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Our File No.: VH-261

MIRIAN RIVERA, AS EXECUTRIX OF THE
ESTATE OF VIVANA RUSCITTO,

Plaintiffs,

-vs.-

THE VALLEY HOSPITAL, INC., VALLEY
PHYSICIAN SERVICES, INC., trading as
VALLEY MEDICAL GROUP; VALLEY
HEALTH SYSTEM; LINDA MALKIN,
DIRECTOR OF RISK MANAGEMENT AT
VALLEY HOSPITAL; AUDREY MEYERS,
PRESIDENT AND CEO OF VALLEY
HEALTH SYSTEM; MICHAEL MUTTER AS
DIRECTOR OF PATIENT SAFETY AT THE
VALLEY HOSPITAL, KIM ROBLES AS
DIRECTOR OF QUALITY ASSESSMENT
IMPROVEMENT AND REGULATORY
COMPLIANCE AT THE VALLEY
HOSPITAL; HOWEARD H. JONES, M.D.,
EUGENIA C. KUO, M.D., KARL STORZ
ENDOSCOPY-AMERICA, INC., KARL
STORZ GMBH & CO. KG and JOHN DOES (1-
10) AND XYZ CORP. (1-10) (such names and
corporations being fictitious),

Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION – BERGEN COUNTY
DOCKET NO.: BER-L-5459-17

Civil Action

ORDER

THE VALLEY HOSPITAL, INC., VALLEY HEALTH SYSTEM, LINDA MALKIN, DIRECTOR OF RISK MANAGEMENT AT VALLEY HOSPITAL AND AUDREY MEYERS, PRESIDENT AND CEO OF VALLEY HEALTH SYSTEM,

Third Party Plaintiffs,

-vs.-

JONATHAN WEISS, M.D. and WESTMED MEDICAL GROUP,

Third Party Defendants.

NICHOLAS ROCHE, Individually and as guardian of MAXIMO VALENTINO RUSCITTO-ROCHE,

Plaintiffs,

-vs.-

THE VALLEY HOSPITAL, et. al.

Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: BERGEN COUNTY
DOCKET NO. BER-L-5728-17

Civil Action

THIS MATTER having been opened to the Court on motion by Farkas & Donohue, LLC, attorneys for defendants The Valley Hospital, Inc., Valley Health System, and Audrey Meyers the Court having considered the papers and arguments of counsel, and for good cause having been shown;

IT IS on this 28 day of April 2021;

ORDERED that Defendant's Motion for Summary Judgment is denied.

~~**ORDERED** that partial summary judgment is granted in favor of defendants, The Valley Hospital, Valley Health System, and Audrey Meyers and it is further~~

~~ORDERED~~ that plaintiff's Complaint and all crossclaims seeking punitive damages against defendants, The Valley Hospital, Valley Health System, and Audrey Meyers are hereby dismissed with prejudice; and it is further

ORDERED that a copy of this Order be served upon upload to E-Courts.

Peter G. Geiger, J.S.C.

PETER G. GEIGER, J.S.C.

Opposed x

See attached Rider.

**MIRIAN RIVERA, AS EXECUTRIX OF THE ESTATE OF VIVIANA RUSCITTO V.
VALLEY HOSPITAL et als.
DOCKET NO.: BER-L-5459-17
RIDER TO ORDER DATED APRIL 28, 2021**

THIS MATTER has been brought to the Court by way of motions on behalf of Linda Malkin, The Valley Hospital, Inc., Valley Health System, Audrey Meyers, and Dr. Jones (collectively, the “Defendants”), seeking partial summary judgment against Mirian Rivera, Executrix of the Estate of Viviana Ruscitto (“Plaintiff”), as to Plaintiff’s punitive damages claim. For the reasons set forth below, Defendants’ motion for summary judgment is denied.

FACTUAL BACKGROUND

This matter pertains to a product liability and medical malpractice suit. On October 17, 2014, Defendant Dr. Jones performed a power morcellation procedure on Viviana Ruscitto (“Decedent”). Viviana Ruscitto died on September 3, 2015.

Plaintiff filed its Complaint on August 11, 2017. Plaintiff alleged Decedent suffered injuries, including metastasized stage four cancer, as a result of the power morcellator used during Decedent’s laparoscopic supracervical hysterectomy and bilateral salpingectomy for the treatment of Decedent’s uterine fibroids.

Plaintiff filed its Complaint against numerous defendants, including: The Valley Hospital; Audrey Meyers, the CEO and President of Valley Health Systems; Linda Malkin, the former Director of Risk Management and Claims Services at the Valley Hospital; and Dr. Jones, the surgeon who performed Plaintiff decedent’s surgery. Plaintiff alleged that Defendants: were negligent in allowing Dr. Jones to utilize a power morcellator during surgery; were negligent in failing to implement a new Policy and Procedure regarding power morcellation; and failed to place a moratorium on the use of power morcellation pending adoption of the Policy and Procedure.

In April of 2014, the Federal Drug Administration (“FDA”) issued an alert regarding power morcellation in which it advised physicians of statistics regarding the risk of a fibroid being an undiagnosed leiomyosarcoma. In the alert, the FDA discussed information that it believed a patient should be provided prior to undergoing power morcellation. The alert provided that “the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids” because there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis.

Defendants filed the instant motions for partial summary judgment, seeking an Order to remove Plaintiff’s punitive damages claim. Defendants argue that there is no evidence that any of their clients acted in a willful or wanton manner as to the Decedent’s safety. Defendants conclude that punitive damages can only be awarded when there is clear and convincing evidence that the defendants acted with actual malice accompanied by a wanton and willful disregard of others.

Defendant Dr. Jones argues that he was an experienced surgeon who was familiar with minimally invasive gynecological procedures, including the power morcellator device. Defendant Dr. Jones submits that he met with Decedent on four occasions prior to the surgery and fully explained the risks, benefits, and alternatives of the gynecological procedure. Defendant Dr. Jones concludes that it obtained informed consent from Decedent before the power morcellation procedure.

Defendant Linda Malkin submits that upon receipt of the FDA alert, she shared it with the appropriate parties to evaluate power morcellation and to develop a policy and procedure for its continued use. Defendant Linda Malkin, who is not a clinician, further argues that the proposed policy and consent forms were under review by the legal department by June 4, 2014 and were approved on July 1, 2014. Defendant Linda Malkin argues that creating policy or procedure is not

within her responsibilities as Risk Manager. Defendant Linda Malkin concludes that it was represented to her that power morcellation was a safe procedure with the consent of the patient.

Defendants Valley Hospital, Valley Health System and Audrey Meyers argue that upon receipt of the FDA alert, Defendants evaluated the power morcellator issue and began drafting new policy and consent forms with the appropriate parties. Defendants argue that at all relevant times, the power morcellator remained an FDA approved device. Defendants argue that Plaintiff's claims are based on facts which only amount to degrees of negligence.

In opposition, Plaintiff argues that a jury could reasonably conclude that the acts, and more specifically the omissions, of Defendants were recklessly indifferent and evinced a wanton and willful disregard for Decedent's life. Plaintiff argues that Defendants knew that power morcellation posed an unnecessary fatal risk of spreading cancer and upstaging Decedent's cancer diagnosis, and despite this knowledge, Defendants continued to use the power morcellator without any moratoriums, restrictions, limitations or guidance on its use.

Plaintiff submits that on November 22, 2013, Dr. Jones performed a power morcellation procedure on Ms. Sumaira Khan at Defendant Valley Hospital after her MRI showed a similar large fibroid that was suspicious for uterine leiomyosarcoma. After the surgery, Ms. Khan was diagnosed with leiomyosarcoma and died. Plaintiff asserts that Defendants never reported this morcellation as an adverse event at Defendant Valley Hospital.

Plaintiff submits that on November 24, 2014, the FDA issued a "black box" warning for all power morcellator labels, specifically warning that "If 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 long-term survival Because of the risk and the availability of alternative surgical options for

most women, the FDA is warning against the use of laparoscopic power morcellators in the majority of women undergoing myomectomy or hysterectomy for treatment of fibroids.” Plaintiff argues that Defendant Valley Hospital performed the power morcellation procedure on thirty-six other women after the April 2014 FDA alert at Valley Hospital and one patient after the November 2014 “black box” warning.

Plaintiff argues that Defendant Dr. Jones testified that he was aware of an October 2013 power morcellation case, the FDA alert, Ms. Khan’s death after her surgery, and the ad hoc committee formed by Defendant Valley Hospital to determine an appropriate response to the FDA alert. Plaintiff further argues that Defendant Dr. Jones could have suspected that Decedent had cancer as he concluded that two out of three possible diagnoses of Decedent’s conditions were cancer. Plaintiff concludes that Decedent never received informed consent about the use of the power morcellator as Decedent testified at her *de bene esse* deposition that she “never, never, ever, ever” gave her consent to Dr. Jones to use the power morcellator.

Plaintiff submits that Defendant Audrey Meyers failed to ensure action after Defendant Linda Malkin formed an ad hoc group with other hospital employees to investigate what should be done after the April 2014 FDA alert. Plaintiff argues that Defendant Audrey Meyers abdicated any responsibility to Defendant Linda Malkin. Plaintiff argues that Defendant Audrey Meyers failed to: (1) formulate a committee with minutes; (2) impose any reasonable time limits on when a comprehensive power morcellator policy should be implemented; and (3) place any interim restrictions or limitations on the power morcellator.

Plaintiff argues that Defendant Linda Malkin similarly failed to: (1) undertake a leadership role; (2) implement an immediate moratorium on the use of the power morcellation device; and (3) consider and implement any restrictions, limitations or control over its use by any of the

surgeons at Defendant Valley Hospital. Plaintiff argues Defendant Linda Malkin failed to treat the situation in a more dire manner and never implemented a policy or consent form.

Plaintiff argues that Defendant Valley Hospital's alleged systemic misconduct constitutes willful and wanton disregard for Decedent's safety. Plaintiff submits that Defendant Valley Hospital had no controls over physical access and use of the power morcellation device in its operating room suite. Plaintiff submits that Defendant Valley Hospital did not have an operating room manager at the time of Decedent's surgery. Plaintiff concludes that Defendant Valley Hospital did not have the requisite managerial controls over its equipment and employees.

For the reasons set forth below, Defendants' motions are denied.

PUNITIVE DAMAGES ACT

Punitive damages may be awarded to the Plaintiff if 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 foreseeable 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." N.J.S.A. 2A:15-5.12. Actual malice is defined as "an 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." Id.

SUMMARY JUDGMENT

Summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories and admissions on file, together with 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.” R. 4:46- 2(c). The Supreme Court of New Jersey, in *Brill v. Guardian Life Ins. Co. of Am.*, 142 N.J. 520, 540 (1995), articulated the analysis as follows: A determination whether there exists a ‘genuine issue’ of material fact that precludes summary judgment requires the motion judge to consider whether the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational fact finder to resolve the alleged disputed issue in favor of the non-moving party.

The Court in *Brill* also held that a non-moving party cannot defeat a motion for summary judgment merely by pointing to any fact in dispute, but rather must point to competent evidence that leads to substantial issue of material fact. *Id.* At 529. In sum, “where the party opposing summary judgment points only to disputed issues of fact that are of an insubstantial nature, the proper disposition is summary judgment.” *Id.* Since New Jersey does not follow the “scintilla of evidence rule,” it is plaintiff’s burden to establish “by competent evidential material that a genuine issue of material fact exists.” *Goldome Realty Credit Corp. v. Harwick*, 236 N.J. Super. 118, 124 (Ch. Div. 1989).

“On a motion for summary judgment the court must grant all the favorable inferences to the nonmovant.” *Shelcusky v. Garjulio*, 172 N.J. 185, 200 (2002). A “judge’s function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial.” *Brill*, 142 N.J. at 540.

ANALYSIS

In considering these motions for summary judgment, the non-moving party, here the Plaintiff, is entitled to all favorable inferences that reasonably may be drawn. According to the non-moving party, there are still issues of material fact that are best suited for a jury to decide. After reviewing all papers submitted to the Court, and oral argument having taken place, the Court

concludes that there are issues of material fact that give rise to a denial of these motions for summary judgment.

There is an issue as to whether Defendant Dr. Jones informed Decedent of the risks of power morcellation. On April 17, 2014, six months prior to Decedent's power morcellation procedure, the FDA issued a Safety Communication alert that stated, "the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids" and estimated that 1 in 350 women undergoing hysterectomy or myomectomy for the treatment of fibroids is found to have an unsuspected uterine sarcoma. Decedent testified on August 28, 2015 at her *de bene esse* deposition that she "never, never, ever, ever" consented to have Dr. Jones use the power morcellator.

Defendant Dr. Jones further testified that he was aware of the 2014 FDA alert regarding the power morcellator prior to Decedent's procedure. In addition, Defendant Dr. Jones performed a similar power morcellation procedure on Ms. Sumaira Khan on November 22, 2013, with a similar pre-operative MRI which revealed a large fibroid that was suspicious for uterine leiomyosarcoma. Ms. Khan was later diagnosed with leiomyosarcoma and died on December 18, 2013. Defendant Dr. Jones never reported this procedure as an adverse event to Defendant Valley Hospital.

There is an issue as to whether Defendants acted with willful disregard as to Decedent's safety. Defendants Valley Hospital, Linda Malkin, and Audrey Meyers allowed the use of the power morcellator without any moratoriums, restrictions, limitations, or guidance on its use after the April 2014 FDA alert. For example, after the April 2014 FDA alert, Defendant Valley Hospital performed the power morcellation procedure on thirty-six other women and one patient after the November 24, 2014 "black box" warning. According to Arthur Shorr, Plaintiff's Expert in

Hospital Administration, Defendants Audrey Meyers, Linda Malkin, and Valley Hospital should have “immediately implemented a temporary moratorium, preventing the power morcellation device from being used until the stakeholders timely developed and implemented a hospital policy and procedure and a power morcellation informed consent form.”

Defendant Audrey Meyers delegated any responsibility of investigating power morcellation to Defendant Linda Malkin. Defendant Audrey Meyers, Linda Malkin, and Valley Hospital never formulated a formal committee with minutes and failed to impose any reasonable time limits on when the ad hoc group was required to implement a policy. Despite Defendant Valley Hospital’s legal department approving the informed consent form on July 16, 2014, delays within the hospital management prevented any informed consent form ever being implemented.

The Court finds that there is an issue of material fact as to whether Defendants’ actions or inactions were accompanied by a willful and wanton disregard for Decedent’s safety, which is best suited for a jury to decide. The evidence presented by the Defendants is not so one-sided that it must prevail as a matter of law. When viewing the totality of the timeline of events, and granting Plaintiff all favorable inferences, the Court finds that a fair-minded jury could reasonably return a verdict for the Plaintiff on the evidence presented as it relates to the issue of Plaintiff’s punitive damages claim.

The issues set forth above, although not exhaustive of all the issues of material fact encompassing this matter, clearly preclude the issuance of summary judgment in favor of Defendants. While Defendants may ultimately be successful in dismissing any and all claims against it, this Court cannot determine as much at this stage of the litigation. Therefore, for the abovementioned reasons, these motions are denied.

