Ford v Riina
2017 NY Slip Op 30890(U)
May 2, 2017
Supreme Court, New York County
Docket Number: 805242-2012
Judge: George J. Silver

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK: PART 10

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CATHERINE FORD, as Guardian of the Person and Property of JOHN ROBERT FORD, JR., and CATHERINE FORD, Individually,

Plaintiffs,

Index No. 805242-2012

-against-

DECISION/ORDER

Motion Sequence 001

HOWARD RIINA, M.D., NEW YORK PRESBYTERIAN HOSPITAL and CONCENTRIC MEDICAL, INC.,

Defendants.

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HON. GEORGE J. SILVER, J.S.C.

Recitation, as required by CPLR § 2219 [a], of the papers considered in the review of this motion:

Papers	Numbered
Notice of Motion, Attorney's Affirmation, Collective Exhibits Annexed & Memorandum of Law	1, 2, 3, 4
Affirmation In Opposition, Collective Exhibits Annexed & Memorandum of Law	5, 6
Reply Affirmation & Collective Exhibits Annexed	7, 8

In this action sounding in medical malpractice and products liability, defendant Concentric Medical, Inc. (Concentric) moves pursuant to CPLR § 3212 for an order granting it summary judgment and dismissing the complaint of Catherine Ford, as Guardian of the Person and Property of John Robert Ford, Jr, (Ford) and Catherine Ford, individually (Plaintiff). Plaintiff opposes the motion.

The underlying facts are not in dispute. During a March 9, 2010 procedure by co-defendant Howard Riina, M.D. (Riina) to treat an aneurysm in Ford's brain, a coil escaped and migrated further into Ford's nuerovasculature. Riina attempted to retrieve the coil using a device called an alligator and device called a snare. These attempts failed and Riina resorted to a device called a Merci Retriever. Riina first used a V Series Merci Retriever size 2.0. Riina was able to capture the migrated coil using this Merci Retriever but the retriever fractured when Riina attempted to retract it. Riina then used a V Series Merci Retriever size 2.5, which was larger than the size 2.0, in an attempt to retrieve the fractured Merci Retriever and the coil. The second

Merci Retriever also fractured. Riina was then able to capture the size 2.5 Merci Retriever using a snare but could not capture the first Merci Retriever and coil. Ford was ultimately brought for an emergency craniotomy and suffered a major stroke that rendered him severely brain damaged. By stipulation, plaintiff and Concentric, the manufacturer of the Merci Retriever, agreed that plaintiff's claims against Concentric would be limited to defects in design, inadequate or improper warnings and/or instructions and breach of implied warranty.

The Merci Retriever's Instructions for Use (IFU) state that Merci Retrievers are intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy or also candidates fore treatment. According to the IFU, Merci Retrievers are also indicated for use in the retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vasculature. Under a subsection entitled "Warnings" the IFU states that in order to reduce the risk of vessel damage, physician-users should take care to appropriately size the retriever to the vessel diameter at the intended site of deployment. Physician-users should not perform more than six retrieval attempts in the same vessel using Merci Retriever devices and should maintain retriever position in the vessel when removing or exchanging the microcatheter. The IFU further states that one retriever fracture was reported during Multi Merci clinical investigation and that to reduce the risk of fracture physician-users should: (1) immediately after unsheathing all retriever loops, position the microcatheter tip marker just proximal to the loops and maintain the microcatheter tip marker just proximal to the retriever loops during manipulation and withdrawal; (2) not rotate the retriever more than 5 revolutions in total, counting both clockwise and counter-clockwise rotations; (3) not withdraw filamented retriever into the microcatheter after retriever deployment into vessel; (4) not use filamented retriever for more than 2 retrieval attempts; (5) follow instructions for reloading filamented retriever into insertion tool; (6) not torque or bend the retriever when reloading it; (7) not reload or reuse filamented retriever if filaments, core wire, helical loops or platinum coils appear damaged; and (8) use caution when passing the retriever through arteries.

In support of the motion, Concentric submits the affidavit of Patrick T. Coghill (Coghill), director of engineering at Stryker Neurovascular where he is responsible for design transfer and manufacturing of the legacy Concentric medical devices[1]. According to Coghill, Merci Retrievers are manufactured in lots and each device is associated with a specific lot number. Based upon co-defendant New York Presbyterian Hospital's medical records containing a list of all the devices potentially used during Ford's March 2010 procedure, Coghill was able to determine the specific lot number of each Merci Retriever opened and potentially used by Riina. According to Coghill's review of the records maintained by Concentric specific to each lot, there were no reported fractures, other than the fracture during Ford's procedure, from the 4 subject lots identified as opened during Ford's procedure.

Coghill avers that the V Series Merci Retriever was one of only three types of medical devices indicated for retrieval of foreign bodies in the neurovasculature in 2010 and was state of the art. Coghill contends that the V Series Merci Retriever product line has experienced a very

[1] Concentric was acquired by Stryker in 2011.

small number of reported fractures and estimates the number to be less tan ten. More specifically, Coghill claims that from 2008, after the Food and Drug Administration cleared the V Series Merci Retriever and device became available for distribution, through March 9, 2010, less than one quarter of one percent of Merci Retrievers reportedly fractured during commercial use. In those instances where the failure mode of V Series Merci Retrievers was able to be determined through a failure analysis investigation, Concentric attributed the fractures to user error, excessive rotations and/or users not following the IFU. Coghill also contends that the IFU clearly and consistently warns of the risk of device fracture and contains numerous and detailed warnings to reduce the risks of device fracture and vessel damage.

Concentric also submits the affidavit of Matthew J. Gounis, Ph.D. (Gounis), a bioengineer. According to Gounis, at the time of Ford's procedure and to the present, the Merci Retriever was and is a state of the art medical device for foreign body removal. Gounis further contends that the utility of the Merci Retriever for foreign body removal outweighs the attendant risks, including the risk of device failure, and that in 2010 there was no alternative feasible design for the Merci Retriever. Gounis additionally opines that the Merci Retriever's labeling adequately, clearly and unequivocally conveyed the potential risk of device fracture and vessel damage to medical professionals in general and to Riina, for whom the label was intended.

According to Gounis, the Merci Retriever was the first device of its kind cleared by the Food and Drug Administration to restore blood flow in the neurovascular by mechanically removing thrombus in patients experiencing ischemic stroke who were ineligible for drug treatment therapy with intravenous tissue plasminogen activator (IV tPA) or who failed IV tPA therapy. The Merci Retriever was the first device that introduced the concept of mechanically removing obstructive clots, and mechanical thrombectomy is, today, generally accepted as the most effective stroke treatment ever developed for the emergent large vessel occlusions and has become the standard of care. Gounis contends that the Merci Retriever is also indicated for the retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vasculature.

Gounis states that the V Series Merci Retriever utilized during Ford's procedure was designed with a flexible, tapered super-elastic nickel-titanium (Nitinol) core wire with helical loops and polymer filaments at the distal end. According to Gounis, the distal part of the Merci Retriever is shaped into a helix by a unique property of Nitinol that allows heat shaping the device to a remembered form[2]. The device can then be elastically deformed for delivery through tiny microcatheters to the tortuous and small-caliber vessels of the brain. When the device warms to body temperature and is unconstrained from the delivery system, it reverts back to its remembered shape, a helix, that is designed to capture occlusive clots or foreign bodies. The Merc Retriever has a shaft marker to indicate proximity of the Retriever tip relative to the microcatheter tip and a torque device is provided with the Retriever, the purpose of which is to facilitate manipulation. The torque device is marked to facilitate counting the number of revolutions. In a clinical setting, the Merci Retriever is placed disitally to the thrombus or

[2] Gounis claims no material could provide the same level of strength, super-elasticity, biocompatibility and functionality in removing a thrombus or foreign object from the vasculature of the brain as Nitinol and that Nitinol was the enabling material that made the Merci Retriever and subsequent thrombectomy technology possible.

foreign body using a microcatheter which is retracted to deploy the loops of the Merci Retriever. The Merci Retriever, the thrombus or foreign body, and the microcatheter are then removed from the body. Gounic contends that the Merci Retriever can withstand more than 3 pounds of force in pure tension, which is many times more than would be used in a medical device designed for cerebrovascular applications. Over-torqueing the device, however, can cause a loop or curl to form in the core wire just proximal to the helix loops of the device. Once a curl has formed, pulling the device during retraction causes a bend fracture at much lower forces than the straight wire in pure tension. According to Gounis, as warned in the IFU, positioning the microcatheter tip marker just proximal to the Retriever loops, the area where the curl is known to occur, reduces the risk of curl formation by constraining the core wire.

In clinical trials of the X Series Meric Retriever, the earlier generation device, there were 11 device fractures in 341 embolectomy devices, representing a fracture rate of 3%. According to Gounis, the trial concluded that the majority of fractures were the result of over-torquing. Concentric then initiated Corrective and Preventive Action to make a plan to reduce the risk of fracture by changing the design of the X Series Merci Retrievers. These design changes, known as Proximal Fracture Improvements (PFI) included a stainless steel coil reinforcement with a polymer sheath over the curl-prone area. According to Gounis, the PFI, together with the implementation of training programs, a modified IFU, and a physician advisory reduced the fracture rate of the X Series to less than 0.1%. Gounis contends that the design improvements made to the X Series were included in the V Series Merci Retrievers and that additional design changes were made to the V Series to further reduce the risk of fracture. Such design changes included a smaller nominal helix and core wire diameter, alignment of the helix with the proximal core wire and the addition of a length of 304 stainless steel coil proximal to the helix. Moreover, the V Series IFU and training materials emphasized not over-torquing the device by recommending a maximum of 5 total revolutions in either direction[3].

Gounis further opines that the V Series Merci Retriever design was a rigorous and optimized balance of diametric considerations - the stiffness and strength needed for efficacyof grabbing and holding on to the foreign body and for fracture resistance (the strength to withstand normal tensile and rotational loading) versus the tip flexibility required to minimize the potential damage to the delicate intracranial vasculature. According the Gounis, any additional changes to further reinforce the proximal takeoff region of the V Series Merci Retriever, control the physician's ability to torque the device, or the use of different underlying materials would negatively impact the device's effectiveness and safety. While the risk of fracture remained, Gounis contends that fracture was an exceptionally rare occurrence in the V Series and the benefits of the V Series' design/utility outweighed the risk of fracture, which is inherent in retrieval devices.

In further support of the motion, Concentric submits the affidavit of Tudor G. Jovin, M.D. (Jovan), a board certified neurologist licensed to practice medicine in the Commonwealth

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[3] According to Gounis, a torque device that locks or prevents the physician-user from rotating the device more than 5 revolutions is not feasible, practical or safe because it is critical for the physician-user to tactile feedback and full control of how the device is working within the vascular space. A torque monitoring system, according to Gounis, would dampen such feedback and create an unsafe environment.

of Pennsylvania. Jovan states that the Merci Retriever is a novel, minimally invasive, FDA cleared class II medical device consisting of a flexible, tapered core wire with helical loops and polymer filaments at the distal end and platinum coils to permit fluoroscopic visualization. The Merci Retriever has a hydrophilic coating to reduce friction during deployment and a shaft marker to indicate proximity of the retriever tip relative to the microcatheter tip. According to Jovan, the Merci Retriever is primarily used to remove blood clots (thrombus or occlusion) and to restore blood flow in the neurovasculature. Both blood clot and foreign body removal are FDA cleared indicated uses for the Merci Retriever.

According to Jovan, once the location of a clot or a foreign body has been identified through angiography a guide catheter is inserted through a small puncture in the femoral artery located in the groin. Under x-ray guidance the guide catheter is maneuvered up into the common cartoid artery, internal artery or vertebral artery, depending on the clot or foreign body location and the catheter accessibility, in the neck. A guide wire and the Merci Retriever are then deployed through the guide catheter and then placed just beyond the clot or foreign body. The physician then deploys the Merci Retriever to engage or ensnare the clot or foreign body. As the Merci Retriver exits the catheter and enters the area distal to the body or occlusion the Merci Retriever self-deploys an becomes shape like helix so that it can capture he foreign body or occlusion. Before deployment of the retriever in its helix shape, the retriever is delivered through the vasculature in linear form through the use of memory-wire construction using Nitinol. Once the clot or foreign body is captured it is pulled into the guide catheter and out of the body. Jovan claims that the ability of the Merci Retriever helix loops to straighten is a fundamental feature of the device, enabling delivery, capture and extraction through the guide catheter.

Jovan further avers that a torque device is included with the Merci Retriever to facilitate manipulation but the torque device is not connected the retriever and is not part of the retriever itself. The primary purpose of the torque device is to manipulate the Merci Retriever when in use in the vasculature. The torque device is marked to facilitate counting the number of revolutions and has a small protrusion of the side that serves as a marker to facilitate a 360° rotation and help keep track of the number of rotations. Jovan opines that a torque locking mechanism which would prevent the physician-user from rotating the retriever more than 5 revolutions is neither feasible nor desirable. According to Jovan, such a feature would limit the physician-user's ability to manipulate the retriever to accomplish thrombus or foreign body removal and could be dangerous because there could be circumstances where the risk of exceeding the 5 revolutions expressly warned against in the IFU could be justified based upon individual patient factors and the circumstances of the particular procedure.

Jovan opines that the risk of fracture of the retriever and vessel damage are expressly warned of the device labeling and are generally known and accepted in the relevant medical community. Jovan further opines that the IFU adequately, clearly and unequivocally conveyed the risk of device fracture and vessel damage to the medical professionals generally the physician-user specifically and that the precise event complained of by plaintiff, i.e., vessel damage, is warned of in the device labeling. According to Jovan, Merci Retriever fracture and vessel damage are anticipated risks, generally accepted and known in the relevant medical community, reflected in published literature and clinical experience of physician-users and strongly conveyed in the IFU. Jovan further opines that the Merci Retriever was reasonably safe

for its intended use of foreign object retrieval, including retrieval of a migrated coil.

Concentric also submits the affidavit of Brad James, Ph.D. (James), a registered professional engineer. According to James, the Merci Retriever consists of a single, flexible Nitinol core wire with helical loops and polymer filaments at the distal end. Before insertion into the body, the Merci Retriever is loaded into a microcatheter. This loading process causes the retriever's helical loops to expand into a relatively straight form while inside the catheter lumen. During the neurointerventional procedure the microcatheter, with the Merci Retriever sheathed within it, is placed distal to the foreign body or thrombus. Once distally placed, the microcatheter is retracted and the Merci Retriever's coils expand to the their shape. According to James, the Merci Retriever is then pulled back to engage the thrombus or foreign body in the retriever's loops. The retriever, microcatether and foreign body are then withdrawn from the body.

James states that Nitinol is a nickel-titanium alloy with shape memory and super-elastic properties and is commonly used for cardiovascular and endovascular medical devices such as stents. According to James, it is the super-elastic/shape memory ability of the Nitinol alloy that allows the Merci Retriever to deform from a helical shape to a straight wire and then back to a helical shape while still maintaining sufficient strength to engage the thrombus/foreign body and to pull it through the vasculature. James claims that Nitinol's shape memory and super-elastic properties are caused by Nitinol's ability to undergo a reversible phase transformation that can be induced either by temperature changes or by mechanical stress. The shape memory effect allows Nitinol to "remember" its shape from an original phase after being deformed in another phase while super-elasticity allows Nitinol to withstand exceptionally large strains in an effectively elastic manner. James contends that it is the super-elastic effect that allows the Merci Retriever and most other Nitinol medical devices to withstand the large strains associated with the designs and that no other commercial engineering or biomedical alloy can come close to the recoverable strain offered by Nitinol.

James opines that the Merci Retriever utilized by Riina could not have been manufactured using any material other than Nitinol to provide the same level of functionality in removing a thrombus or foreign body from the neurovasculatire of the brain. James contends that in 2010, and through the present day, there exists no other commercially available alternative material that could be used for the Merci Retriever's self-expanding helical core wire design. According to James, there is no other commercially available alloy that provides Nitinol's combination of strength, super-elasticity and biocompatibility. There are, however, trade-offs to the benefits of Nitinol. One such trade-off is that when Nitinol is subjected to very high compressive bending strains, such as kinking or knotting of a wire, it can be susceptible to compressive damage and decreased strength. Another trade-off, according to James, is Nitinol's relatively low resistance to fatigue crack growth, meaning that fatigue cracks can propagate relatively quickly through Nitinol structures. James contends, however, that fatigue crack growth performance does not affect the Merci Retriever because each retriever is subjected to too few loading cycles during use to be at risk for fatigue fracture.

In sum, James opines that there is no other commercially available material with the same characteristics as Nitinol necessary to manufacture the Merci Retriever for its intended use in that there is no other commercially available material that can be loaded into a microcatheter, sheathed as a straight form, and then later expanded to a helical shape for clot or foreign body

removal without significant permanent deformation. James further opines that if the Merci Retriever was manufactured with any other commercially available bicompatible alloy, it would permanently deform upon sheathing into the microcatether rendering it unable to self-expand upon deployment into a shape that could capture a thrombus or foreign body.

In opposition to the motion, plaintiff submits the affidavit of Karl Puttlitz, Ph.D. (Puttlitz), a metallurgist/materials scientist. Puttlitz contends that Concentric was negligent and that the Merci Retriever was defective because Concentric (1) failed to warn that the Merci devices had the potential of a loop-induced failure mode which would cause a dramatic loss of strength, condition which Puttlitz contends existed throughout the Merci device program and during Ford's intervention; (2) failed to follow standard scientific and industry practices to both ascertain and assure Merci devices were capable of withstanding those conditions in which the devices were intended or which were foreseeable; (3) failed to determine and/or to provide key operational parameters as part of the V Series IFU provided with each device that would have avoided the conditions that gave rise to the Merci device failures during Ford's intervention; (4) failed to take into account the foreseeable event of a device becoming stuck within a blood vessel, a condition which made it much easier for device failure to occur; (5) failed to provide an integrated fail-safe feature which was available at the time the V Series was designed or to undertake any efforts to consider one that would have prevented the device failures that occurred during Ford's intervention and; (6) failed to provide such a capability despite having known from the earliest days of the Merci Retriever program that all series Merci devices, including the V Series utilized in Ford's intervention, possessed an inherent weakness that exposed them to sudden, premature failure. Puttlitz also contends that if the Merci devices utilized during Ford's intervention possessed a fail-safe capability, or improved alternate design, the failures would not have occurred.

More particularly, Puttlitz argues that Concentric failed to take fundamental steps at the very beginning of the Merci Retriever development program to determine the mechanical limitations of the device. Puttlitz avers that he performed a series of controlled laboratory tests utilizing the same Nitinol wire stock that Concentric utilized for the V2.0 and V2.5 Merci Retriever core wire. The tests specimens were tested under a variety of conditions and the assessment took into account key operational parameters including the rate of applying twists or revolutions to be within the range a physician might apply during an intervention procedure, the direction of rotation, the torque necessary to cause wire failure and the number of revolutions to cause wire failure. Puttlitz also conducted a study focused on tensile testing of the same Nitinol wire used to fabricate V Series Merci retrievers. Specimens were subjected to various conditions including a series of samples previously prepared at Arizona State University to evaluate the effect loop size had on the formation of cracks and loss of tensile strength. Puttlitz also evaluated the effect of wire size, the combination of torque and tensile forces and simulated blood vessel constraint. An exemplar V2.0 Merci Retriever was also tested. According to Puttlitz, the tensile tests he conducted demonstrated a sudden and dramatic loss of strength which was observed to range from essentially zero to only about 4½ percent of the material's inherent strength, a loss of approximately 95%. Puttlitz clams that the testing verified that in the presence of loop formation, cracks can easily form and that even a slight pull on the wire will cause cracks to propagate, resulting in wire fracture and separation. Puttlitz opines that this slight application of force was

the cause of the two Merci Retriever failures during Ford's procedure. Based upon the torque and tensile tests, as well as extensive Scanning Electon microscopy analysis performed on representative samples, Puttlitz concludes, based upon a reasonable degree of metallurgical and engineering certainty, that (1) the device failures Concentric reported were due to torque overload could not have failed in that way and (2) given the differences in fracture morphology and characteristics between the two types of failure mode, torque overload versus loop formation failures, there should not have been any confusion by Concentric in identifying that the failures did not occur due to a torque overload. Puttlitz opines that Concentric was negligent in failing to conduct basic testing to provide a fundamental and necessary understanding of the factors that had the potential for a negative impact on the Merci Retriever's mechanical integrity.

With respect to IFU, Puttlitz argues that it was wrong because testing he conducted and observed showed that a loop could be formed in fewer than 5 rotations if the distal end of the device was stuck or entangled in the vessel. Thus, Puttlitz claims that even if Riina knew that the Merci Retriever could fracture, he did not know how or under what conditions and, therefore, the learned intermediary doctrine does not apply here. According to Puttlitz, the testing on exemplar V Series Merci Retrievers established that if the distal end of the device became "stuck", loop formation could occur with fewer than the 5 rotations allowed for in the IFU. In fact, Puttlitz contends that a loop was noted to form during testing in as few as 2 rotations. Puttlitz argus that Concentric failed to consider a "stuck" condition in the testing it conducted to determine the maximum allowable number of rotations. Puttlitz claims that a "stuck" condition posed a much greater potential for failure due to the ease of loop formation when compared with situations where the device's distal end was free to rotate or only partially stuck (i.e., some of the helical coil's proximal loops were not constrained).

Puttlitz further opines that given the potential for a sudden loop induced failure an the almost complete loss of wire strength under a stuck condition, it was necessary for Concentric to provide a fail-safe capability to prevent premature failure, especially since the user-physician had no way of knowing during a procedure that a loop was forming. Puttlitz claims the most obvious way to prevent a loop induced failure was to allow the physician-user to see the loop forming or formed, which could have been done through the use of radiopaque materials. The use radiopaque materials would have provided a physician-user with ample warning if a loop had formed and the ability to dissipate it before cracks were created in the Nitinol core wire. Puttlitz claims that the use of radiopaque materials or coating would not have required any drastic design changes, any changes to the core wire material or any changes to the device's key physical features. Puttlitz claims that through using Scanning Electron Microscopy it was possible to determine the threshold diameter for crack creation in kinked loops and that the crack formation threshold diameter was sufficiently small to allow loop detection prior to causing loop-induced cracks and wire integrity. Thus, if a radiopaque loop-monitoring capability had existed and been part of the design of the Merci Retriever, Puttlitz contends that the two devices would not have failed during Ford's procedure because Riina, upon discovering the loop, would only have had to rotate the device in the opposite direction to dissipate the loop.

Plaintiff also submits the affidavit of David H. Frakes, Ph.D. (Frakes), a biomedical engineer. Frakes opines that the "crux" of plaintiff's design defect claim is that Concentric failed to consider the foreseeable scenario in which a Merci Retriever became completely stuck,

entangled or embedded in a vessel, a scenario which Frakes claims was clearly foreseeable. Frakes claims that during Concentric's test of the Merci Retriever, only 4 of the 7 loops that comprise the formed variable pitch helical coil were clamped, thereby allowing torsional stresses to be accommodated by the 3 most proximal coils that were not clamped when the device was rotated in a machine. Concentric used these test results as the basis for their maximum 5 rotations guideline. Frakes, however, contends that experiments conducted by him and Puttlitz utilizing an exemplar V2.0 Merci Retriever with all 7 loops clamped simulated a clearly foreseeable stuck device situation. According to Frakes, these experiments and testing demonstrated that a loop could form in as few as 2 rotations. Thus, according to Frakes, IFU for the V Series Merci Retriever was not only deficient, it was incorrect.

According to Frakes, the IFU, which advised that the microcatheter should be placed just proximal to the loops, was also deficient because Concentric never defined the maximum allowable distance that the microcatheter could be positioned from the so-called proximal take off to minimize loop formation and assure safe operation. Frakes claims that his testing on a exemplar V2.5 device determined the critical distance parameter and established that a loop could not be formed given a definite exact placement. Frakes contends Concentric should have determined the specific distance guideline established by his testing and provided that information in IFU.

Moreover, Frakes opines that the IFU's guideline that physician-users should not advance or withdraw the device against resistance without a determination of the cause of such resistance through te use of flouroscopy is essentially useless because the only portion of the device visible under flouroscopy is the far distal end. Therefore, if the resistance is the result of the device being stuck in the vasculature, which Frakes reiterates was foreseeable, a physician-user would not know that, nor could they visualize a loop forming. Frakes also contends that any attempt to remove the device could be problematic since twisting and pulling the device culd easily cause loop formation and fracture. According to Frakes, the IFU guideline in dealing with resistance was inadequate because a physician-user could unknowingly be in catastrophic situation.

Frakes further opines that the Merci Retriever, once attached to a clot or foreign body, could not be disengaged. Unlike the alligator, which could be de-clamped, or the snare, which could be loosened, the Merci Retriever, because it was designed to grab hold of clots or foreign bodies so that they could be pulled out or retrieved, does not have a disengagement capability. That is, if the Merci Retriever grabs hold of either a thrombus or foreign body that cannot be pulled out without doing more damage to the patient's vasculature, the physician-user has no recourse.

Frakes next contends that the IFU was deficient because it did not provide the physician-user with guidelines in the event of a formation of a loop. According to Frakes, proper design anticipates operator errors and doing so calls for informing users as to how those errors can be counteracted.

Frakes further contends that Concentric should have had zero tolerance for the possibility of catastrophic device failure but was instead satisfied to merely reduce the failure rate through its PFI. Frakes claims that the tests and analyses he participated in supported the conclusion that fracture prevention was completely achievable through the incorporation of fail-safe feature or capability. As to alternative or improved designs, Frakes claims that any features existed at the

time the V Series was manufactured that would have prevented what happened to Ford. Frakes, also opines that the V Series was defectively designed because it did not have any features that would have warned or prevented the physician-user from exceeding the 5 rotation limit called for in the IFU. According to Frakes, Concentric only supplied a torque application device, a raised wing to supposedly help keep track of the number of rotations and facilitate manipulation of the device within the vasculature. Frakes claims that Concentric left the issue of how a physician-user should handle an encounter with excessive resistance while rotating or pulling the device completely up to the discretion of the user. According to Frakes, because the high variance of forces various physician-users could apply to the device, it was essential that Concentric provide a fail-safe capability to prevent sudden premature failure and removing the need for the physician-user to make the determination of what is excessive resistance. Frakes claims there were several fail-safe mechanism which were feasible and available at the time the V Series was designed and manufactured which would have prevented a physician-user exceeding the maximum allowable stress level. As examples, Frakes opines that the device could have had the capability to count the number of rotations clockwise and counterclockwise and/or a locking mechanism that prevented exceeding the limit. According to Frakes, rotational counting mechanisms are pervasive throughout engineering history. Frakes also contends that a torque-sensing device that would tell the physician-user how much torque was being applied to the device also could have been incorporated into the Merci Retriever's design and that technologies for accomplishing this task are long-standing and described in the specific context of endovascular catheters at least as far back as 1997. Frakes also opines that Concentric could have utilized a torque-application device which would have limited the amount of torque that could applied to the device and claims that torque-limiting handles were clearly present in medical devices at and before the time of Ford's intervention. Frakes contends that another means of rotational counting, MEMS-based accelerometers, existed and at the time of the design of the V Series Merci Retriever and could have been incorporated into the design. Finally, Frakes argues that in light of the importance of a physician-user knowing if a loop was formed or being formed, the ability of the physician-user to visualize such a condition was paramount. Thus, Frakes contends that a radiopaque coating used proximal to the proximal takeoff, which Concretric had utilized on an earlier version of the Merci Retriever, and which would have facilitated the visualization of loop formation under fluoroscopy, should have been incorporated into the design of the V Series. Frakes opines that all of the above designs features were available to Concentric, were within the state of the art and adaptable to the Merci Retriever. Frakes also claims that these alternative designs were also economically feasible and would not have contributed significantly to the cost of the device.

To obtain summary judgment, the movant must establish its cause of action or defense sufficiently to warrant the court as a matter of law in directing judgment in its favor (CPLR § 3212 [b]; *Bendik v Dybowski*, 227 AD2d 228 [1st Dept 1996]). This standard requires that the proponent of a motion for summary judgment make a *prima facie* showing of entitlement to judgment as a matter of law by advancing sufficient "evidentiary proof in admissible form" to demonstrate the absence of any material issues of fact (*Winegrad v New York Univ. Med. Ctr.*, 64 NY2d 851, 853, 476 NE2d 642, 487 NYS2d 316 [1985]; *Zuckerman v City of New York*, 49 NY2d 557, 562, 404 NE2d 718, 427 NYS2d 595 [1980]; *Silverman v Perlbinder*, 307 AD2d 230

[1st Dept 2003]; *Thomas v Holzberg*, 300 AD2d 10, 11 [1st Dept 2002]). Thus, the motion must be supported "by affidavit [from a person having knowledge of the facts], by a copy of the pleadings and by other available proof, such as depositions" (CPLR § 3212 [b]).

To defeat a motion for summary judgment, the opposing party must show facts sufficient to require a trial of any issue of fact (CPLR § 3212 [b]). Thus, where the proponent of the motion makes a prima facie showing of entitlement to summary judgment, the burden shifts to the party opposing the motion to demonstrate by admissible evidence the existence of a factual issue requiring a trial of the action, or to tender an acceptable excuse for his or her failure to do so (*Vermette v Kenworth Truck Co.*, 68 NY2d 714, 717, 497 NE2d 680, 506 NYS2d 313 [1986]; *Zuckerman*, 49 NY2d at 560, 562; *Forrest v Jewish Guild for the Blind*, 309 AD2d 546 [1st Dept 2003]). Like the proponent of the motion, the party opposing the motion must set forth evidentiary proof in admissible form in support of his or her claim that material triable issues of fact exist (*Zuckerman*, 49 NY2d at 562). The opponent "must assemble and lay bare [its] affirmative proof to demonstrate that genuine issues of fact exist" and "the issue must be shown to be real, not feigned, since a sham or frivolous issue will not preclude summary relief" (*Kornfeld v NRX Technologies, Inc.*, 93 AD2d 772 [1st Dept 1983], *affd*, 62 NY2d 686, 465 NE2d 30, 476 NYS2d 523 [1984]). Mere conclusions, expressions of hope or unsubstantiated allegations or assertions are insufficient (*Alvord and Swift v Stewart M. Muller Constr. Co.*, 46 NY2d 276, 281-82, 385 NE2d 1238, 413 NYS2d 309 [1978]; *Fried v Bower & Gardner*, 46 NY2d 765, 767, 386 NE2d 258, 413 NYS2d 650 [1978]; *Plantamura v Penske Truck Leasing, Inc.*, 246 AD2d 347 [1st Dept 1998]). Summary judgment is a drastic remedy that should only be employed where no doubt exists as to the absence of triable issues (*Leighton v Leighton*, 46 AD3d 264 [1st Dept 2007]). The key to such procedure is issue-finding, rather than issue-determination (*id.*).

Generally, a person injured by an allegedly defective product may assert a claim against the manufacturer of a product based on negligence or strict products liability (*see Voss v Black & Decker Mfg. Co.*, 59 NY2d 102, 106, 450 NE2d 204, 463 NYS2d 398 [1983]). The injured party may claim that the product is defective either because there was a mistake in the manufacturing process, an improper design, or the manufacturer did not provide adequate warnings with regard to the use of the product (*see Liriano v Hobart Corp.*, 92 NY2d 232, 237, 700 NE2d 303, 677 NYS2d 764 [1998]; *Voss*, 59 NY2d at 107; *Gray v R.L. Best Co.*, 78 AD3d 1346, 1348-1349 [3rd Dept 2010])

Liability for a defectively designed product "attaches when the product, as designed, presents an unreasonable risk of harm to the user" (*Voss*, 59 NY2d at 107). A successful cause of action for defective design exists where a plaintiff is able to establish "that the manufacturer breached its duty to market safe products when it marketed a product designed so that it was not reasonably safe and that the defective design was a substantial factor in causing plaintiff's injury" (*id.*; *see Fisher v Multiquip, Inc.*, 96 AD3d 1190, 1193 [3rd Dept 2012]; *Steuhl v Home Therapy Equip., Inc.*, 51 AD3d 1101, 1103 [3rd Dept 2008]). To demonstrate a product was not "reasonably safe," the injured party must demonstrate both that there was a substantial likelihood of harm and that "it was feasible to design the product in a safer manner" (*Voss*, 59 NY2d at 108). A claim may be defeated where a defendant demonstrates that the product's "utility outweighs its risks [because] the product has been designed so that the risks are reduced to the

greatest extent possible while retaining the product's inherent usefulness at an acceptable cost" (*id.*). This risk-utility analysis requires consideration of "'(1) the product's utility to the public as a whole, (2) its utility to the individual user, (3) the likelihood that the product will cause injury, (4) the availability of a safer design, (5) the possibility of designing and manufacturing the product so that it is safer but remains functional and reasonably priced, (6) the degree of awareness of the product's potential danger that can reasonably be attributed to the injured user, and (7) the manufacturer's ability to spread the cost of any safety-related design changes'" (*Hall v Husky Farm Equip., Ltd.*, 92 AD3d 1188, 1189 [3rd Dept 2012], *quoting Denny v Ford Motor Co.*, 87 NY2d 248, 257, 662 NE2d 730, 639 NYS2d 250 [1995]). Generally, the risk/utility analysis presents a factual question for a jury (*see Hoover v New Holland N. Am., Inc.*, 23 NY3d 41, 54, 988 NYS2d 543, 11 NE3d 693 [2014]; *Fisher*, 96 AD3d at 1194; *Steuhl*, 51 AD3d at 1104).

To succeed on a failure-to-warn claim, a plaintiff is required to prove that the product did not contain adequate warnings and that the inadequacy of those warnings was the proximate cause of the injuries (*Glucksman v Halsey Drug Co.*, 160 AD2d 305, 307 [1st Dept 1990]). The manufacturer's duty, under New York law, is to warn the medical community, not the patient (id.) of the product's risk. The warning must provide sufficient information to that class of prescribing physicians "who may be expected to have the least knowledge and experience with the" product (*Martin v Hacker*, 83 NY2d 1, 9, 628 NE2d 1308, 607 NYS2d 598 [1993]). Whether the cause of action for failure to warn is based on negligence or strict liability, the courts of this state have consistently held that a manufacturer's duty is to warn only of those dangers it knows of or are reasonably foreseeable (*see Rastelli v Goodyear Tire & Rubber Co.*, 79 NY2d 289, 297, 591 NE2d 222, 582 NYS2d 373 [1992]). Knowledge, actual or constructive, of a danger inherent in a product is an essential factor in determining whether a manufacturer is liable (*see e.g. Goldberg v Union Hardware Co.*, 162 AD2d 658, 659 [2d Dept 1990]). The lack of such knowledge is fatal to a failure-to-warn claim, and in the absence thereof, summary judgment is warranted (*see Daley v McNeil Consumer Prods. Co., a Div. of McNeil-PPC, Inc.*, 164 F Supp 2d 367, 373 [SDNY 2001]).

Concentric's submission establishes prima facie that the IFU conveyed to physician-users the most current knowledge available concerning the potential risk of fracture associated with the Merci Retriever, which is all the law requires (*Mulhall v Hanafin*, 45 AD3d 55, 58 [1st Dept 2007]). In addition to adequately conveying the risk of fracture, the IFU also set forth various steps which the physician-user could take to reduce that risk. Concentric's submission also establishes its prima facie entitlement to summary dismissal of plaintiff's design defect claim by establishing that the Merci Retriever was state of art for removing thrombus and foreign bodies from the neurovasculature, that the device was properly designed and manufactured using Nitinol and that the v Series incorporated changes made to the predecessor X Series as well as other modifications that minimized the risk of fracture (*Reeps v BMW of N. Am., LLC*, 94 AD3d 475, 476 [1st Dept 2012]; *cf Boyle v City of New York*, 79 AD3d 664, 665 [1st Dept 2010]).

In response to Concentric's prima facie showing, plaintiff has failed to carry her burden of raising a triable issue of fact. Plaintiff, relying on the opinions of her experts, argues with respect to both her design defect claim and her failure-to-warn claim that the Merci Retrievers used by Riina during Ford's procedure in an attempt to retrieve the migrated coil were subject to

loop formation and fracture after not 5 rotations but after only 2 rotations when "fully stuck" in the vasculature. "An expert's affidavit - - offered as the only evidence to defeat summary judgment - - must contain sufficient allegations to demonstrate that the conclusions it contains are more than mere speculation and would, if offered alone at trial, support a verdict in the proponent's favor'" (*Ramos v Howard Indus., Inc.*, 10 NY3d 218, 224, 885 NE2d 176, 855 NYS2d 412 [2008] *quoting Adamy v Ziriakus*, 92 NY2d 396, 402, 704 NE2d 216, 681 NYS2d 463 [1998]). An expert opinion that is "speculative and conclusory" does not constitute evidence in admissible form (*see Arredondo v Valente*, 94 AD3d 920, 922 [2d Dept 2012]). In setting forth their opinions that the IFU incorrectly warned physician-users against performing more than 5 rotations instead of no more than 2 and that the Merci Retriever was defective because it did not incorporate a fail-safe feature or the capability to either track or limit the number of rotations, Puttlitz and Frakes make repeated reference to various tests and experiments they performed which they contend replicated the foreseeable event of a Merci Retriever being "fully stuck" within a patient's cerebral vasculature. However, noticeably absent from both affidavits is any description by Puttlitz or Frakes of the actual tests and experiments they performed or the conditions under which they performed them. Neither expert establishes that the tests and experiments performed on the exemplar Merci Retriever or the Nintinol wire were based on accepted industry standards (*Pellechia v Partner Aviation Enters., Inc.* 80 AD3d 740, 741 [2d Dept 2011]) and their opinions are unsupported by any scientific basis, statistics, analysis or empirical data (*Stalker v Goodyear Tire & Rubber Co.*, 60 AD3d 1173, 1175 [3rd Dept 2009]; *Brown v City of Yonkers*, 119 AD3d 881, 882 [2d Dept 2014]). Simply stated, there is nothing in the experts' affidavits from which the validity of their ultimate conclusions about the design of the Merci Retriever and the adequacy of the IFU can be inferred (*Romano v Stanley*, 90 NY2d 444, 451, 684 NE2d 19, 661 NYS2d 589 [1997]). In the absence of any reference to a foundational scientific basis for their conclusions, Puttlitz and Frakes' opinions lack sufficient probative value to raise a triable issue of fact as to whether the Merci Retriever was reasonably safe in its design and whether the IFU sets forth adequate warnings with respect to the risk of fracture.

The parties stipulated at oral argument that plaintiff's breach of warranty claim would rise or fall with plaintiff's failure-to-warn and design defect claims. Since those claims are dismissed, so to is plaintiff' breach of warranty claim. Accordingly, it is hereby

ORDERED that co-defendant Concentric Medical, Inc.'s motion for summary judgment is granted and the complaint against it is dismissed; and it is further

ORDERED that the Clerk is directed to enter judgment accordingly; and it is further

ORDERED that Concentric Medical, Inc. is to serve a copy of this order, with notice of entry, upon plaintiff within 20 days of entry.

George J. Silver, J.S.C.

Dated: 5/2/17
New York County

GEORGE J. SILVER