O'Shea v Rumore
2014 NY Slip Op 32691(U)
October 9, 2014
Supreme Court, Suffolk County
Docket Number: 10-43835
Judge: Jerry Garguilo

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COPY

SHORT FORM ORDER

INDEX No. 10-43835
CAL. No. 14-00247MM

SUPREME COURT - STATE OF NEW YORK
I.A.S. PART 47 - SUFFOLK COUNTY

PRESENT:

Hon. JERRY GARGUILO
Justice of the Supreme Court

MOTION DATE 7-7-14
ADJ. DATE 8-13-14
Mot. Seq. # 004 - MD

JANICE M. O'SHEA, as Executrix of the Estate of MARGUERITE CULLEN, Deceased, Plaintiff, - against - PETER RUMORE, M.D., GAIL KRICHLOW, M.D., MAX HAMBURGER, M.D. and RHEUMATOLOGY ASSOCIATES OF LONG ISLAND, LLP. Defendants.	SULLIVAN PAPAIN BLOCK McGRATH & CANNAVO P.C. Attorney for Plaintiff 120 Broadway New York, New York 10271 AARONSON RAPPAPORT FEINSTEIN & DEUTSCH, LLP Attorney for Defendants Max Hamburger M.D. & Rheumatology Associates of Long Island, LLP 600 Third Avenue New York, New York 10016

Upon the following papers numbered 1 to 25 read on this motion for summary judgment; Notice of Motion/ Order to Show Cause and supporting papers (004) 1-17; Notice of Cross Motion and supporting papers _; Answering Affidavits and supporting papers 18-25; Replying Affidavits and supporting papers 26-27; Other _; (~~and after hearing counsel in support and opposed to the motion~~) it is,

ORDERED that motion (004) by defendants, Max Hamburger, M.D. and Rheumatology Associates of Long Island, LLP, pursuant to CPLR 3212 for summary judgment dismissing the complaint as asserted against them is denied.

In this action for medical malpractice, the plaintiff, Janice M. O'Shea, as executrix of the estate of Marguerite Cullen, seeks damages on behalf of the estate and derivatively for severe personal injuries and death of the decedent on May 18, 2010 due to the defendants' alleged negligent departures from good and accepted standards of medical care and practice and failure to provide informed consent. Marguerite Cullen was under the care and treatment of the defendants from about September 24, 2002 through, and including May 17, 2010 at the offices of Rheumatology Associates of Long Island, LLP (Rheumatology Associates), for the intravenous infusion of Tocilizumab (Actemra), a drug used to treat rheumatoid arthritis. During the administration of Actema on May 5, 2010, the decedent developed a reaction and was transferred to St. Catherine of Siena Medical Center for treatment and discharged. During the subsequent administration of Actema on May 17, 2010, the plaintiff's decedent had an anaphylactic

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reaction, developed Stevens-Johnson Syndrome, anaphylactic shock, and died. It is alleged, inter alia, that defendants negligently administered said medication on May 17, 2010 despite plaintiff's decedent demonstrating sensitivity to the medication on May 5, 2010 and that defendants failed to timely and appropriately treat the decedent's allergic reaction, failed to administer epinephrine, resulting in a coma and the death of the decedent.

The proponent of a summary judgment motion must make a prima facie showing of entitlement to judgment as a matter of law, tendering sufficient evidence to eliminate any material issues of fact from the case (***Friends of Animals v Associated Fur Mfrs.***, 46 NY2d 1065, 416 NYS2d 790 [1979]; ***Sillman v Twentieth Century-Fox Film Corporation***, 3 NY2d 395, 165 NYS2d 498 [1957]). The movant has the initial burden of proving entitlement to summary judgment (***Winegrad v N.Y.U. Medical Center***, 64 NY2d 851, 487 NYS2d 316 [1985]). Failure to make such a showing requires denial of the motion, regardless of the sufficiency of the opposing papers (***Winegrad v N.Y.U. Medical Center***, *supra*). Once such proof has been offered, the burden then shifts to the opposing party, who, in order to defeat the motion for summary judgment, must proffer evidence in admissible form...and must "show facts sufficient to require a trial of any issue of fact" (CPLR 3212[b]; ***Zuckerman v City of New York***, 49 NY2d 557, 427 NYS2d 595 [1980]). The opposing party must assemble, lay bare and reveal his proof in order to establish that the matters set forth in his pleadings are real and capable of being established (***Castro v Liberty Bus Co.***, 79 AD2d 1014, 435 NYS2d 340 [1981]).

In support of motion (004), defendants submitted, inter alia, an attorney's affidavit; affirmation of Richard Furie, M.D.; copies of the summons and complaint, defendants' answer and the plaintiff's verified bill of particulars and supplemental verified bill of particulars; uncertified copy of plaintiff's medical record from Rheumatology Associates, St Catherine of Siena, and an autopsy report which fail to comport with CPLR 3212 and 4518 (***Friends of Animals v Associated Fur Mfrs***, *supra*); scant, incomplete copies of transcripts of the examinations before trial of Janice O'Shea (which is also unsigned), Peter Rumore, M.D. (which is unsigned), Gail Crichlow-Hall, M.D. (which is unsigned), Max Hamburger, M.D. (which is signed), Paul E. Schulman, M.D. (which is signed and certified), all of which leave this court to speculate as to the contents of the missing sections in the transcripts. However, in searching the submissions, a complete copy of the transcript of Dr. Hamburger has been noted.

Expert testimony is limited to facts in evidence (*see also* ***Allen v Uh***, 82 AD3d 1025, 919 NYS2d 179 [2d Dept 2011]; ***Marzuillo v Isom***, 277 AD2d 362, 716 NYS2d 98 [2d Dept 2000]; ***Stringile v Rothman***, 142 AD2d 637, 530 NYS2d 838 [2d Dept 1988]; ***O'Shea v Sarro***, 106 AD2d 435, 482 NYS2d 529 [2d Dept 1984]; ***Hornbrook v Peak Resorts, Inc.***, 194 Misc2d 273, 754 NYS2d 132 [Sup Ct, Tomkins County 2002]). Uncertified medical records and incomplete deposition transcripts are not in evidence.

The requisite elements of proof in a medical malpractice action are (1) a deviation or departure from accepted practice, and (2) evidence that such departure was a proximate cause of injury or damage (***Holton v Sprain Brook Manor Nursing Home***, 253 AD2d 852, 678 NYS2d 503[1998], *app denied* 92 NY2d 818, 685 NYS2d 420). To prove a prima facie case of medical malpractice, a plaintiff must establish that defendant's negligence was a substantial factor in producing the alleged injury (*see* ***Derdiarian v Felix Contracting Corp.***, 51 NY2d 308, 434 NYS2d 166 [1980]; ***Prete v Rafla-Demetrious***,

221 AD2d 674, 638 NYS2d 700 [1996]). Except as to matters within the ordinary experience and knowledge of laymen, expert medical opinion is necessary to prove a deviation or departure from accepted standards of medical care and that such departure was a proximate cause of the plaintiff's injury (*see* ***Fiore v Galang***, 64 NY2d 999, 489 NYS2d 47 [1985]; ***Lyons v McCauley***, 252 AD2d 516, 517, 675 NYS2d 375 [1998], *app denied* 92 NY2d 814, 681 NYS2d 475; ***Bloom v City of New York***, 202 AD2d 465, 465, 609 NYS2d 45 [1994]).

Dr. Max Hamburger, M.D. testified to the extent that he has been the managing partner of Hematology Associates of Long Island since 1980 and practices exclusively in the specialty of rheumatology which encompasses immunology, not primarily allergy. Prior to 1980, he was an assistant professor of medicine in the division of allergy, rheumatology, and clinical immunology at Stony Brook University Hospital. He is board certified in internal medicine and rheumatology. He began treating the decedent, Marguerite Cullen, in the 1990s for rheumatoid arthritis, which he described as an inflammatory disease of the joints that can cause swelling and pain, and erosion of the bone and loss of cartilage. The underlying cause of rheumatoid arthritis is disease of the immune system, but the specific cause has not yet been identified. He continued that the immune system's first step is to recognize the difference between its owner and everything else, and unleash its weapons when something gets into the owner that shouldn't be there. The immune system recognizes some antigen or chemical in the host (owner) to be foreign, so it tries to get rid of things that don't belong there. The immune system destroys tissues, and in rheumatoid arthritis, it is capable of destroying tissues in the joints and many other tissues as well. Dr. Hamburger testified that goals in treating rheumatoid arthritis are to prevent disability, preserve function and structure, and to relieve symptoms. He uses medications, essentially steroidal and non-steroidal anti-inflammatories, to prevent damage to the joints, but also administers biologics.

Dr. Hamburger discussed his care and treatment of the plaintiff, commencing in 1994 and his diagnosis of rheumatoid arthritis, including the various medications the decedent was prescribed and the effects of those medications. It was his role to decide how the decedent's treatments are working, and future treatment, the safest route for treatment with the most benefit with the least risk. He discussed different drugs and classifications of drugs used to treat rheumatoid arthritis, including biologics. There are eight biologics, he stated, and there is no evidence-based approach as to which one is used first, and which one second; it is just patient specific. He prescribed Actemra for the decedent. He stated that Actemra is a biologic, a protein, which is highly targeted by the body with an antibody response. Sometimes patients can be desensitized to a drug, but he was not aware of desensitization to a biologic, and later stated that biologics do not have the ability to be desensitized for patients. He testified that he familiarized himself with the package insert for Actemra. He felt the package insert would be very similar to the Physicians Desk Reference (PDR). He uses the insert in part to determine whether or not to use the medication on the patient. Adverse reactions and events are set forth in the package inserts. He also attended meetings, listened to lectures by experts, and read medical literature and journal about clinical trials and updates on medication.

Dr. Hamburger testified he first used Actemra in early 2010 commercially or outside the trial. The decedent was one of the first patients who received the drug commercially. He did a clinical trial with Actemra in April or May 2009 before it was released commercially in December 2009. He did not recall if he collected any clinical data with the trial. He stated that if his practice entered into a post-marketing

study agreement, his practice then would have received payment. He did not know if any compensation or exchange was given to his practice in exchange for the drug manufacturer, Genentech, providing the medication for free. He stated he would have to inquire with his clinical trials department, specifically Dr. Knell, who was out on disability due to a concussion, and was therefore unavailable. He has about fifteen staff members working in his clinical trials department. His firm gets paid for the clinical trials. Dr. Hamburger testified that he did not recall any allergic reactions during his trial. He was not aware of any studies which indicated that allergic reactions, if they do occur, or if they happen on a third or fourth infusion, or after the first two infusions.

Dr. Hamburger testified that there were other biologics available in 2010 for rheumatoid arthritis, and that the decedent had been given Embrel and Orencia previously. He was aware of clinical trials for Actemra, and that there were patients who experienced allergic reactions, infusion reactions, hypersentivitiy reactions and anaphylactic reactions. Dr. Hamburger stated that there was a series of forms which he had to complete for the clinical trials to submit to Genentech regarding the reaction, but he did not know where they were because, "after the patient's demise the chart was, by my direction, sealed." Genentech determined that the decedent had antibodies against the infused proteins in Actemra, so that might have been the mechanism causing the anaphylactic shock. The decedent was the first death in the American series that led to a letter being sent to doctors around the country.

Dr. Hamburger testified that in the spring of 2009, the decedent experienced dizziness with infusion of Orencia, a biologic, however, he felt this was an infusion reaction as the dizziness was not associated with anything else. The Orencia was discontinued. On September 16, 2009, he started her on Medrol (steroid) with good response, and by January 2010 she was cushingoid (showing effects of steroids). She had severe swelling of the joints. The decedent was first infused with Actemra in February or March 2010, at his office, on a low dose, as limited by the package insert, with dosage amounts to be increased over two to three months to reach a potentially effective dose. Her first dose of Actemra, 212 mg, was on February 9, 2010, with no reaction noted. On March 10, 2010, Actemra, 224 mg, was infused, without a reaction. A third infusion was administered on April 7, 2010, 220 mg, without any reaction. On May 5, 2010, when 224 mg was to be infused, the infusion was terminated prematurely due to the decedent experiencing dizziness, her blood pressure was 91/58, she was having difficulty breathing, and had a slight wheeze in one lung base. Dr. Shulman from his office was present during this reaction. He stated that he also learned that her blood pressure had a drop to 84/50 and 84/54, but stated it was a small drop. When asked if the pallor she had could be a sign of a drop in blood pressure or vasodilation, he said it could be, but she was anemic. When questioned, he stated that he was aware she was using accessory muscles to breathe, a sign of respiratory difficulty. He stated that Dr. Schulman listened to her lungs and noted she was not moving air well.

Dr. Hamburger did not know the dose of Actemra the decedent actually received on May 5, 2010, and he was not present. He testified that he did not consider her constellation of symptoms as an allergic reaction. He thought the difficulty breathing she experienced was due to her joint disease, however, he never diagnosed her with rheumatoid lung. Dr. Hamburger stated that the decedent initially refused to go to the emergency room on May 5, 2010 after the reaction, but agreed and went to St. Catherine's by ambulance. Dr. Shulman, he continued, spoke to him during the process, and ordered Decadron (corticosteroid) intravenously. Dr. Hamburger testified that Decadron could be used for an allergic

reaction or for an infusion reaction. The symptoms documented, he continued, would have been consistent with an allergic reaction, but, because she had no mucosal or cutaneous manifestations, no hives or angioedema, and there was rapid reversal of her symptoms, he felt the reaction was consistent with an infusion reaction. He then testified that she could have had an allergic reaction without mucosal or skin reaction. He stated that the wheeze could have been caused by swelling or anything which causes partial obstruction of an airway, including an allergic reaction. He indicated that the hospital sheet stated she had a reaction to the medication, and stated they were able to safely continue treatment because a minor allergic reaction would not be a reason to uniformly discontinue treatment. Rather, prophylactic means would be used in administering Actemra. However, he had not ruled out an allergic reaction on May 5, 2010.

Dr. Hamburger testified that an allergic reaction could cause wheezing and potentially more serious reactions which would be considered anaphylactoid, or anaphylactic reactions, and includes a drop in blood pressure to the degree of shock. He continued that an anaphylactic reaction is also commonly called anaphylactic shock. An allergic reaction, he continued, could also cause airway compromise leading to significant impairment and inability to ventilate or difficulty breathing, clamminess, bradycardia, fast heart rate, leakiness of blood vessels, and cardiac arrest, due to swelling of the tissues caused by IGE antibodies, histamines, and other chemcals that are released in the allergic reaction. Dr. Hamburger described *priming* as when the body does not respond to an antigen in an adverse way the first time, but with multiple exposures an immune response can occur, and subsequent exposures or allergic reactions could be of a much more significant nature than previous exposures. Changing the dose of the medication would not likely influence the reaction. An anaphylactic reaction would be the most severe example of an allergic reaction, he stated. The goal of treatment would be to stop the reaction, give oxygen, raise the blood pressure, and relieve the airway compromise. If a patient has a severe reaction, then the drug would be discontinued. He considered a severe allergic reaction would present with signs of airway compromise, or significant clinically meaningful change in blood pressure or other clinical event that caused the compromise of vital signs. Pruritus (itchiness), or perhaps minimal evidence without clinically significant change in vital signs, might be a non-severe allergic reaction.

Dr. Hamburger testified that an infusion reaction is related more to the amount, or more particularly to the rate of flow of the intravenous, and some reactions will alleviate when the intravenous is stopped, and then resumed at a slower rate, alleviating the symptoms. He stated that infusion reactions and allergic reactions are not synonymous. Symptoms associated with infusion reactions might include fever, chills, headache, nausea, itching, rash, hives, angioedema, back pain, chest tightness, chest pain, and fatigue, and may occur during an infusion or perhaps within 24 hours after the infusion. He then went on to testify that physicians may call these symptoms infusion reaction, or hypersensitivity reactions, or allergic reactions. He later testified that infusion reactions and allergic reactions cannot be 100% separated, and when he talks about infusion reactions, he sometimes allows room for the fact that there might be a minor allergic component.

Dr. Hamburger continued that for a non-severe allergic reaction, the possibility that there may have been an allergic reaction would be discussed with the patient, including a description of the ways in which these allergic reactions could be managed with pre-administration of antihistamine and corticosteroids. He stated that there was no specific format of prophylactic medication for the use of

Actemra. The patient would be advised that there would be monitoring of the infusion by the infusion nurse as it is begun, with a decision as to how to continue based upon the patient's tolerance. The full spectrum of risks, including anaphylaxis and death as possibilities are discussed. Although the decedent signed a consent form for treatment, Dr. Hamburger noted that the consent form did not include death as a possibility.

Dr. Hamburger continued that not all reactions that seem to be allergic become anaphylactic reactions. He continued that many of the reactions that are seen during the infusion or administration of biologic drugs are addressed with premedicating patients with corticosteroids or antihistamines, with overwhelming success. Premeditating, he stated, may stop the allergic reaction or control the severity of the reaction, or prevent an allergic reaction. Premedicating, he stated, may not work. With an allergic reaction, while it is happening, corticosteroids and antihistamines counteract it. With a severe anaphylactic reaction, epinephrine is given. Dr. Hamburger testified that if a patient has some type of medication reaction to an infusion of a biologic, clinical judgment is used to confirm that it was in fact a reaction, based upon the timing of the administration of the medication and the emergency of the symptoms. Generally, an allergic reaction would present clinically with itching, hives or other skin reaction, wheezing or shortness of breath, change in vital signs: blood pressure, pulse, and respiratory rate. He did not know if the rate of the infusion affected the severity of an anaphylactic reaction. He was not aware of how many infusions of Actemra that a reaction would usually occur.

Dr. Hamburger testified that if his office staff suspects an allergic reaction, the procedure is to stop the infusion, take vital signs, administer any of a list of medications, and provide supportive measures depending upon the symptoms, including antihistamines, corticosteroids, maybe epinephrine if there is low blood pressure, and eventually, oxygen. There is always a physician in the office when the infusions are being administered. The infusions are administered by registered nurses. The physician must order the epinephrine if it is to be given. EMS is called if the reaction is perceived as being more severe. He did not know if his office had any type of intubation equipment other than an Ambu Bag with a face mask. He had no mechanical ventilators in his office. The staff was trained in ALCS (advanced life support). He stated that if someone is having a hypersensitivity reaction, then very shortly after they receive a small amount of the drug, they react. Since decedent's death, office policy has been changed to provide two to three infusion nurses and enough staff to continue to care for the 20 other patients in the building while caring for the patient with the reaction. A phone call policy was instituted to call the front of the building where the physicians are so the physician can come to the back where the infusion area is, and upon arrival of the physician, the nurses can return to the care of their other patients.

Dr. Hamburger stated that he looks at the total picture because his obligation is to try as best as he can to characterize the reaction, and decide whether he can safely continue the medication with appropriate care, or tell the patient that they can no longer receive the drug. He felt the decedent was beginning to respond to the Actemra and she was desirous of continuing it. The risk of not taking Actemra would have been the continued progression of rheumatoid arthritis. People with rheumatoid arthritis die younger than other patients with mortality shortened anywhere from 3 to 17 years, and they are treated with consideration to their co-morbidities, he stated. He wanted to afford the decedent the opportunity of staying on Actemra. He had no idea how long she would have lived had the Actemra not been given and she had not died. Dr. Hamburger noted that on other occasions, the decedent had low

pressure during the infusions of Actemra, but before May 5, 2010, never experienced difficulty breathing, used accessory muscles to breathe, her oxygen saturation level did not decrease to 85, no wheezes were perceived, pallor was not noted, and sweating or diaphoresis was not noted. Because he believed that the decedent had suffered an infusion reaction on May 5, 2010, it meant to him that he could premedicate her and proceed with the infusion of Actemra on May 17, 2010, which he stated was "pretty much the standard of care."

Dr. Hamburger continued that if he thought the decedent had an allergic reaction on May 5, 2010, he would have premedicated her with corticosteroids prior to the May 17, 2010 infusion. He felt the decedent's reaction was minor enough that he could continue to treat her with Actemra rather than discontinue it. He testified that he could not exclude that the decedent had a "minor allergic reaction" on May 5, 2010. It is not his custom or practice to send patients to the emergency room for evaluation for infusion reactions or for just minor reactions, but Dr. Shulman, on May 5, 2010, wanted to rule out a cardiac event as she had shortness of breath and a drop in oxygen level. Dr. Hamburger testified that he was not present on May 17, 2010 when the decedent received the infusion of Actemra, and went into anaphylactic shock due to an allergic reaction. Dr. Rumore was present. He felt that the May 17, 2010 reaction was the decedent's first severe reaction to Actemra. The decedent's prior reaction on May 5, 2010, he stated, may have well included allergic elements. He stated that the decedent came to him already severely impaired before the current generation of drugs became readily available, that she suffered terribly and was severely compromised.

Dr. Hamburger stated that he did not take part in the conclusion or recommendation by way of letter of September 2010 from Genentech which set forth that, "[t]he diagnosis of hypersensitivity or anaphylaxis should be considered in any patient experiencing an infusion reaction during or following Actemra or RoActemra administration. If an anaphylactic or other serious hypersensitivity reaction occurs, administration of Actemra or RoActemra should be stopped immediately."

The moving defendants submitted the affirmation of Richard Furie, M.D., who affirms he is licensed to practice medicine in New York State and is board certified in internal medicine and rheumatology. He set forth his education and training, as well as his work experience. He indicated that he reviewed various materials, including but not limited to records from Rheumatology Associates, EMS, St. Catherine of Siena, the autopsy report, and the deposition transcripts of defendants Hamburger, Rumore, Gail Crichlow, and Dr. Schulman. It is Dr. Furie's opinion within a reasonable degree of medical certainty that at all times, the care and treatment rendered to the decedent by Dr. Hamburger and the staff at Rheumatology Associates fully comported with the standard of care.

Dr. Furie set forth that the plaintiff began treating at Rheumatology Associates on December 2, 1994, for rheumatoid arthritis, an autoimmune disease which causes inflammation of the joints with loss of joint function, pain, swelling, stiffness, and an inability to function in everyday life. Dr. Furie continued to set forth the decedent's treatment with Rheumatology Associates, including changing her medication "numerous times" in response to widespread pain and a deteriorating physical condition, with some improvement noted. In September 2009, Dr. Hamburger noted the decedent's RAPID score was 30, indicative of high disease activity. On November 16, 2009, when Dr. Hamburger saw the decedent, he prescribed a Medrol dose pack (a steroid) for six days for severe pain. A second dose pack was prescribed

"just prior to December 14, 2009." On December 14, 2009, Dr. Hamburger prescribed Prednisone, a steroid, however, by January 18, 2010, the decedent was cushingoid in that she was showing signs of steroid side effects. Dr. Furie continued that in light of the plaintiff's worsening symptoms, Dr. Hamburger decided to proceed with a course of Actemra, which had been FDA approved in December 2009.

Dr. Furie stated that Dr. Hamburger informed the decedent she would be started on the lower of two doses of Actemra, in accordance with the protocol. He discussed risks and benefits, and alternatives to Actemra with the decedent in detail, and he advised the decedent that Actemra could be associated with allergic reactions, anaphylactic reactions, and that anaphylactic reactions could cause death. He continued that the decedent signed a consent form on February 9, 2010, which consent set forth that the infusion of Actemra may cause reactions which are uncommon, but included hives, difficulty breathing, fever or chills, headache, or changes in blood pressure. He continued that the consent form also stated that the patient signing it is aware that more serious reactions may occur, and that by signing the form, the decedent agreed not to hold Dr. Hamburger or his staff liable for adverse events which may occur as a result of Actemra infusion.

Dr. Furie indicated that the decedent received her first infusion of Actemra on February 9, 2010. Although Dr. Furie did not set forth the dose, or the duration of the infusion, he stated she did not have any reaction after the infusion. During the second infusion of 224 milligrams of Actemra on March 10, 2010, she did not have any reaction to the infusion. At the time of her third infusion on April 7, 2010, of 220 milligrams of Actemra, she tolerated it without difficulty. Dr. Furie indicated that on May 4, 2010, Dr. Hamburger saw the decedent and noted her complaints had improved. Her fourth infusion was started on May 5, 2010, with 224 milligrams of Actemra to be infused over one hour. However, the infusion was stopped after about seven minutes as the decedent experienced shortness of breath, slight wheezing, and dizziness, without a change in her blood pressure. Thereafter, Paul Schulman, M.D. saw the decedent after the infusion was stopped. Oxygen was started. Decadron, a glucocorticoid, and intravenous fluids were given, and the decedent gradually improved. Dr. Schulman's differential diagnosis included an infusion reaction, allergic reaction, congestive heart failure, or primary lung problem, so he had the plaintiff transported to St. Catherine of Siena Hospital emergency room for evaluation. At St. Catherine of Siena, she was diagnosed with a medication reaction, treated, and was discharged.

Dr. Furie continued that the decedent had a mild infusion reaction and that it was within the standard of care to premedicate her and continue the Actemra because it was providing some relief to the decedent. Therefore, the decedent was instructed to take an antihistamine, Zyrtec, on May 16, 2010 and on the morning of May 17, 2010, prior to the next infusion with Actemra. Nurse Crichlow was present for the administration of the infusion with Actemra when the decedent complained of feeling dizzy and lightheaded after receiving 10 cc of Actemra. She was administered oxygen and Decadron, as well as intravenous saline solution. Dr. Furie stated that Dr. Rumore evaluated the decedent upon being notified of her reaction, and after a "very brief period," EMS was called. The decedent's pulse began to fade and CPR was commenced, an AED was set up for EKG monitoring, and she was administered epinephrine. Upon arrival to St. Catherine of Siena emergency room, the decedent was intubated and resuscitated. Her differential diagnosis was anaphylaxis for which she was administered high doses of intravenous steroids. However, the decedent died on May 18, 2010 from anaphylaxis.

It is Dr. Furie's opinion within a reasonable degree of medical certainty that at all times, the care and treatment rendered by Dr. Hamburger and the staff at Rheumatology Associates fully comported with the standard of care. Dr. Furie continued that Dr. Hamburger appropriately initially prescribed Actemra on February 9, 2010 in light of her physical condition and diagnosis; that he appropriately advised the decedent of the risks, potential complications and alternatives to treatment with Actemra, including allergic reactions, anaphylactic reactions and death; and appropriately obtained decedent's consent for administration of the drug. He continued that the proper dosage of medication was prescribed, the decedent was appropriately monitored on February 9, 2010, March 10, 2010, and April 7, 2010. Dr. Furie stated that Dr. Hamburger prescribed Actemra in an appropriate dosage on May 5, 2010, in accordance with the standard of care, and Dr. Schulman and the nursing staff appropriately responded when the decedent developed symptoms, timely called EMS, and had her transported to St. Catherine of Siena for evaluation.

Dr. Furie opined that Dr. Hamburger comported with the standard of care in prescribing Actemra on May 17, 2010 despite the decedent's previous infusion reaction, as the decedent's previous reaction did not comport with a moderate or worse allergic reaction to Actemra because there was an absence of mucosa, cutaneous, and respiratory symptoms, and no hypotension. Dr. Furie continued that Dr. Hamburger appropriately balanced the decedent's severe and progressive course of rheumatoid arthritis with her favorable response to Actemra, the decedent's desire to continue the medication, and the prior infusion reaction in considering whether to continue treatment with Actemra. He continued that it was within the standard of care for Dr. Hamburger to use his best medical judgment to prescribe Actemra on May 17, 2010, with antihistamines and steroids prior to its administration to prevent an infusion reaction; that appropriate and sufficient antihistamines and steroid medication were ordered in accordance with the standard of care; and that he ordered an appropriate dosage of Actemra on May 17, 2010. Dr. Furie added that the staff nurse Crichlow, and Dr. Rumore, comported with the standard of care in their treatment of the decedent after she developed symptoms on May 17, 2010; recognized and responded to those symptoms, and timely and appropriately administered CPR.

It is noted that the discharge summary from St. Catherine of Siena, by Lalitha K. Ranga, M.D., dated May 18, 2010, indicated that the patient was a 67 year old female with past medical history of severe rheumatoid arthritis who was being infused with tocilizumab (Actemra) at the office of her regular hematologist, Dr. Hamburger. She had three prior infusions of tocilizumab, but during the second infusion, she experienced hypotension and dyspnea with shortness of breath. Because she was symptomatic, she was given steroids and sent to the emergency room where she received steroids, intravenous fluids, was stabilized and discharged home. On May 17, 2010, the day of her third infusion, a few minutes into the infusion, she developed dizziness, and was dyspneic with respiratory distress, and hypotensive with a systolic pressure in the 90s. The infusion was stopped, Decadron 4 mg was given, and she was transferred to the emergency room, where she arrived in asytole. CPR was started and she was successfully resuscitated over 20 minutes in the emergency room. She was intubated, and placed on pressers. After various workups, it was determined that plaintiff was in renal failure with severe metabolic acidosis, and encephalopathy secondary to cardiac arrest. Seizure activity developed and was treated. Dr. Ranga stated that after much discussion, the family signed DNR papers, however, full treatment continued and she died on May 18, 2010.

The autopsy report by Odette R. Hall, M.D., dated July 23, 2010, stated the cause of death of the decedent was "anaphylaxis during intravenous infusion of tocilizumab for the treatment of rheumatoid arthritis."

Based upon the foregoing, it is determined that even if defendants' evidentiary submissions were in admissible form, defendants have not established prima facie entitlement to summary judgment, and plaintiff has raised factual issues which preclude summary dismissal of the complaint as to Dr. Hamburger and Rheumatoid Associates. Although Dr. Furie stated that Dr. Hamburger and the defendants comported with the standards of care in ordering and in the administration of Actemra for the plaintiff, even after the first allergic reaction/infusion reaction of May 5, 2010, he does not set forth the standard of care concerning administration of Actemra after such reaction. Nor did he indicate the warnings and precautions contained in the literature about continued use of Actemra after such reaction. There are factual issues raised by Dr. Furie concerning whether the decedent suffered an infusion reaction or an allergic reaction on May 5, 2010, and he does not define the terms to differentiate between both conditions, or state the bases for his opinions. There are factual issues concerning whether Dr. Hamburger should have considered whether the decedent suffered an allergic reaction on May 5, 2010, whether Dr. Hamburger should have stopped the Actemra after May 5, 2010, whether Dr. Hamburger should have ordered premeditation with steroids in addition to the antihistamines prior to administration of Actemra on May 17, 2010; and whether Dr. Rumore should have administered epinephrine at the office with the onset of the anaphylactic shock. Although Dr. Furie stated that Dr. Rumore administered epinephrine, Dr. Rumore stated that epinephrine was not ordered by him. The ambulance record indicates epinephrine and atropine were administered by them. There are factual issues as to whether or not the epinephrine was timely administered and whether Dr. Rumore departed from the standard of care in not having epinephrine administered prior to when it was on May 17, 2010. These factual issues preclude summary judgment to Dr. Hamburger and Rheumatology Associates.

To rebut a prima facie showing of entitlement to an order granting summary judgment by the defendant, the plaintiff must demonstrate the existence of a triable issue of fact by submitting an expert's affidavit of merit attesting to a deviation or departure from accepted practice, and containing an opinion that the defendant's acts or omissions were a competent-producing cause of the injuries of the plaintiff (*see* ***Lifshitz v Beth Israel Med. Ctr-Kings Highway Div.***, 7 AD3d 759, 776 NYS2d 907 [2d Dept 2004]; ***Domaradzki v Glen Cove OB/GYN Assocs.***, 242 AD2d 282, 660 NYS2d 739 [2d Dept 1997]). "Summary judgment is not appropriate in a medical malpractice action where the parties adduce conflicting medical expert opinions. Such credibility issues can only be resolved by a jury" (***Bengston v Wang***, 41 AD3d 625, 839 NYS2d 159 [2d Dept 2007]).

Here, the plaintiffs have opposed the within applications by submitting a redacted expert affidavit without submitting an unredacted affidavit to the court for *in camera* inspection, as required (***Marano v Mercy Hospital***, 241 AD2d 48, 670 NYS2d 570 [2d Dept 1998]). Therefore, the redacted version of the expert affidavit submitted by the plaintiff lacks evidentiary value (***Marano v Mercy Hospital***, 241 AD2d 48, 670 NYS2d 570 [2d Dept 1998]). "A party may successfully oppose a summary judgment motion without disclosing the names of the party's expert witnesses. In opposition to such a motion the party defending against a summary judgment motion may serve the movant with a redacted copy of its expert's affirmation/affidavit as long as an unredacted original is provided to the court for its in camera inspection

(***Marano v Mercy Hospital***, *supra*). This procedure preserves the confidentiality of the name of plaintiff's medical expert while also preserving plaintiff's obligation in opposing defendant's motion, in that by submitting a redacted affirmation and by offering the original to the court for in camera inspection, plaintiff has opposed the motion by evidence in admissible form (***Rubenstein v Columbia Presbyterian Medical Center***, 139 Misc2d 349, 527 NYS2d 680 [NY County 1988]). A copy of the affidavit with the expert's name and signature have not been provided to this court under separate cover. Accordingly, plaintiff's expert affidavit is not in admissible form sufficient to raise a triable issue of fact as to the defendants' alleged malpractice (***Rose v Horton Medical Center***, 29 AD3d 977, 816 NYS2d 174 [2d Dept 2006]). However, defendants have not objected to the same[1], and in considering said expert affidavit, it is determined that the plaintiff raises factual issues to preclude summary judgment, even had defendants demonstrated prima facie entitlement to summary judgment, which they did not.

Plaintiff's expert avers that he/she is licensed to practice medicine in California and is board certified in internal medicine, rheumatology, and allergy-clinical immunology. He set forth his education and training, and the records and materials reviewed. Plaintiff's expert stated that an allergic reaction occurs when the immune system aggressively reacts to a non-threatening substance, causes the release of, among other chemicals, histamines and leukotrienes from tissue, which in turn trigger an inflammatory response. During an anaphylactic reaction, mast cells and basophil cells release histamine which can cause inflammation of the airway with attendant difficulty breathing. Within the cardiovascular system, vasodilation, or widening of the blood vessels occur. The blood vessels become porous and leak vital plasma and fluid, with poor perfusion to the skin and vital organs, causing pallor. The dilated blood vessels also make cardiac function difficult, typically causing a drop in blood pressure with attendant dizziness and lightheadedness. Leukotrienes, he stated, have a slower onset with more powerful and longer lasting effects. The plaintiff's expert continued that anaphylactic responses carry the risk of death due to lack of oxygen or cardiac and/or organ failure due to poor perfusion. Once the immune system recognizes a normally non-threatening substance as threatening, it will likely continue to do so, with subsequent reactions typically more intense, as the body engages in boosting to produce more and more antibodies to fight the threat.

Plaintiff's expert stated that once a patient demonstrates clinical signs and symptoms of an anaphylactic reaction, the trigger of the reaction should either be discontinued permanently or administered with caution and with sufficient epinephrine to counter the reaction. Epinephrine, he stated, is the standard treatment for anaphylactic reactions and should be administered as soon as there are indications of an anaphylactic reaction. Plaintiff's expert continued that Dr. Hamburger's decision to administer Actemra on May 17, 2010 was a departure from good and accepted medical practice. The failure to administer epinephrine immediately was also a departure from good and accepted medical practice.

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[1]Defendants object to plaintiff's expert out-of-state affidavit because it lacks a certificate of conformity, however, because the person administering the oath for the out-of-state affidavit is a notary, the affidavit does not require authenticating certificate (*see* CPLR 2309 (c), ***Midfirst Bank v Agho***,__ AD3d__, 991 NYS2d 623, NY Slip Op 05788 [2d Dept 2014]; ***Ford Motor Credit Company v Prestige Gown Cleaning Service, Inc.***, 193 Misc2d 262, 748 NYS2d 235 [Civ Ct Queens 2002]; ***Firstcom Broadcast Services v New York Sound, Inc.***, 184 Misc2d 524, 709 NYS2d 329 [Civ Ct New York County 2000]).

Plaintiff's expert stated that on May 5, 2010, seven minutes after receiving intravenous Actemra, the decedent began to suffer an adverse respiratory reaction to the medication with a wheeze, shortness of breath and accessory muscle breathing; she was not moving air well; she became pale and experienced a drop in blood pressure; lightheadedness, and dizziness. She was administered Decadron, oxygen, and normal saline, and was seen at St. Catherine of Siena where she was stabilized and discharged. Thereafter, on May 17, 2010, Dr. Hamburger decided the decedent could continue receiving Actemra and that she should be pre-medicated with an antihistamine and an anti-inflammatory "to diminish the likelihood of recurring and magnitude." After administration of 100 ml of the medication, the decedent became dizzy and lightheaded; the Actemra was stopped and saline infused. Her oxygen saturation dropped to 86% and her blood pressure dropped. Decadron was administered "with no improvement noted." Plaintiff's expert continued that epinephrine was not administered. The decedent became unresponsive and was taken to St. Catherine of Siena Medical Center, where she died on May 18, 2010.

Plaintiff's expert disagrees that the reaction the decedent experienced on May 5, 2010 was " a minor allergic reaction." He opined that it was a major anaphylactic reaction to Actemra manifested by respiratory distress secondary to constriction of her airway, drop in blood pressure, dizziness, lightheadedness, and paleness due to vasodilation. He continued that even assuming the reaction was minor, the mechanism of boosting would cause subsequent reactions to be predictably worse. Therefore, stated plaintiff's expert, conflicting with the opinion of Dr. Furie, the decision by Dr. Hamburger to administer Actemra to the plaintiff on May 17, 2010, was a departure from good and accepted standards of medical practice. Thereafter, when the decedent suffered another severe anaphylactic reaction to the Actemra, Epinephrine, the only medication that can reverse the effects of anaphylactic reaction, was not timely administered. This failure to administer epinephrine, he stated, was a departure from good and accepted standards of medicine. These failures and departures from the standard of care, concluded plaintiff's expert, were the proximate cause and a substantial factor in causing the plaintiff's decedent's death due to severe anaphalytic reaction to Actemra administered on May 17, 2010.

Accordingly, motion (004) for summary judgment dismissing the complaint as asserted against Max Hamburger, M.D. and Rheumatology Associates is denied in its entirety.

Dated: Oct. 9, 2014

J.S.C.
HON. JERRY GARGUILO

____ FINAL DISPOSITION ___X___ NON-FINAL DISPOSITION