Millican, of counsel and on the briefs).

John Zen Jackson argued the cause for amici curiae Medical Society of New Jersey and American Medical Association Litigation Center (Greenbaum, Rowe, Smith & Davis, attorneys; John Zen Jackson, on the brief).

James DiGiulio argued the cause for amicus curiae New Jersey Hospital Association (O'Toole Scrivo, attorneys; James DiGiulio and Andrew Gimigliano, of counsel and on the brief, and Alex Daniel and Julia E. Duffy, on the brief).

Theodora McCormick argued the cause for amicus curiae New Jersey Doctor-Patient Alliance (Epstein Becker & Green, attorneys; Anthony Argiropoulos, William Gibson, and Maximilian Cadmus, of counsel and on the brief).

Bruce H. Nagel argued the cause for amicus curiae New Jersey Association for Justice (Nagel Rice, attorneys; Bruce H. Nagel, of counsel and on the brief, and Randee M. Matloff, on the brief).

JUSTICE PIERRE-LOUIS delivered the opinion of the Court.

In this medical malpractice and products liability matter, the Court must determine whether defendants' summary judgment motions seeking dismissal of the punitive damages claim were properly denied.

Viviana Ruscitto passed away from leiomyosarcoma, a rare cancer. Ruscitto's cancer was discovered after she underwent a laparoscopic hysterectomy at The Valley Hospital with the use of a power morcellation device -- a device used to cut uterine and fibroid tissue into smaller pieces to facilitate removal. Roughly six months before the surgery, the U.S. Food and Drug Administration (FDA) issued a Safety Communication warning to health care providers about the dangers of using power morcellation for hysterectomies because its usage could spread or "upstage" unsuspected uterine cancer. In response to the FDA Communication, Valley Hospital administrators and physicians collaborated in the drafting of an informed consent form to reflect the concerns expressed in the FDA Communication. The form was drafted and approved by the legal department in the months following the FDA Communication but was never implemented.

Plaintiffs, the heirs and executor of Ruscitto's estate, filed complaints seeking compensatory and punitive damages on numerous counts. Defendants filed motions for partial summary judgment to dismiss the punitive damages claim. The trial court issued an order denying all defendants' motions for

partial summary judgment. Defendants sought leave to appeal, which the Appellate Division denied.

We find that under the facts of this case, partial summary judgment should have been granted in defendants' favor because there is no genuine issue of material fact as to whether defendants' acts or omissions reflected actual malice or wanton and willful disregard for Ruscitto's health such that punitive damages would be appropriate in this case. Based on the facts before the trial court on the summary judgment record, plaintiffs' allegations have not established by clear and convincing evidence that punitive damages may be warranted in this case. Accordingly, we reverse the trial court's denial of the defendants' motions for partial summary judgment on the punitive damages claim.

I.

A.

We recount the following factual statements from the summary judgment record but do not make any factual findings.

In December 2012, Viviana Ruscitto was diagnosed with uterine fibroids. Following the birth of her son in July 2013, Ruscitto's fibroids became symptomatic and she subsequently experienced heavy bleeding and anemia, prompting her to take time off from work. Ruscitto's endocrinologist,

Dr. Ali Nasseri, referred her to defendant Dr. Howard Jones, a gynecologic surgeon at Valley Hospital.

Ruscitto and Dr. Jones met for a total of four appointments before she underwent her surgical procedure. Dr. Jones sent letters to Dr. Nasseri after appointments with Ruscitto to update him on Ruscitto's condition and potential treatment.

The first appointment was on June 30, 2014, during which Dr. Jones reviewed her medical history, performed a physical examination and endometrial biopsy, and ordered a pelvic MRI to determine whether Ruscitto's fibroids were benign or raised any suspicion of cancer.

On July 14, 2014, at their second appointment, Dr. Jones reviewed with Ruscitto her endometrial biopsy and MRI. The MRI revealed an 8-centimeter degenerating or deteriorating fibroid, and the endometrial biopsy revealed benign or noncancerous tissue. Dr. Jones discussed with Ruscitto all treatment options, including hysterectomy, removal of the uterus; myomectomy, a surgical procedure to remove fibroids; and uterine fibroid embolization, a minimally invasive procedure that causes the fibroids to shrink. According to Dr. Jones, a hysterectomy and uterine fibroid embolization were not realistic options at the time because Ruscitto was considering having more children and such procedures were incompatible with future pregnancy. Dr. Jones's letter

to Dr. Nasseri noted that he discussed with Ruscitto the difficulty of a laparoscopic myomectomy for degenerating fibroids and the correlation between degenerating fibroids and potential leiomyosarcoma.[1]

The third appointment occurred on September 8, 2014. At that time, Ruscitto decided to proceed with surgical management of her fibroids, but she did not decide on the specific procedure. According to Dr. Jones, she was considering either myomectomy or robotic-assisted laparoscopic hysterectomy. Dr. Jones advised Ruscitto that myomectomy would result in a significantly longer recovery time and greater postoperative pain, particularly because it took Ruscitto over a month to recover from her C-section. Dr. Jones acknowledged, however, that this procedure would preserve her uterus. Alternatively, Dr. Jones advised Ruscitto that the better option was robotic-assisted laparoscopic hysterectomy. In his post-appointment letter to Dr. Nasseri, Dr. Jones noted that he "counsel[ed] her about the risk of morcellation including morcellation of a malignancy."

The fourth and final appointment occurred on September 17, 2014. The purpose of this appointment was to further discuss surgical options and to

[1] Uterine leiomyosarcoma is a rare cancer that is difficult to diagnose because "uterine sarcomas are [clinically] difficult to distinguish from [noncancerous] uterine fibroids" preoperatively. Innie Chen et al., Clinical Characteristics Differentiating Uterine Sarcoma and Fibroids, 22 J. Soc'y Laparoscopic & Robotic Surgeons 1,1 (2018).

obtain Ruscitto's consent on a specific procedure. That day, Ruscitto signed a consent form agreeing to a "DaVinci Assisted Laparoscopic supracervical hysterectomy possible total hysterotomy possible laparotomy and bilateral salpingectomy." The form described the procedure in simple terms as the "[l]aproscopic removal of uterus possible removal of cervix possible open incision and both tubes." The consent form did not mention the use of a power morcellation device. Ruscitto later testified at her deposition that Dr. Jones never mentioned the use of a power morcellator to her, but she conceded that Dr. Jones told her that he would "chop up" her uterus.

Ruscitto's surgery was scheduled for October 17, 2014. On that date, Dr. Jones performed a hysterectomy on Ruscitto using a power morcellation device. According to the preoperative report generated by Valley Hospital, Ruscitto was "interviewed in the preoperative area, where consent was confirmed." There were no complications with the surgery.

After the procedure, a pathology report detailing Ruscitto's post-surgery diagnosis was generated. The report revealed that the tissue from Ruscitto's uterus revealed "high grade" leiomyosarcoma with an estimated tumor size of 8 centimeters. Another report further stated, "This is unfortunately leiomyosarcoma . . . . It has all the features required for the diagnosis of a leiomyosarcoma."

Ruscitto subsequently began cancer treatment to treat her Stage 4 leiomyosarcoma. Ruscitto ultimately passed away on September 3, 2015.

B.

On April 17, 2014, approximately six months before Ruscitto's surgery, the FDA issued a Safety Communication titled "Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy" (FDA Communication). The purpose of the communication was to warn health care providers and the general public of the risks involved with using power morcellation to treat uterine fibroids. In the communication, the FDA discouraged the use of power morcellation:

> When used for hysterectomy or myomectomy in women with uterine fibroids, laparoscopic power morcellation poses a risk of spreading unsuspected cancerous tissue, notably uterine sarcomas, beyond the uterus. Health care providers and patients should carefully consider available alternative treatment options for symptomatic uterine fibroids. Based on currently available information, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids.
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> . . . .
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> Importantly, based on an FDA analysis of currently available data, it is estimated that 1 in 350 women undergoing hysterectomy or myomectomy for the treatment of fibroids is found to have an unsuspected uterine sarcoma, a type of uterine cancer that includes leiomyosarcoma. <u>If laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma,</u>

> there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient's likelihood of long-term survival. For this reason, and because there is no reliable method for predicting whether a woman with fibroids may have a uterine sarcoma, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids.

The FDA also provided specific recommendations for health care providers, including informing patients that "their fibroid(s) may contain unexpected cancerous tissue and that the laparoscopic power morcellation may spread the cancer."

C.

One day after the issuance of the FDA Communication, on April 18, 2014, a Valley Hospital administrator emailed both Dr. Noah Goldman, Co-Director of the Division of Oncology at the hospital, and Dr. Jones and asked "[d]id you see the article below on 'power morcellations.' Does it affect what we do here?" Dr. Goldman responded that,

> [w]hen you look at the numbers it is less than a percent chance of having something bad happen. Unfortunately, what people don't understand is that without the morcellator these cases would be open instead of laparoscopic. This increases morbidity (i.e. SSI) and hospital costs as people stay longer and have increased complications. This is a reaction to a single case, which unfortunately was a physician's wife.

> Our policy is to discuss this with patients and if they do not want to take the risk, they can have their procedure via laparotomy.

Dr. Jones later responded that "[t]he article below suggests the FDA thinks that the number could be 1 sarcoma in 350 operations, which seems incredibly high, especially not in line with the numbers at Valley. [Dr. Goldman's] absolutely right, think of the alternative to minimally invasive treatment."

Several days later, on April 20, 2014, defendant Audrey Meyers, Chief Executive Officer and President of Valley Hospital, emailed Dr. Goldman, writing, "See headline story. What are we doing? Thanks." Dr. Goldman responded with information similar to his previous email response and added that he and defendant Linda Malkin, the hospital's Director of Risk Management, were discussing proactive measures in response to the FDA Communication:

> In an effort to be proactive about this, I have contacted Linda Malkin with regards to what we should be telling our patients. I'd like to create some criteria for the use of the morcellator, as well as talking points for providers to discuss and document with the patients. We are going to meet in the next couple weeks to flesh this out, and then present to the OR and the OB/GYN department for approval.
>
> I think this will allow us to continue to use the morcellator safely and provide minimally invasive procedures to our patients. In the end, it will be the patient's decision so long as they are properly informed

> about the potential, albeit small, risk. I am happy to discuss this with you further at your convenience.

Sometime in April 2014, a "power morcellation group," was convened to draft an informed consent form to reflect the concerns expressed in the FDA Communication. An email sent by Malkin on April 21, 2014 revealed that the group was formed, or was in the process of being formed, within three days of the FDA Communication.

The group was comprised of Malkin, Dr. Goldman, Dr. Ruth Schulze (chair of the Obstetrics/Gynecology Department), Jackie Stahlmann (Quality Assessment Coordinator), and Donna Lagasi, RN (Director of Operating Room Services).

On May 19, 2014, Malkin emailed Dr. Goldman and attached a notice from Ethicon, a medical device company and subsidiary of Johnson & Johnson. In the email, Malkin advised Dr. Goldman that Ethicon had "decided to suspend global commercialization of its Morcellation Devices until the role of morcellation of patients with symptomatic fibroid diseases is further redefined by FDA and the medical community." Dr. Goldman responded, "Just an FYI. W[e] use the Storz morcellator so this should not be an issue." Malkin replied, "I just wanted you to see what we are up against!" to which Dr. Goldman responded, "Believe me. I know. The other reps are freaking out."

On May 21, 2014, Meyers emailed Malkin inquiring about the "outcome on your discussions." Malkin responded by informing her that

> [Dr. Goldman] and I met with Jackie Stahlmann and Donna Lagasi to review the FDA recommendations for using the morcellator and then developed the attached talking points that follow the FDA outline but [Dr. Goldman] added even additional safeguards. Ruth Schulze agrees with our approach but we will need everyone to approve the guidelines.
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> This is a good device if used within the strict guidelines and used by a skilled surgeon. Under those circumstances, and given the patients extensive informed consent, I am comfortable with using this device. I welcome your thoughts and input.

By July 1, 2014, the Valley Hospital legal department approved the new consent form titled "Laparoscopic Uterine Power Morcellation Patient Information and Discussion Guide." The form stated the following in the first two paragraphs:

> In accordance with the April 2014 FDA Safety Communication regarding the use of laparoscopic power morcellators, the Valley Hospital will provide patients with complete information regarding the risks, benefits and alternatives to this surgical procedure.
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> . . . .
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> The use of laparoscopic power morcellator will not be scheduled without this documentation.

As of August 2014, the consent form was not yet finalized because Dr. Schulze had concerns about some of its wording. In an August 28, 2014 email,

Dr. Goldman stated that he believed the form should be approved as is. The consent form, while approved by the legal department, was never implemented or used prior to or after Ruscitto's surgery in October 2014.

D.

On November 24, 2014, the FDA issued an updated Safety Communication. While the April FDA Communication noted that the FDA discouraged the used of power morcellators, the updated communication explicitly warned against the use of power morcellators "in the majority of women undergoing myomectomy or hysterectomy for the treatment of fibroids." The FDA further recommended a "black-box warning"[2] which included the following language:

> The FDA warns that uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.

[2] FDA black box warnings "are the highest safety-related warning that medications or medical devices can have assigned by the [FDA]." Claire Delong & Charles V. Preuss, Black Box Warning, Nat'l Libr. of Med., https://www.ncbi.nlm.nih.gov/books/NBK538521/?report=reader. "These warnings are intended to bring the consumer's attention to the major risks" of a drug or medical device. Ibid.

Subsequent to the FDA's issuance of the updated communication, on December 24, 2014, Valley Hospital discontinued the use of the power morcellation device.

II.

In 2017, plaintiffs Mirian Rivera (Ruscitto's sister) as executrix of Ruscitto's estate and Nicholas Roche (Ruscitto's husband) filed separate yet related complaints[3] against several defendants, including the parties to this appeal: Dr. Jones and Valley Physician Services, Inc. (collectively, Dr. Jones); and Meyers, Malkin, and Valley Hospital (collectively, the Valley Hospital defendants).[4] Plaintiffs sought compensatory and punitive damages for several counts, including medical malpractice, lack of informed consent, and products liability.

In January 2021, defendants filed separate motions for partial summary judgment to dismiss the punitive damages claim. In April 2021, the trial court issued an order denying all defendants' motions for partial summary judgment. In its statement of reasons, the court found that there was an issue of material fact as to whether defendants' actions or inactions were accompanied by

[3] This matter was filed as two separate actions that were later consolidated.

[4] Additional defendants to the action included Dr. Goldman, Karl-Storz Endoscopy America, and other parties not involved in this appeal.

wanton and willful disregard for Ruscitto's safety, which was best suited for a jury to decide. The court reasoned that defendants' evidence was "not so one-sided that it must prevail as a matter of law," and in affording plaintiffs all favorable inferences, a reasonable jury could return a verdict for plaintiffs on the punitive damages claim.

In May 2021, defendants filed notices of motions for leave to appeal to the Appellate Division. The Appellate Division issued a one-page order denying leave to appeal.

We granted defendants' motions for leave to appeal. 248 N.J. 552 (2021) (granting Dr. Jones's motion); 248 N.J. 557 (2021) (two orders granting leave to appeal to the Valley Hospital defendants). We also granted the applications of the New Jersey Association for Justice, the New Jersey Doctor-Patient Alliance, the New Jersey Hospital Association, the New Jersey Defense Association, and the Medical Society of New Jersey and the American Medical Association Litigation Center to participate as amici curiae.

III.

A.

Defendants collectively argue that the trial court's denial of summary judgment on the punitive damages claim must be reversed. Dr. Jones reasons that plaintiffs cannot sustain the burden of proving by clear and convincing

evidence that he acted with actual malice or wanton and willful disregard for Ruscitto which led to her passing. Dr. Jones argues that the totality of the evidence, viewed in a light most favorable to plaintiffs, falls short of such a standard. Dr. Jones asserts that at worst, a jury might conclude that his actions constituted negligence, but a factfinder would not conclude that he acted with actual malice towards his patient.

Similar to Dr. Jones, Malkin argues that there is no evidence suggesting she exhibited actual malice toward Ruscitto and the trial court erred in failing to apply the clear and convincing standard required for establishing a punitive damages claim. Malkin also challenges the trial court's reliance on plaintiffs' expert report, which suggested that Malkin should have implemented a moratorium to prevent the power morcellator from being used and should have mandated the timely creation of an informed consent form even though the FDA Communication did not require such action. Malkin argues that, despite her limited authority, she provided immediate notice to the hospital administrators when she received the FDA Communication and engaged in meaningful discussion with the power morcellation group.

Meyers and Valley Hospital argue that their actions cannot be considered willful if the FDA did not recall or remove power morcellators from the marketplace. As does Dr. Jones, Meyers and Valley Hospital argue

that plaintiffs' evidence poses a general negligence inquiry rather than one involving punitive damages. Meyers and Valley Hospital also suggest that if the punitive damages claim is not dismissed, the healthcare industry will suffer irreparable harm because hospitals and hospital administrators would prioritize minimizing legal exposure rather than focusing on the expansion of medical innovation and optimization of patient care.

Several amici support defendants' positions and emphasize the harm the medical profession would suffer if punitive damages claims such as this are allowed to proceed to trial. The New Jersey Doctor-Patient Alliance argues that this Court should reverse the trial court because the Punitive Damages Act intentionally limits punitive damages to a small number of cases for the most egregious of circumstances and allowing such damages in routine medical malpractice actions will have dire impacts on physicians and patient care in New Jersey. The New Jersey Hospital Association, the New Jersey Defense Association, the Medical Society of New Jersey, and the American Medical Association Litigation Center all argue that plaintiffs failed to put forth sufficient evidence upon which a jury could find that defendants acted with actual malice or wanton and willful disregard for Ruscitto's safety.

B.

Plaintiffs argue that the trial court correctly denied defendants' motion for summary judgment on the punitive damages issue. As to Dr. Jones, plaintiffs assert that he acted in wanton and willful disregard of Ruscitto's safety. Plaintiffs contend that Dr. Jones was aware that two of three differential diagnoses were cancer and thereby should have reasonably suspected that Ruscitto had cancer. Plaintiffs allege that Dr. Jones never explained power morcellation or the risks associated with the procedure to Ruscitto and never presented her with lower-risk alternative methods as viable options. Plaintiffs argue that the lack of informed consent supports Dr. Jones's reckless disregard for Ruscitto's safety.

Plaintiffs similarly argue that Malkin acted with reckless disregard for Ruscitto's health and safety. Plaintiffs assert that Malkin failed in her capacity as the Director of Risk Management because she was responsible for expediting the implementation of appropriate policies like the informed consent form. According to plaintiffs, Malkin abdicated her duties by enabling Ruscitto's death even after a previous patient suffered the same fate. Plaintiffs claim that Malkin simply rubber-stamped the hospital administration's endorsement of the morcellation procedure without seeking reasonable restrictions of its use in the form of a moratorium.

Plaintiffs assert that Meyers, as the President of The Valley Hospital, should have immediately implemented a temporary moratorium, which would have prevented the power morcellation device from being used until the timely development and implementation of a hospital policy regarding its use and an informed consent form. Plaintiffs also emphasize that Meyers had a nondelegable duty to ensure the safety of all the hospital's patients and abdicated her responsibility by claiming that she delegated certain tasks and responsibilities to the proper entities.

Plaintiffs argue that after the FDA Safety Communications, the Valley Hospital defendants permitted surgeons to continue using the power morcellation device with no restrictions, limitations, and guidance, and without the patient's informed consent. Based on defendants' reckless actions, omissions, and failures to protect patient safety, plaintiffs argue that punitive damages are warranted.

Amicus curiae the New Jersey Association for Justice supports plaintiffs' position. Amicus contends that the trial court correctly denied summary judgment on the punitive damages claims, reasoning that there is sufficient evidence to defeat summary judgment and that a jury should determine if punitive damages are warranted.

IV.

We review the grant or denial of a motion for summary judgment de novo. Town of Kearny v. Brandt, 214 N.J. 76, 91 (2013). Rule 4:46-2(c) provides that summary judgment should be granted when "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." Significantly, "[a]n 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." Ibid.

"[W]hen the evidence 'is so one-sided that one party must prevail as a matter of law,' the trial court "should not hesitate to grant summary judgment." Brill v. Guardian Life Ins. Co. of Am., 142 N.J. 520, 540 (1995) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986)). "[A] court should deny a summary judgment motion only where the party opposing the motion has come forward with evidence that creates a 'genuine issue as to any material fact challenged.'" Id. at 529 (quoting R. 4:46-2(c)). A non-moving party cannot defeat such a motion by simply pointing to any fact in

dispute -- such disputed issues of fact must be substantial in nature. Ibid. In determining the existence of a genuine issue of material fact, the motion judge must evaluate whether the presented evidentiary materials, when viewed most favorably to the non-moving party, are sufficient to permit the jury to resolve the alleged contested issue in favor of the non-moving party. Id. at 540.

V.

In 1995, the Legislature enacted the Punitive Damages Act (PDA), N.J.S.A. 2A:15-5.9 to -5.17. N.J.S.A. 2A:15-5.12(a) provides that

> [p]unitive damages may be awarded to the plaintiff only if the plaintiff proves, by clear and convincing evidence, that the harm suffered was the result of the defendant's acts or omissions, and such acts or omissions were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions. This burden of proof may not be satisfied by proof of any degree of negligence including gross negligence.
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> [(emphases added.)]

N.J.S.A. 2A:15-5.10 defines the critical terms encompassed in N.J.S.A. 2A:15-5.12. "Clear and convincing evidence" is defined as the "standard of evidence which leaves no serious or substantial doubt about the correctness of the conclusions drawn from the evidence. It is a standard which requires more than a preponderance of evidence, but less than beyond a reasonable doubt, to

draw a conclusion." N.J.S.A. 2A:15-5.10. "Actual malice" is defined as "intentional wrongdoing in the sense of an evil-minded act." Ibid. "Wanton and willful disregard" is defined as "a deliberate act or omission with knowledge of a high degree of probability of harm to another and reckless indifference to the consequences of such act or omission." Ibid.

The Legislature also enumerated the following four factors that "the trier of fact shall consider" in determining whether punitive damages are to be awarded:

> (1) The likelihood, at the relevant time, that serious harm would arise from the defendant's conduct;
>
> (2) The defendant's awareness of reckless disregard of the likelihood that the serious harm at issue would arise from the defendant's conduct;
>
> (3) The conduct of the defendant upon learning that its initial conduct would likely cause harm; and
>
> (4) The duration of the conduct or any concealment of it by the defendant.
>
> [N.J.S.A 2A:15-5.12(b).]

The PDA codified common law principles underlying punitive damages, under which punitive damages were limited "to only 'exceptional cases . . . as a punishment of the defendant and as a deterrent to others from following his example.'" Pavlova v. Mint Mgmt. Corp., 375 N.J. Super. 397, 404 (App. Div. 2005) (omission in original) (quoting Di Giovanni v. Pessel, 55 N.J. 188, 190

(1970)). N.J.S.A. 2A:15-5.12(a) expressly provides that "the burden of proof [in awarding punitive damages] may not be satisfied by proof of any degree of negligence including gross negligence." Our case law also instructs that "mere negligence, however gross, is not enough" to warrant the awarding of punitive damages. Pavlova, 375 N.J. Super. at 405. Accordingly, to sustain a punitive damages claim, "[a] plaintiff must demonstrate a 'deliberate act or omission with knowledge of a high degree of probability of harm and reckless indifference to consequences.'" Ibid. (quoting Berg v. Reaction Motors Div., 37 N.J. 396, 414 (1962)).

The PDA's legislative purpose was to establish and enforce more restrictive standards in the awarding of punitive damages. Id. at 403 (citing N.J.S.A. 2A:5-5.9; A. Ins. Comm. Statement to S. 1496 (L. 1995, c. 142)). The PDA's legislative history reveals that the "bill was intended to limit the use and amount of punitive damages which may be awarded in a lawsuit." Sponsor's Statement to S. 1496 4 (L. 1995, c. 142). The PDA thus marked a departure from the liberal imposition of punitive damages in favor of a more limited approach designed to more closely reflect the original purpose of such damages:

> The awarding of punitive damages was originally intended to punish defendants for malicious or wanton actions and to deter others from engaging in similar activities. However, many persons believe that in

> recent years these damages have been awarded indiscriminately for actions that are merely careless. This has increased the number of punitive damage claims and contributed to the high cost of litigation.
>
> This bill, the "Punitive Damages Act," establishes reasonable and fair standards with regard to the awarding of punitive damages in civil cases.
>
> [Ibid.]

VI.

Guided by those principles, we hold as a matter of law that the evidence presented, even affording plaintiffs all favorable inferences, does not establish that defendants' acts or omissions were motivated by actual malice or accompanied by wanton and willful disregard for Ruscitto's health and safety. A reasonable jury could not find by clear and convincing evidence that punitive damages are warranted based on these facts.

As an initial matter, we acknowledge that the FDA Communication warned health care professionals of the risks associated with the use of power morcellation to treat uterine fibroids that might contain unsuspected cancer. At the time, the FDA "estimated that 1 in 350 women undergoing hysterectomy or myomectomy for the treatment of fibroids is found to have an unsuspected uterine sarcoma, a type of uterine cancer that includes leiomyosarcoma." Simply stated, the FDA Communication advised that there

was roughly a 0.28 percent chance that women undergoing either a hysterectomy or myomectomy would have undiagnosed cancer. The FDA Communication did not call for a recall of power morcellation devices from the marketplace or prohibit the performance of procedures with the device by hospitals and medical professionals. As plaintiffs' counsel acknowledged at oral argument, the FDA has never recalled power morcellators or prohibited procedures with the use of the device.[5] Given the purely advisory nature of the FDA Communication, any argument that seeks to treat the use of the power morcellator after that communication as per se evidence of wanton and willful disregard for Ruscitto's safety falls short of meeting the clear and convincing standard required by the PDA.

With regard to Dr. Jones, the summary judgment record revealed, through Dr. Jones's deposition testimony and contemporaneous letters to Dr. Nasseri, an accounting of four appointments Dr. Jones had with Ruscitto in the months leading up to the surgery. In those letters, Dr. Jones recounted, among other things, his assessment of Ruscitto's condition and the discussions he had

[5] As previously noted, Ethicon voluntarily ceased commercial sale of its power morcellators subsequent to the FDA Communication and then voluntarily recalled the devices after the FDA's updated communication in November 2014. Ethicon was not the only manufacturer of power morcellators, and the device used in this matter was manufactured by a different company.

with her about the different treatment options. At the first appointment, Dr. Jones ordered testing, an MRI and a biopsy, to try to determine whether Ruscitto's fibroids raised any suspicion of cancer. During the next appointment, Dr. Jones reviewed the results with Ruscitto, explained that the biopsy revealed noncancerous tissue, and discussed treatment options with her. In his letter to Dr. Nasseri regarding the third appointment, Dr. Jones noted that he "counsel[ed] [Ruscitto] about the risk of morcellation, including morcellation of a malignancy," i.e., cancerous tissue. Prior to the surgery, Ruscitto signed the consent form -- and while the form did not expressly include the words "power morcellation," Ruscitto testified at her deposition that Dr. Jones told her he would "chop up" her uterus during the surgery.

Although Dr. Jones's letters and the consent form do not provide the exact nature of the conversations between Dr. Jones and Ruscitto, they also contain nothing suggesting the doctor acted with actual malice warranting a jury finding by clear and convincing evidence that punitive damages are warranted. Nothing in the facts before the Court, including Dr. Jones's four meetings with Ruscitto prior to the surgery, suggests that Dr. Jones acted with actual malice towards her, which the statute defines as "intentional wrongdoing in the sense of an evil-minded act." See N.J.S.A. 2A:15-5.10.

The evidence is also devoid of any indication that Dr. Jones treated Ruscitto with wanton and willful disregard of her health. The statute defines "wanton and willful disregard" as "a deliberate act or omission with knowledge of a high degree of probability of harm to another and reckless indifference to the consequences of such act or omission." N.J.S.A. 2A:15-5.10 (emphases added). Here, the FDA Communication noted that 1 out of every 350 women undergoing hysterectomy or myomectomy for the treatment of fibroids is found to have an unsuspected uterine sarcoma, and a previous patient of Dr. Jones passed away after her cancer was upstaged by a power morcellation procedure. Certainly, there is risk to virtually every medical procedure. As noted in an April 2014 email, Dr. Jones agreed with Dr. Goldman's assessment of the increased risks and potential morbidity and complications that can occur with open surgeries as opposed to non-invasive laparoscopic procedures. Here, the FDA Communication noted that there was less than a one percent risk that a woman would have unsuspected uterine sarcoma, and leiomyosarcoma unfortunately cannot be reliably diagnosed preoperatively. Dr. Jones performed the power morcellation procedure on Ruscitto after meeting with her four times and conducting tests. Based on that evidence, the wanton and willful standard that required Dr. Jones to have acted with "knowledge of a high degree of probability of harm" and with "reckless

indifference to the consequences" of his actions such that punitive damages may be awarded has not been met.

As several defendants have conceded, the facts of this case thus far present genuine issues of fact regarding whether Dr. Jones and the Valley Hospital defendants were negligent and deviated from accepted standards of care. As noted quite explicitly in the PDA, however, the clear and convincing standard of establishing actual malice or wanton and willful disregard "may not be satisfied by proof of any degree of negligence, including gross negligence." N.J.S.A. 2A:15-12(a). Plaintiffs cannot recover damages here by simply recasting their negligence claims as wanton and willful actions based on the same alleged conduct. See Entwistle v. Draves, 102 N.J. 559, 562 (1986).

Plaintiffs' punitive damages claim against the Valley Hospital defendants is even less compelling than the claim against Dr. Jones. The record reveals that the Valley Hospital defendants, within one day of the release of the FDA Communication, began discussions regarding power morcellation in response to the communication. The numerous emails among Valley Hospital administrators and physicians illustrate that the Valley Hospital defendants took proactive steps, shortly after the issuance of the FDA Communication, to respond to the advised risks of power morcellation. Again,

the FDA Communication never mandated that hospitals create an informed consent form for the morcellation procedure. The formation of a power morcellation group to adopt an informed consent policy was a voluntary decision by the Valley Hospital defendants in response to the concerns expressed within the FDA Communication. That the informed consent form was never officially implemented before discontinuation of the morcellation procedure does not equate to defendants' acting with actual malice or in wanton and willful disregard of Ruscitto's safety.

The trial court, in denying summary judgment, relied on plaintiffs' expert report, which provided that "[t]here was no sense of urgency to implement the patient safety elements proposed by the FDA Advisory, as a result, the talking points, patient information, and informed consent form were not implemented in time for [Ruscitto's] surgery." The report also pointed out that, despite the absence of an informed consent form, the Valley Hospital defendants permitted more than 37 additional patients to be put at risk without their knowledge or consent for the morcellation procedure between the issuance of the FDA Communication and the hospital's discontinuation of the procedure in December.

Again, the efforts taken by the Valley Hospital defendants illustrate that they did not simply sit on their hands and do nothing in response to the FDA

Communication. And although the draft consent form was never fully adopted and implemented, plaintiffs' arguments regarding the lack of informed consent for the power morcellation procedure after the FDA Communication sound in ordinary negligence, not in actions taken with an "evil mind." See Howard v. UMDNJ, 172 N.J. 537, 548 (2002) ("[I]nformed consent is 'a negligence concept predicated on the duty of a physician to disclose to a patient information that will enable him to "evaluate knowledgeably the options available and the risks attendant upon each before subjecting that patient to a course of treatment."'" (quoting Perna v. Pirozzi, 92 N.J. 446, 459 (1983)). The Valley Hospital defendants' efforts simply do not demonstrate that they were acting with a reckless disregard for Ruscitto's health or the dangers associated with the morcellation procedure.

Partial summary judgment should have been granted because there was no genuine issue of material fact as to whether defendants knew that their actions or omissions involved a high probability of harm to Ruscitto and that their conduct evinced reckless indifference to her health. Under the facts of this case, the evidence proffered by the plaintiffs may establish defendants' negligence, but does not constitute conduct that can be characterized as wanton and willful. See Pavlova, 375 N.J. Super. at 405.

In sum, plaintiffs have failed to articulate how the same conduct that supports their negligence claims could lead a reasonable jury to find by clear and convincing evidence that defendants acted with actual malice or wanton and willful disregard for Ruscitto's safety such that punitive damages should be awarded.

It bears repeating that punitive damages are available only in "exceptional cases." Id. at 404. Under the facts of this case, this matter does not qualify as such.

VII.

For the foregoing reasons, we reverse the trial court's denial of defendants' partial summary judgment motion as to the punitive damages claim and remand to the trial court for further proceedings.

CHIEF JUSTICE RABNER; JUSTICES PATTERSON and SOLOMON; and JUDGE FUENTES (temporarily assigned) join in JUSTICE PIERRE-LOUIS's opinion.