

DEFENSE PRACTICE UPDATE

MARTIN CLEARWATER & BELL LLP



THE CONTINUOUS TREATMENT DOCTRINE SET FORTH IN CPLR §214-A NOT APPLICABLE WHERE A PATIENT IS SEEN FOR REASONS OTHER THAN TREATMENT RELATED TO THE ORIGINAL TREATMENT

BY: ROSALEEN T. MCCRORY AND GREGORY A. CASCINO

The Continuous Treatment Doctrine set forth in CPLR §214-a provides for a toll of the statute of limitations in the event a patient continues to treat with the medical provider for the same condition. As noted by the Court of Appeals in *Young v. New York City Health & Hosps. Corp.*, “[t]he toll of the continuous treatment doctrine was created to enforce the view that a patient should not be required to interrupt corrective medical treatment by a physician and undermine the continuing trust in order to ensure the timeliness of a medical malpractice action or notice of claim.”¹

A “patient is not entitled to the benefit of the toll in the absence of continuing efforts by the doctor to treat a particular condition because the policy reasons underlying the continuous

This toll is only applicable to return visits instigated by the patient seeking treatment related to the original condition, and does not apply where a patient is seen for other unrelated reasons.

treatment doctrine do not justify the patient’s delay in bringing suit in such circumstances.”² “Because a patient who is not aware of the need for further treatment is not faced with the dilemma that the doctrine is designed to prevent, the primary focus in determining whether the doctrine applies in a given case must remain on the patient.”³ *Continued...*

1. 91 N.Y.2d 291, 296 (1998), quoting *Rizk v. Cohen*, 73 N.Y.2d 98, 104 (1989); *Borgia v. City of New York*, 12 N.Y.2d 151, 156 (1962).
2. *Massie v. Crawford*, 78 N.Y.2d 516, 519 (1991).
3. *Young*, 91 N.Y.2d at 296, quoting *Allende v. New York City Health & Hosps. Corp.*, 90 N.Y.2d 333, 337-338 (1997).

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THE CONTINUOUS TREATMENT DOCTRINE...

This toll is only applicable to return visits instigated by the patient seeking treatment related to the original condition, and does not apply where a patient is seen for other unrelated reasons. The toll also does not apply where a patient initiates return visits merely to have his or her condition checked, or where a patient simply has a continuing general relationship with a physician.⁴ Nor is it applicable where a physician merely performs routine or diagnostic examinations, even when conducted repeatedly over time, such as routine annual mammograms.⁵

Omissions do not amount to a course of treatment, thus a continuing failure to diagnose and establish a course of treatment for a condition does not amount to a “course of treatment.”⁶ A patient’s consultation with a new physician will sever the continuous treatment with the original physician where it manifests a termination of the continuing trust and confidence in the original physician with respect to his or her treatment for the original condition.⁷

CASE EXAMPLE

The limitations on this toll have been recently reaffirmed by the Supreme Court in a case against a major hospital and its highly specialized neurosurgical practice that was defended by MCB. In this case, Plaintiff was involved in multiple workplace incidents which resulted in constant and debilitating head and neck pain. She began undergoing physical therapy and was seen by a local pain management specialist, neurologist, and neurosur-

geon. Her condition did not improve despite conservative treatment, and in October 2007 she sought treatment from the Defendants who diagnosed her with multiple complex conditions. She also was independently diagnosed with a related hereditary connective tissue disorder.

Plaintiff underwent four procedures/tests from Defendants in 2008 to address her numerous conditions. She then had six visits with Defendants over the next four years for routine examinations and clerical issues, after which Plaintiff returned to Defendants in 2012 seeking treatment, and a month later she underwent a fifth and final procedure. Plaintiff claimed that her symptoms worsened following these procedures, and in April 2015 she commenced a medical malpractice action against Defendants.

Following discovery, MCB moved for summary judgment and dismissal of Plaintiff’s complaint on behalf of all Defendants, arguing as a threshold matter that the first four procedures occurred outside of the 2 ½ year statute of limitations, therefore her claims related thereto are time barred. Although Plaintiff did have six visits to Defendants between 2008 and 2012, she did not undergo any actual “treatment” during these visits as they were for routine examinations, to obtain assistance with disability and workers’ compensation applications and health insurance coverage issues, and/or for medical clearance for procedures performed by other physicians. Thus, since these visits were not part of a

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“continuous treatment,” she could not rely on the tolling provisions of CPLR §214-a. In opposition, Plaintiff argued that these six visits plus a number of e-mails between her and Defendants between 2008 and 2012 established a continuous course of treatment.

In a lengthy Decision & Order, the Nassau County Supreme Court held that Plaintiff’s first four procedures occurred outside of the 2 ½ year statute of limitations, and that her claims related thereto are time barred. Notably the Supreme Court agreed with MCB’s position that Plaintiff did not undergo any actual “treatment” during the six visits between 2008 and 2012, and that the e-mails exchanged during this interval did not relate to treatment either.

5. See *Flaherty v. Kantrowich*, 144 A.D.3d 542 (1st Dep’t 2016); *Vendetti v. St. Catherine of Siena Med. Ctr.*, 98 A.D.3d 1035 (2d Dep’t 2012); *Nespola v. Strang Cancer Prevention Ctr.*, 36 A.D.3d 774 (2d Dep’t 2007).

4. See *Massie v. Crawford*, 78 N.Y.2d 516 (1991); *Marks v. Model*, 53 A.D.3d 533 (2d Dep’t 2008).

6. *Young*, 91 N.Y.2d at 297.

7. See *Gomez v. Katz*, 61 A.D.3d 108 (2d Dep’t 2009).

As noted by the Supreme Court, “the continuous treatment doctrine does not contemplate circumstances where a patient initiates return visits merely to have his or her condition checked.” Rather the doctrine contemplates “a timely return visit instigated by the patient to complain about and seek treatment for a matter related to the initial treatment.” Thus, since Plaintiff did not schedule these six visits to seek “treatment” related to the procedures she had previously undergone, they were not part of a “continuous treatment,” and she cannot rely on the tolling provisions of CPLR §214-a.

This case exemplifies the well settled legal principle that under CPLR

§214-a, a patient’s continuing general relationship with a physician or routine health examination will not satisfy the doctrine’s requirement of ‘continuous treatment’ of the condition upon which the allegations of medical malpractice are predicated. Accordingly, wherever there is a significant interval between the procedures alleged in a complaint, the extent of the doctor/patient relationship during this interval must be explored as a means of potentially limiting the claims alleged.



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DEFENSE OF A HOSPITAL BASED CLINICAL TRIAL

BY: BRUCE G. HABIAN

Clinical trial litigation, although commonly presented as a medical malpractice matter, involves much broader issues than just departure testimony from established standards of care. Why?; because there is no established standard of care - remember, the undertaking is called a “clinical trial.” In addition to negligence causes of action, plaintiff’s counsel typically pleads breach of contract and fraud theories of recovery. The broad subject matter involved, and the extensive documentation that exists with regard to Institutional Review Board (IRB) data, allow for multiple areas of liability exposure. This discussion will outline the pertinent subjects that are involved in these cases.

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established multiple data points for the protection of human subjects. Pure experimentation is to be avoided and the hospital sponsored trials must adhere to established FDA protocols. A teaching hospital based clinical trial - as opposed to a commercial based study - involves the hospital’s IRB, and it’s support of the Principal Investigator’s (PI) plan of study.

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The investigational minutes outline the scope of the study. Multiple meeting notes are discoverable by plaintiff’s counsel, and the various members of the IRB, in different medical disciplines, are subject to deposition testimony. Many of these individuals practice in medical specialties distinct from the Principal Investigator’s expertise. Administrative personnel also staff the IRB. In addition, during the several years’ duration wherein the data is collected and the refinement of the clinical trial is established, there can be a “musical chair” aspect to the IRB membership, with participants being frequently replaced. This can give rise to a lack of uniformity concerning the progression of the clinical trial data. Essentially the IRB takes the data from the PI, and determines if the FDA protocols are being satisfied. However, the focus of the clinical trial,

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DEFENSE OF A HOSPITAL BASED CLINICAL TRIAL

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its safety and efficacy sufficiencies, rests entirely with the Principal Investigator.

The concept of ethics is pertinent in these cases; great care is outlined by the Federal regulations so that human subjects are not misled into joining a clinical trial, particularly those with extreme life-threatening illnesses. Phase I safety clinical trials should have no focus on beneficial treatment, as such data belongs in an efficacy trial (Phase II studies). Realistically, there is some natural crossover between Phase I and Phase II studies, as most subjects who join a clinical trial do expect some health benefit relative to their participation.

The Principal Investigator must adhere to the established criteria for the trial; there can be no deviation, based upon any nuances of the subject's health status, that can be allowed to expand the cohort for the clinical trial. The PI can be criticized for violation of what is known as the "common rule"; this issue addresses the various vulnerabilities of the patients, when their treating physician recommends them for inclusion in the trial. There cannot be any perceived coercion for these subjects relative to clinical staffing.

Pertinent to the selection process is the issue of informed consent. There must be a dedicated consent form that outlines the focus of the clinical trial for the disease entity in question, the inclusion data, and how the study protocol may differ from standard medical practices for the condition in question. This must be written in simple language and reviewed in detail with the subject patient. The timing of execution of the consent form must be well in advance of the start of the clinical trial protocols. This allows for pertinent reflection over an extended period of time between patient and family members so as to demonstrate a true informed consent. Once again, the Federal regulations have stringent requirements for the consenting process. There should be no exculpatory language contained in the form, and no waiver of potential litigation rights if there are breaches of care in the future.

Concerning adverse events, the Federal rules require early reporting of such events whether they were foreseeable or not. New data that was unanticipated concerning the mechanism of the adverse event must be listed in detail for the protection of subsequent members of the patient population yet to be enrolled in the trial.

In presenting the defense of the clinical trial, the natural consequences of the underlying disease entity must be understood. This allows for potential data concerning improved clinical status for the patient or extended life expectancies.

CONCLUSION

This litigation has a minefield of possibilities for recovery. Only a thorough review of all the information involved in crafting the clinical trial, as well as interim changes in the safety protocols, will allow for a successful defense. The interview process of all IRB members, past and current, including those critical of the study, must be undertaken well in advance of their depositions, so that a consistent defense position will be established.



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POTENTIAL MALPRACTICE EXPOSURE ASSOCIATED WITH RETAIL MEDICAL CLINICS

BY: DANIEL L. FREIDLIN AND MICHELLE A. FRANKEL

Increasingly, patients are searching for convenient 24/7 access to health care. In recent years, large retail stores have partnered with health insurers to deliver medical care. Retail health clinics can now be found within supermarkets, discount superstores and drug stores. The development of retail medical clinics (hereinafter “Clinics”) are appealing to patients because they enable obtaining medical care, filling prescriptions and purchasing other goods all in one place at one time. While there are benefits to Clinic care, patients need to understand what services can and cannot be provided. Similarly, health care providers who practice at these Clinics must be aware of the potential for professional malpractice risk if services are not provided in accordance with the standard of care.

Clinics are generally suited to provide patients with easy access to health care for simple health issues, such as the common cold and flu. Proponents of Clinic care argue that it limits unnecessary emergency department visits and is more convenient than a visit to one’s primary care physician because typically no appointment is necessary. While Clinics provide benefits such as convenient, cost-effective access to health care, there are potential concerns. These concerns include the lack of direct physician oversight, fragmentation of healthcare and that individuals may seek clinic care for a healthcare problem that is beyond the scope of the expertise of the healthcare provider rendering the services.

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As Clinics are typically staffed with a mid-level provider, such as a physician assistant or nurse practitioner, the scope of what medical services can be provided is dictated by state law and will vary. Clinics may not be equipped to provide pediatric care. In addition to these legal limitations, the scope of treatment that can be rendered at Clinics is further constrained by a relative lack of available medical equipment as compared to a hospital emergency department, urgent care center or physician office. In this regard, the American Medical Association House of Delegates (AMA HOD) recently suggested that Clinics should have a “well defined and limited scope of clinical services”, should list the services they offer, and should make available the qualifications of the health care professional that will be providing care. This assists patients in making an informed decision as to whether

to rely on the clinic for health care or whether to present to their primary care physician or even the emergency department. The AMA HOD has also recommended that retail health clinics neither expand their scope of services beyond minor acute illnesses including but not limited to sore throat, common cold, flu symptoms, cough, and sinus infection nor expand their scope of services to include infusions or injections of biologics.¹

In addition to having the list of services available for patients, the health care professional providing the medical treatment at the Clinic must remain cognizant that the patient’s presenting complaint i.e. persistent cough may be a sign of a more serious underlying medical problem. If the more serious underlying issue goes undiagnosed and untreated, this can result in a negative outcome for the patient and malpractice exposure for the healthcare provider.

Another potential issue and concern that has been raised includes that healthcare providers treating patients in a Clinic do not communicate with primary care providers about the care rendered and that patients who receive clinic care rarely seek or receive follow-up care. The healthcare providers evaluating the patient in a Clinic setting have limited information regarding the patient’s prior medical history beyond what the patient chooses to share. Further, there may be limitations in the continuity of care following treatment rendered at a Clinic. In this regard, the AMA

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1. See, Reports of the Council on Medical Service, 2017 Annual Meeting, available at <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/hod/a17-cms-reports.pdf>

POTENTIAL MALPRACTICE EXPOSURE...

HOD recommends the use of electronic medical records to transfer information about the care rendered to the patient's primary care physician. As with any transfer of private health information, patient consent is required to comply with HIPAA. Any such communication should be documented so that there is a record that it occurred. The AMA HOD also recommends that patients be provided with visit summaries, and that these summaries are also provided to the patient's local physicians. It has also been recommended that Clinics use local physicians as Medical Directors or Supervisors of clinic care.²

Despite the trend toward patients seeking convenient care from Clinics, there have been few lawsuits directed at Clinic care. However, it can be anticipated that the number of lawsuits will rise as Clinic care continues to become more prevalent. While the AMA HOD evaluated the potential issues associated with Clinic care mainly from the perspective of patient safety, the same themes can likely be applied to what a prospective plaintiff's attorney might argue when advancing their claim. Specific issues that may give rise to litigation will of course include alleged misdiagnosis and improper treatment, but also there is the potential for claims including failure to have proper policies and procedures in place, failure to ensure proper physician supervision, failure to properly refer the patient to a physician or emergency department, and the failure to communicate with a patient's primary care physician. These

theories may create direct liability for the Clinic and their staff and may also create vicarious liability for the Clinic and/or retail location housing a clinic. With regard to the latter, even if the medical care providers are not employed by the retail store, there may be vicarious liability under an ostensible or apparent agency theory where the patient reasonably believes that the medical services are being provided by the retail store. If the medical care is being provided by an independent contractor that is not employed by the retail location, consideration should be given to making that clear in writing to the patient to try to limit potential vicarious liability. A physician who directly or indirectly supervises a mid-level provider rendering the care may also be vicariously liable. Whether a supervising physician can be held liable is a fact specific analysis that is also dependent on whether there is a collaborative practice agreement, the degree of independence afforded to the mid-level⁴ provider and individual state laws.

While there have been few lawsuits directed at Clinic care, there is no reason to believe that these cases will not be evaluated like other malpractice cases. Therefore, it is important that all symptoms, complaints, testing, diagnoses, treatment recommendations be well documented. There is currently no specific requirement that the mid-level provider rendering treatment in a Clinic communicate directly with the patient's primary care

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physician, but such communication has been recommended by the AMA HOD and thus we can anticipate that a plaintiff's lawyer will argue that it is required. To avoid a potential HIPAA violation, consent should be obtained from the patient prior to any transfer of health information.



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2. *Id.*

3. As one example, in *Medeck v. Antis*, a plaintiff sued a nurse practitioner, her supervising physician, Minute Clinic, LLC and CVS Caremark Corporation for failure to diagnose *Streptococcal* sepsis in a patient believed to have a routine sinus infection. The plaintiff alleged a failure to diagnose and failure to timely refer for further treatment.

4. Many states, including New York, afford mid-level providers such as Nurse Practitioners the ability to practice independently.

MCB CASE RESULTS

October 2018: Senior Trial Partner Daniel Freidlin assisted by Partner Aryeh Klonsky and Associate Jacqueline Wild obtained a defense verdict in Supreme Court, Queens County. The case involved a 71-year-old married woman who claimed that our client radiology facility and employed technologist negligently performed a mammogram resulting in rupture of her 29-year-old breast implant. Although the compression forces used during the mammogram at issue were triple those used in the past, the defense established through our expert (and plaintiff's expert) plastic surgeon that breast implants have a known lifespan of 10-20 years and that rupture was an accepted risk of mammography. Further, we established through experts for both sides that the rupture was present on the first view of the subject mammography, and thus it would be impossible to prove when the rupture occurred or that it was due to negligent compression (implant rupture is generally asymptomatic). In addition to arguing that mammography was focused on breast cancer prevention and not breast implant protection, we argued that the plaintiff's claim was speculative since nobody could prove when the rupture occurred. The jury returned a unanimous defense verdict in under an hour.

October 2018: Senior Trial Partner Jeff Shor and Associate Conrad Chayes obtained a dismissal in Supreme Court, Bronx County. The case involved a 47-year-old woman who alleged that our client dentist was negligent in the dental work performed over a number of years resulting in removal of all of her teeth, bone scoring and grafting. Our client dentist passed away which complicated the defense given that he had not entered a single progress note in the record over the last seven months of treatment. The defense moved to dismiss on numerous grounds including statute of limitations and failure to properly serve the Estate. Our proof included obtaining an Affidavit from the Suffolk County Public Administrator showing that service was improper. Our motion was granted and all claims were dismissed.

November 2018: Senior Trial Partner Jeff Lawton, assisted by Associate Michael Bastone, obtained a defense verdict in Supreme Court, New York County. The case involved an 87-year-old woman who alleged that our client Hospital and surgeon failed to timely diagnose a bowel perforation following a robotic-assisted hysterectomy. It was claimed that this led to sepsis and ultimately death. The defense was able to establish that the patient was clinically stable in the immediate postoperative period. It was established that the defendants timely initiated treatment when the patient developed abdominal distention, pain, fever and hypotension. The jury returned a defense verdict in less than an hour.

November 2018: Senior Trial Partner Tom Mobilia, Partner Yuko Nakahara and Associate Jason Kaufman obtained summary judgment in Supreme Court, Queens County. The case involved a 45-year-old married woman who presented to the hospital with transient neurological complaints. Plaintiff alleged that our client Hospital and emergency department physician failed to administer "clot busting" tPA to treat a stroke resulting in severe, permanent, neurological deficits. Although the patient did present to the emergency department with neurological deficits, they were transient in nature and thus we argued that tPA was not indicated. Further, we argued that our clients appropriately deferred to the codefendant neurology consultants. In opposing our motion, the plaintiff improperly relied upon a new theory of liability not claimed in the Bill of Particulars. In Reply, we emphasized that plaintiff could not raise new theories of liability in opposition to a summary judgment motion. Justice Peter O'Donoghue agreed with our position and dismissed the case.

February 2019: Senior Partner Rosaleen McCrory, assisted by Of Counsel Elizabeth Sandonato, obtained a defense verdict in Supreme Court, Nassau County. The case involved a 73-year-old woman who called our client internist's medical practice reporting that she felt ill with fever and a deep cough. She declined to present for an office visit as she felt too sick. She was told to schedule an appointment when she felt well enough and in the interim was prescribed antibiotics. On examination five days later, she reported feeling better but was fatigued and felt as though she pulled a muscle in her chest from coughing. Two days later, she was diagnosed with a heart attack and died one week later. Plaintiff contended that the complaints were signs of an ongoing "stuttering" heart attack. The defense established through expert testimony that it was reasonable to treat decedent for a presumed infection, and that the trend of the cardiac enzymes demonstrated that the heart attack occurred after the last contact with the defendants. The jury returned a unanimous defense verdict.

WHAT'S NEW AT MCB?

NEW MCB PARTNERS

Martin Clearwater & Bell LLP is pleased to announce the addition of four new partners to the Firm, effective January 1, 2019. Please visit our website at mcblaw.com to read their bios and learn more about their areas of practice.



Matthew M. Frank



Aryeh S. Klonsky



Jeffrey W. Stupak



Christopher A. Terzian



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In addition to the Tier 1 ranking above, the Firm also received recognition as National “Best Law Firm” in Health Care Law, Tier 3, and as Regional “Best Law Firm” in New York City in Health Care Law, Tier 2. The U.S. News website states: “Firms included in the 2019 Edition of “Best Law Firms” are recognized for professional excellence with consistently impressive ratings from clients and peers. Achieving a tiered ranking signals a unique combination of quality law practice and breadth of legal expertise.”

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