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THE MEDICAL MALPRACTICE ISSUE

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President's Column

GARY A. ROME, ESQ.*

Dear DANY Members, Colleagues, and Sponsors:

It has been a privilege and an honor to have served as President of DANY during the past year. As we welcome Margaret Klein as President of DANY, I would like to take the time to thank so many individuals who have allowed the past year to be such a striking success.

Many thanks are owed to our sponsors who allowed DANY to reach new heights in offering informative and timely CLE programs, our two annual dinners, our golf outing, the diversity program and its 10 monthly sessions, our amicus briefs, and of course the Defendant. Without your continued and overwhelming support, DANY could not have enjoyed the success we have achieved over the last year.

I would also like to thank all of the committee chairs, my fellow officers, and all board members who unselfishly gave their time, effort, financial, and moral support to so many of our programs. Whenever the need arose, these individuals responded with the support that was needed to make every event that DANY held a smashing and often record breaking success for the organization. In particular, I would like to thank the CLE committee, the diversity committee, our amicus committee, those who have submitted articles and those who have worked on publishing the Defendant, and our golf committee. What a terrific effort and what terrific results you have enjoyed.

Of course, without the support of our membership, none of our goals could have been achieved. I would like to thank all the members who attended the many events that were held this year or who contributed to one of those events. On behalf of the board, we extend our sincere gratitude and look forward to another stellar year. Please continue to offer comments and suggestions as to how DANY can best serve the defense bar in New York.

Most of all, and without in any way attempting to lose focus on the superb efforts already mentioned, I would like to thank our Executive Director, Tony Celentano. Tony, who has indicated a desire to retire from his position at DANY in the near future, has been the heart and soul of DANY for nearly four decades. Tony's unquestioned devotion to the organization is unparalleled. Without Tony's leadership, DANY could never have come close to being the organization that it has become. On behalf of everyone associated with DANY, thank you Tony for all your efforts over the years. This organization will be forever indebted to you for your service.

Reflecting on the three agenda items that DANY sought to pursue this past year, we are very thankful for the results that were achieved. DANY continues to partner with other bar associations in various forums including CLE programs and our diversity program. We have at least two CLE programs scheduled for the fall with other bar associations and have received inquiries from other organizations as well. In addition, discussions have been held with other bar associations who are seeking to co-sponsor a diversity program for next year as well.

Speaking of the diversity program, we are so justifiably proud of the accomplishments that were enjoyed this year. Over ten months, our diversity committee, the volunteer mentors, our guest lecturers and panelists, and all of the participants, worked incredibly hard at making the program one of the most outstanding diversity offerings in the State and in the country. I have received phone calls from all over the United States complimenting the program and raising inquiries as to how their

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* *Gary Rome is a partner at the law firm of Barry, McTiernan and Moore located in New York City.*

President's Column

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organization could offer a similar program. There was no greater honor for DANY over the last year than having Claire Rush accept the New York Law Journal's Diversity Initiative award for being one of the top diversity programs in the State. That award stands as a true testament to the success of our diversity program.

Finally, we have made great strides in turning DANY into a statewide defense organization. Many meetings have been held and we are continuing to add to our current list of upstate attorneys who wish to enjoy the many benefits that DANY has to offer. We are very encouraged by the response we have received to date and look forward to continuing to solicit upstate members with the hope that we can begin to conduct upstate programs in the upcoming year.

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I feel very blessed to have been able to serve as President of DANY at such an exciting time. The hard work and precedents established by so many past Presidents and DANY leaders made my job so much easier.

I know that DANY has a very bright future and many more accomplishments to achieve. Thank you for supporting DANY.

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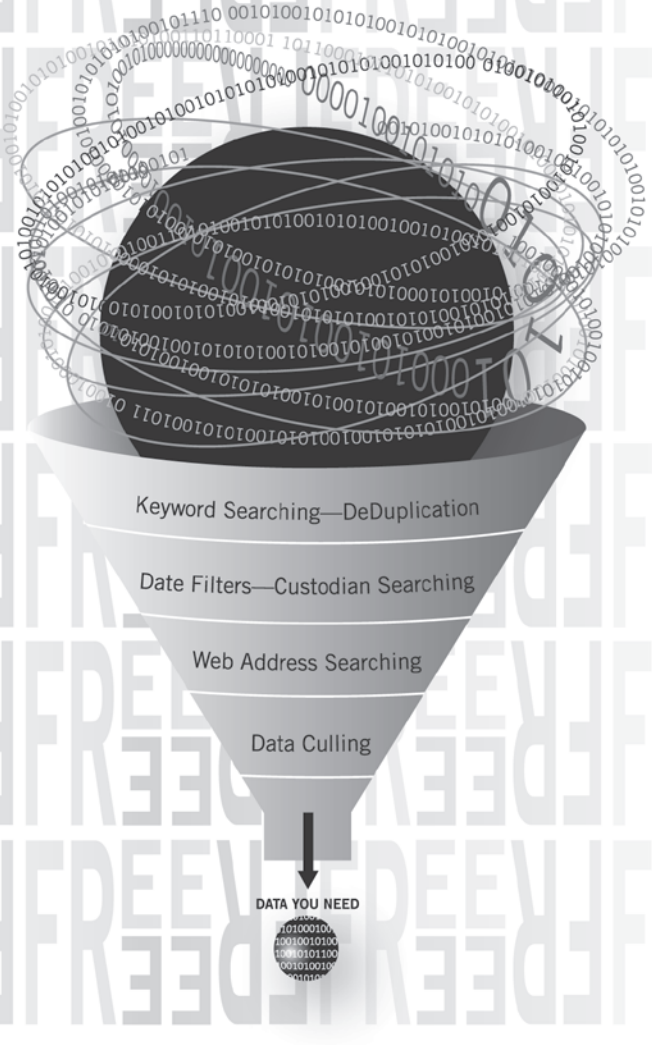

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Federal Preemption and Primary Jurisdiction: Vital Defenses in Prescription Drug and Medical Device Litigation

JOHN J. MCDONOUGH, ESQ. * & RYAN T. KEARNEY**

When tasked with defending prescription drug and medical device litigation, counsel must leave no stone unturned in order to protect their clients from the high exposure potentially incumbent upon them. Two indispensable defenses in such cases rest on the doctrines of federal preemption and primary jurisdiction. These closely related principles hold that states cannot regulate subject matters that are under the exclusive purview of federal laws, regulations and other administrative control, therefore rendering plaintiffs unable to seek redress under causes of action and theories based upon preempted state law. Thus, defense counsel in prescription drug and medical device cases must strive to establish the federal laws and regulatory landscape applicable to plaintiff's allegations, and employ them as grounds for preemption and dismissal of plaintiffs' state law claims.

The doctrine of federal preemption is rooted in the Supremacy Clause of the United States Constitution, at Article VI cl. 2, which reads:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, anything in the Constitution or Laws of any State to the contrary notwithstanding.

The Supremacy Clause therefore invalidates, or "preempts," any "state laws that interfere with, or are contrary to, federal law." *Hillsborough County v. Automated Medical Laboratories,* 471 U.S. 707, 712 (1985). Preemptive effect may be attributed to federal statutes as well as validly promulgated administrative regulations. *See Teixeria v. St. Jude Med., Inc.*, 2015 WL 902616, at *5 (W.D.N.Y. Mar. 3, 2015). Such federal law may then be applied to preempt and invalidate common law precedent as well as state statutes. *See, e.g., Pilot Life Ins. Co. v. Dedeaux,* 481 U.S. 41, 47-48 (1987) (preempting common law tort and contract claims); *Simon v. Smith & Nephew, Inc.,* 18 F.Supp.3d 423, 425 (S.D.N.Y. 2014) (same). Thus, it is imperative for defense counsel to determine the existence and extent of federal laws, regulations and other administrative guidance regarding the particular prescription medication or medical device in question. Such discovery may ultimately provide a complete defense to one or more causes of action asserted in a plaintiff's complaint.

However, it must be noted that courts are often reluctant to preempt a subject traditionally regulated by state law, absent clear Congressional intent to do so. *Potts v. Rawlings Co., LLC*, 897 F.Supp.2d 185 (S.D.N.Y. 2012). *See also Hughes v. Ester C Co.*, 2015 WL 1469197 (E.D.N.Y. Mar. 27, 2015) (stating that a presumption against preemption applies "with particular force" in such situations). In conducting this inquiry, courts may find the necessary Congressional intent indicated through a federal law's "express language or through its structure and purpose." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008) (further stating that "the purpose of Congress is the ultimate touchstone in every pre-emption case").

If the intent to preempt and invalidate state law is not expressly stated, the court may still afford preemptive effect by determining that the intent to preempt was implied in enacting the federal law. Courts may find such implied intent if the "structure and purpose" of the federal law demonstrate an implicit preemptive intent, or "if the federal and state laws are in irreconcilable conflict with one another," otherwise known as "conflict preemption." *See Johnson v. N.Y. State Dep't of Corr. Servs.*,

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Federal Preemption and Primary Jurisdiction: Vital Defenses in Prescription Drug and Medical Device Litigation

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709 F.Supp.2d 178, 187 (N.D.N.Y. 2010). Conflict preemption may be applied to wholly invalidate any state laws in particular subject matters, or it can alternatively be applied to invalidate only the portion of state law that "actually conflicts with federal law." *Hillsborough*, 471 U.S. at 713.

Where no direct conflict is found, preemption may still apply under the related principles of field and obstacle preemption. Field preemption exists "where Congress has legislated so comprehensively that federal law occupies an entire field of regulation and leaves no room for state law." *Atlas Van Lines, Inc. v. Tax Appeals Trib. of the State of New York*, 123 A.D.3d 168, 174 (3d Dep't 2014). Similarly, obstacle preemption may apply where state law creates an obstacle to the accomplishment and achievement of the full purposes and objectives of Congress. *N.Y. SMSA Ltd. P'ship v. Town of Clarkstown*, 612 F.3d 97, 104 (2d Cir. 2010). Thus, in effort to convince the Court that plaintiff's state law claims should be preempted by federal law, counsel should assert alternative arguments under each theory of federal preemption.

Further, in addition to raising the defense of federal preemption, counsel should also assert arguments based on the related doctrine of primary jurisdiction. The April, 2015 decision by the Appellate Division, Second Department in *Schwartz v. E. Ramapo Cent. Sch. Dist.* concisely summarizes this principle as follows:

> The doctrine of primary jurisdiction provides that where the courts and an administrative agency have concurrent jurisdiction over a dispute involving issues beyond the conventional experience of judges . . . the court will stay its hand until the agency has applied its expertise to the salient questions. The doctrine applies where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body; in such a case the judicial process is suspended pending referral of such issues to the administrative body for its views." *Schwartz v. E. Ramapo Cent. Sch. Dist.*, ___ N.Y.S.3d ___, 2015 WL 1447227, at *2 (2d Dep't Apr. 1, 2015) (internal citations omitted).

Thus, where the subject matter of plaintiff's allegations would be more appropriately determined by the expertise of an administrative agency, it is not the province of the Court to usurp the agency's authority. Further, in addition to staying the litigation to allow the relevant agency time to rule on the issue, courts are also entitled to dismiss the action altogether (although likely without prejudice). *Goldemberg v. Johnson & Johnson Consumer Cos.*, 8 F.Supp.3d 467, 476 (S.D.N.Y. 2014). This renders the defense of primary jurisdiction another powerful tool in the hands of counsel defending prescription medication and medical device litigation.

Of course, prescription medications and medical devices are heavily governed by federal statutes and regulations, including but not limited to the Federal Food, Drug and Cosmetic Act of 1938 ("FD&C Act"), the Kefauver-Harris Amendments of 1962, the Medical Device Amendments of 1976, the Prescription Drug Marketing Act of 1987 ("PDMA"), and the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), to name a few. In addition to the extensive statutes and regulations already in place, these industries are also subject to constant supervision and regulation by the Food & Drug Administration ("FDA") and its sub-agency, the Center for Devices and Radiological Health ("CDRH"), which issue advisory opinions and administrative rulings on a regular basis. As such, counsel must be aware of the various laws and regulatory framework potentially applicable to the prescription medication or medical device in question, and continuously monitor what guidance, if any, that is or has been issued by FDA during and prior to the litigation. These efforts are essential to establishing grounds for federal preemption, and thereby conducting an adequate defense in the case at hand.

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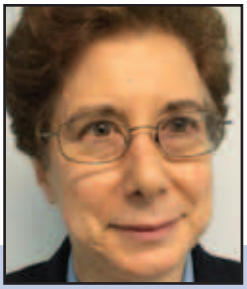
Does a consulting physician form a physician-patient relationship?



JUDITH MAXWELL*

Since at least 1898 in Pike v. Honsinger, 155 N.Y. 201, the Court of Appeals has consistently held that the "law relating to malpractice is simple and well settled,although not always easy of application. A physician and surgeon, by taking charge of a case, impliedly represents that he possesses, and the law places upon him the duty of possessing, that reasonable degree of learning and skill that is ordinarily possessed by physicians and surgeons in the locality where he practices, and which is ordinarily regarded by those conversant with the employment as necessary to qualify him to engage in the business of practicing medicine and surgery."

Defining the physician patient relationship has been at the heart of many summary judgement motions and jury trials. Just a few are: Davis v. Tirell, 110 Misc. 2d 889, 1981; Nevarez v. Mendez, NY Jury Verdicts, April 19, 1994; Lewis v. Capalbo, 280 A.D.2d 257, 2001; Garofalo v. State of New York, Jury Verdicts, November 21, 2003; Dunn v. Khan, Jury Verdict September 28, 2007; Uffelmann-Knepfing v. Fernandez, Suffolk County, N.Y. Misc. 2013.

Today, with the proliferation of hospital systems and large practice groups, where patients go from one physician to another physician in the same practice group and from one hospital to another within the same system, it is becoming harder to evaluate with whom a patient has developed a physician patient relationship.

In addition, it is not infrequent to have a "consulting" physician who is a defendant in a medical malpractice suit argue that he or she only gives recommendations that the attending in the hospital has the duty to evaluate and decide to accept, modify or reject. The attending argues that the reason for having a "consulting" physician evaluate a patient for a particular condition is that condition is outside his or her area of expertise. Therefore, the attending is relying on the "consulting" physician. Does the "consulting" physician have a physician patient relationship? Is there a consulting physician-patient relationship that should be recognized as a legal relationship?

Adding to the difficulty of determining if a physician patient relationship exists is the proliferation of specialties. Once upon a time radiologists argued that they did not have a physician patient relationship and therefore did not have a duty to inform patients of negative results. Today, any New York female who has had a mammography performed in a radiologists office will receive at least a notice of the results if not a copy of the report directly from the radiology facility. This change was not voluntary, it was because of a medical malpractice suit.

Today we have overlapping specialties, such as obstetricians and maternal fetal medicine specialists. We all know that obstetricians pay a very heavy premium for their malpractice insurance because if a delivery goes bad, the jury award may be outrageous. Does a obstetrician protect himself from claims of malpractice by sending his patient to a maternal fetal medicine specialist? Only if the maternal fetal medicine specialist has a physician patient relationship.

There are many scenarios that happen frequently with obstetricians and maternal fetal medicine specialists:

a) a patient is sent by her obstetrician to a maternal fetal medicine specialist early in the pregnancy who finds a normal pregnancy based on an ultrasound or similar testing and refers the patient back to the obstetrician;

b) early in the pregnancy a maternal fetal

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* *Judith Maxwell is a member of the NYS Medical Malpractice Defense Bar Association and is actively engaged in defending physicians in medical malpractice actions.*

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medicine specialist recommends a repeat visit in the second trimester to reevaluate a normal pregnancy;

c) early in the pregnancy a maternal fetal medicine specialist evaluates the patient as a high risk pregnancy, does not assume any of the care, but only sends the patient to her obstetrician for routine prenatal care and does not recommend any other follow-up care;

d) early in the pregnancy a maternal fetal medicine specialist evaluates the patient with a high risk pregnancy and takes over the care of the patient;

e) a patient near or at term is sent by her obstetrician to a maternal fetal medicine specialist who advises hospitalization for monitoring and management to the hospital of the obstetrician's choosing;

f) a patient is at term, goes to a hospital where her obstetrician has privileges and sees her, but is also presented on rounds by the house staff to the hospital's maternal fetal medicine specialist as part of the residency program. The specialist never writes a note, never writes an order, but is named in the residents' notes and nursing notes as being present and discussing the case.

Assume that in each of these scenarios an infant is born who has some type of developmental delays. Since plaintiffs do not care where the money comes from, they name both the obstetrician and the maternal fetal medicine specialist in each of the above scenarios.

Scenario "a" should not establish a physician patient relationship beyond that one and only visit. However, the potential exists for a medical malpractice claim if the evaluation during that visit was questionable. If a plaintiff can prove that a fetus was under stress and has hypoxic brain damage that was probably present at the time of the visit to the maternal fetal medicine specialist, that could be sufficient for the specialist to belong in a medical malpractice action.

In scenario "d" the maternal fetal medicine specialist is clearly in charge of the pregnancy and has a physician patient relationship. In scenario "c" the maternal fetal medicine specialist ends his relationship at the end of the first visit, but was that medical malpractice as the evaluation was a high risk pregnancy? I argue no. As long as the specialist made clear to the obstetrician and the patient that it was a high risk pregnancy, it is up to the obstetrician to send the patient to a physician who will coordinate or manage the care of this patient.

In scenario "b" a recommendation for a second visit should not be determinative of a physician patient relationship. What happens at the second visit, if it takes place, is much more determinative of the relationship. The follow-up visit may be with a different specialist or the patient may not want another visit with a high risk specialist. Also, many of the tests performed by maternal fetal medicine specialists can be done at a hospital. Some patients prefer to utilize a hospital either for insurance or convenience reasons.

Scenario "c" could be a case of abandonment by the maternal fetal medicine specialist. In this situation, at the conclusion of the only visit, the specialist had a duty to inform the obstetrician of the need for future management of the pregnancy by a maternal fetal medicine specialist. If the recommendation was made, there is no abandonment. If no recommendation was made for such care, there is grounds for a medical malpractice action based on abandonment.

In scenario "e" the maternal fetal medicine specialist never takes charge of the patient and arguably has no responsibility for whatever happens at the hospital where the delivery is performed. The specialist has fulfilled his or her duty to the patient by instructing her to go to the hospital of the obstetrician's choosing.

Scenario "f" is what in today's complex medical-legal climate represents a growing problem for medical malpractice insurers; self-insured hospitals; and physicians. The specialist certainly thinks he or she is not involved in a physician patient relationship. The hospital wants to protect its residents and its self-insured fund by arguing that any thing its residents did or did not do was the responsibility of the specialist as documented by the chart notes. The obstetrician wants to rely on the notes that the specialist discussed the case with the residents and\or nurses.

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Does a consulting physician form a physician-patient relationship?

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There is no universal answer in scenario "f" with respect to whether the specialist has a physician patient relationship. As in all medical malpractice actions, the details of the case will dictate what relationships were created while the patient was an inpatient. The testimony of the patient, obstetrician and specialist will differ in important aspects.

Most patients only recall their attending physician by name or physical appearance. Patient testimony will not resolve the issue of whether a specialist had a physician patient relationship.

One possible approach to evaluating a maternal fetal medicine specialists relationship to a patient in a hospital is his billing records and the billing records of the patient's healthcare provider.

Most physicians bill for seeing patients in a hospital. If a maternal fetal medicine specialist does not bill for discussing a patient with residents, (or even with the attending obstetrician), there is substantial evidence that no physician patient relationship existed. Although it is hard to prove a fact from a negative, (not billing), it is hard to dispute that physicians bill for seeing their patients.

While I like to blame managed care for what is wrong in medicine today, I cannot blame the growing complexity of the medical profession and the relationship of various components of the medical field on managed care. Or can I?

New York Nursing Home Litigation: Medical Malpractice, Negligence or Something in Between?

LAUREN A. JONES, ESQ.*

With the rise of the American "baby boomers", more and more of the population will find either themselves or their loved ones living in a Nursing Home and/or Assisted Living Facilities. According to the 2014 US Census, there are 74 million "baby boomers" living in America; those born between 1946 and 1964. As the residency level soars, so, too increasingly has litigation involving these facilities. This article focuses on Nursing Home litigation and attempts to answer common questions as litigants navigate this nuanced area of law. Is a "nursing home case" properly considered general negligence, medical malpractice or a combination of the two?

New York Courts have been battling this question for years, but the answer remains unclear. With the inevitable flood of litigation arising in the upcoming years, deciding what legal standard applies to these cases, somewhat universally, will be essential. I propose "nursing home litigation" is a specialized area of the law requiring its own standard. In its current form it is most akin to medical malpractice, however, the inquiry does not stop there. Many of the tasks nursing homes are charged with implementing, and those employees responsible for them, are both medical and non-medical in nature. New York Courts have not yet universally determined how to deal with this hybrid.

The New York State Court of Appeals considers conduct to be medical malpractice, and not ordinary negligence, "when it constitutes medical treatment or bears a substantial relationship to the rendition of medical treatment." Barresi v. State of New York, 232 A.D.2d 962, 649 N.Y.S.2d 207 (3d Dep't 1996), citing, Scott v. Uljanov, 74 N.Y.2d 673, 543 N.Y.S.2d 369 (1989). In evaluating whether a cause of action is ordinary negligence or medical malpractice, courts look to whether the "alleged conduct derived from the duty owed to the plaintiff as a result of the physician-patient relationship or was substantially related to the patient's medical treatment." Ryan v. Korn, 57 A.D.3d 507, 868 N.Y.S.2d 735 (2d Dep't. 2008); Stanley v. Lebetkin, 123 A.D.2d 854, 518 N.Y.S.2d 205 (2d Dep't. 1986); Lee v. New York City Transit Authority, 175 Misc. 2d 632, 668 N.Y.S.2d 1014 (Sup. Ct. 1998) aff'd as modified on other grounds, 257 A.D.2d 611, 685 N.Y.S.2d 84 (2d Dep't 1999); Borrillo v. Beekman Downtown Hosp., 146 A.D.2d 734, 537 N.Y.S.2d 219 (2d Dep't 1989).

What is alleged in a typical Complaint in a "nursing home case"? Causes of action involving the development of infection, poor hydration and nutrition, improper medication, inadequate staffing, poor training, wandering/elopement, negligent hiring, abuse and falls[1]. This list is not meant to be exhaustive but, by and large, events of this nature are the most commonly plead. Except for falls, abuse and elopement (which can be an article in it of itself), courts seem to agree these allegations substantially relate to the rendering of medical treatment and, therefore, should be considered allegations based in medical malpractice.

One of the biggest differences between medical malpractice and general negligence is whether a jury would require expert testimony to determine liability. A plaintiff's medical care and claimed physical injuries because of said care cannot be understood by a lay person without the benefit of

[1] With regard to bedsore claims these tend to be much more complicated because they may also be governed by federal statutes which view the development of bedsores in Nursing Homes in a completely different light. This requires a separate discussion which is not the focus of this article.

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medical providers. There are various co-morbidities and risk factors elderly or infirm residents face which may affect their overall health and stability which necessarily require explanation.

In a general negligence action, the trier-of-fact is fully equipped to determine the standard of the reasonably prudent person. If a patient slipped on water at a doctor's office or goes missing, the patient would have a claim for ordinary negligence under a premises liability or other negligence theories, since the incident, which neither related to medical treatment nor a physician-patient relationship, would be something a lay jury could assess.

Does medical malpractice occur in a nursing home? Does negligence happen in a nursing home? Does it matter? Yes, it does. The statute limitations defense is a very important tool in the defense attorney's arsenal and should not be waived lightly. With a 6-month shorter statute of limitations, a careful reading of the Complaint and a blown statute of limitations, can position the defense for an aggressive pre-answer motion to dismiss.

It is important to emphasize, the limitations imposed by CPLR §214-a for medical malpractice applies to acts or omissions committed by individuals and entities *other than physicians* where those acts or omissions either constitute medical treatment or bear a substantial relation to the rendition of medical treatment. Gaska v. Heller, 29 A.D.3d 945, 816 N.Y.S.2d 523 (2d Dep't. 2008).

The question to ask has become, "does the care defendant nursing home and its nurses were charged with rendering to a resident resemble the rendering of medical treatment by a trained professional?" By and large, when the care involves treatment, New York courts have held "yes."

In 2009, the Second Department addressed this issue in Pacio v. Franklin Hospital, et al, 882 N.Y.S.2d 847. Defendant Hospital moved for dismissal of plaintiff's claims for negligence, which it alleged should have been plead as medical malpractice and was time barred. Plaintiff alleged defendant facility failed to comply with its own protocols for pressure ulcer prevention and/or treatment, and that failing to comply with the protocols amounted to negligence. Those protocols referred to treatment rendered by nurses including: bathing, toileting, feeding, turning, and positioning, applying skin moisturizers, providing cushions or pads, etc. The Pacio trial court, as affirmed by the Second Department, held:

"Although plaintiff referred to defendant's failure to follow its own "protocol", the essence of the plaintiff's allegation is that defendant, in failing to implement its protocol, failed to properly assess plaintiff's condition and the degree of supervision required. The conduct complained of…**constitutes an integral part of the process of rendering medical treatment to the plaintiff**". *Id. (Emphasis added)*

Even claims routinely included into a Complaint alleging negligent training and supervision of a Nursing Home's staff are currently based in medical malpractice, not ordinary negligence. The Court of Appeals held although a claim of "negligent hiring" may be found to sound in negligence, the same cannot be said with the claims of "negligent training, instruction, education and supervision" of medical staff that assist in the rendition of medical treatment. Scott v. Uljanov, 74 N.Y.2d 673, *Supra.* (Emphasis added).

So, too, do claims for "negligently" administering and/or failing to monitor medication. Courts have held a nursing home's alleged failure to properly administer medical is a claim based in medical malpractice, for which a two and a half year statute applies. Gold v. Park Avenue Extended Care Ctr. Corp, 2010 NY Slip Op 31376 (Sup. Ct. 2010; aff'd by 2nd Dept 935 N.Y.S.2d 597); D'Esposito v. Haym Salomon Home for the Aged, 886 N.Y.S.2d 66 (Sup .Ct. 2006). In D'Esposito, the Court held allegations that defendant failed to monitor decedent's medication levels clearly bore a substantial relationship to the decedent's medical treatment and sounded in medical malpractice.

Recently, Justice O'Donoghue adhered to the above cases in Woods v. Jackson Heights, et al., Index No: 703765/14, wherein he agreed with defendant nursing home's argument that plaintiff's claims of departures (alleging improper nutrition, hydration, medication administration, turning

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and positioning, infection contraction, care plan formulation, and negligent training) were based in medical malpractice and not negligence. As such, the 2.5 year Statute of Limitations applied and the Court dismissed those claims improperly brought as negligence as time barred.

If courts view "nursing home cases" as medical malpractice claims, so what? Well, think about it. Is it fair to hold nurses to the same standard as doctors? The answer seems to be yes and no. Often, when plaintiffs proffer their experts opinion, they opine to a "reasonable degree of medical certainty". Rarely do courts distinguish medical doctors who practice in hospitals and medical doctors who practice in nursing homes. Nursing homes and hospitals are very different facilities, rendering different levels of care, and are, in fact, governed by different federal regulations. They each service a different population and have different services available to them. One provides acute medical care and the other sub-acute care. It seems a new "nursing home standard" should be created. Expert opinions should be given to a reasonable degree of "nursing home standard", based on the unique way nursing homes operate and the unique issues they face. Nursing experts should be permitted to opine on the propriety of the criticized nursing care. Deference should be shown to those Medical Doctors associated with nursing homes to opine on the care being rendered in a nursing home setting. All experts should demonstrate their familiarity with the specific and unique federal and state regulations which govern nursing homes. "Nursing home cases" is not a passing area of law yet still remains somewhat of a novel area. As the litigation continues to grow, it will become increasingly important to refine the laws and standards which apply to these cases.

With or without a specific standard for nursing home care, two things are certain; 1) the nursing litigation will continue to rise dramatically over the next twenty years; and 2) the care and treatment rendered by a Nursing Home, by and large, are not based in negligence and require the use of expert opinion.

Frye Hearings: A Review Of Cases, Utility and Application

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The rule that scientific expert testimony must have gained acceptance in the particular field to which it belongs is a cornerstone of evidentiary law when expert testimony is involved. However, in recent years, the utility and application of the *Frye* motion to address the admissibility of such testimony in civil cases, and medical malpractice in particular, has been reigned in. Many judges do not favor *Frye* motions or hearings on the eve of trial in a motion in limine because they are time consuming and, as discussed below, frequently are made for the wrong reason. Recent decisions in the trial courts and the Appellate Division have curtailed the use of the *Frye* Hearing in civil cases but there are still a number of important situations in which the hearing and preclusion is appropriate.

Background

Opinion testimony proffered by an expert is necessary where the subject matter of the testimony is not within the knowledge or training of ordinary persons. In *People v. Keindl*, 68 N.Y.2d410 [1986] the Court of Appeals ruled that "[o]pinion testimony of an expert witness is admissible where the conclusions to be drawn 'depend upon professional or scientific knowledge or skill not within the range of ordinary training or intelligence' " citing *De Long v. County of Erie,* 60 N.Y.2d 296 (1983). It is within the sound discretion of the trial judge to determine when jurors are able to draw conclusions from the evidence based on their day-to-day experience and when they would benefit from the specialized knowledge of an expert.

Most trial attorneys are aware that the "*Frye test*" is generally applied to determine the admissibility of a novel scientific principle or procedure when the scientific evidence derived from the novel procedure or principle is itself offered as proof. In *People v. Wesley,* 83 N.Y.2d 417 (1994), the first case in New York on the admissibility of DNA evidence, the Court of Appeals endorsed and applied the rule of *Frye v. United States,* 293 F. 1013 (1923) requiring that expert testimony be based on a scientific principles or methods that are sufficiently established to have gained general acceptance in the particular field to which they belong.

In many cases the trial court is able to make a determination as to whether the "Frye" standard has been satisfied by reference to scientific literature or judicial opinions. If these sources are insufficient, the Court must conduct a hearing at which expert testimony will be taken on the issue of general acceptance in the relevant scientific community. In *People v. Middleton*, 54 N.Y.2d 42, 49-50 (1981), a case involving the admissibility of expert testimony that bite marks on the defendant's arm were some proof of the his guilt, the Court of Appeals wrote what is now accepted as the rule for the application of *Frye* that the "*Frye test*" is generally applied to determine the admissibility of a novel scientific principle or procedure when the scientific evidence derived from the novel procedure or principle is itself offered as proof.

The Federal Standard

The Federal Rules of evidence have codified the standard to be applied in admitting expert testimony in Federal Rules of Evidence rule 702:

> **Rule 702. Testimony by Experts**. If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles

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and methods reliably to the facts of the case.

In federal court, the Frye test is still widely applied. In *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 113S.Ct. 2786 (1993) the U.S. Supreme Court noted that the district court judges, when faced with an offer of expert testimony, must make a preliminary assessment of whether the expert testimony reflects scientific knowledge and that there is a connection or "fit" between the testimony and the issues of the case. The testimony's underlying reasoning or methodology must be scientifically valid and thereby reliable as evidence to be applied to the facts at issue. Some of the factors the Supreme Court suggested be considered are: (1) whether the theory or technique in question can be tested (and has been) tested; (2) whether it has been subjected to peer review and publication; (3) whether its potential rate of error is known and is it statistically significant and acceptable; and (4) that general acceptance can yet have a bearing on the inquiry. The fourth factor of general or widespread acceptance within the relevant scientific community reaffirms the Frye test of admitting known techniques into evidence. The Daubert court made clear the rule that it is the function of the trial judge to prevent "junk science" from getting before the jury.[1]

The New York Standard

The legislature has not embraced FRCP 702[2] and the New York Court of Appeals has not chosen to apply the *Daubert* standard of scientific reliability. Instead, New York has retained *Frye's* "general acceptance test". The *Frye* test of "general acceptance" is one measured by the scientists of the relevant scientific community to which the expert's theory belongs. New York trial court courts are encouraged to follow the basic rubric stated by the Supreme Court that trial judges view novel theories and the methodology to establish them with skepticism if they are only minimally supported by the relevant scientific community.[3]

The Hearing

Not every motion results in a hearing. There are many cases where the court can decide the issue on papers. If the court feels that it must hear testimony, a hearing is ordered. In New York the *Frye* hearing is designed to determine whether the proposed expert testimony is based on "a principle or procedure [which] has 'gained general acceptance' in its specified field.44" "[T]he particular procedure need not be 'unanimously indorsed' by the scientific community but must be 'generally acceptable as reliable.' People v. Wesley at 423 (quoting People v. Middleton, 54 N.Y.2d 42, 49)."[5] Chief Judge Kaye, concurring in the result, wrote: "[t]he Court agrees unanimously that where the scientific evidence sought to be presented is novel, the test is that articulated in *Frye v United States,* in essence whether there is general acceptance in the relevant scientific community that a technique or procedure is capable of being performed reliably". [6]

Scope of the Frye Hearing

In most medical malpractice cases where a Frye issue arises, defense counsel is usually challenging a theory of causation propounded in a CPLR 3101 expert disclosure. The defense usually argues that plaintiff's theory of causation has not gained acceptance in the particular medical specialty involved in the case.[7] However, the defense will not meet its burden under the case law if counsel is simply challenging whether the defendant's conduct is the cause of the injury. Rather, you must challenge the specific theory of causation as it relates to the treatment. For example, if plaintiff argues that a particular drug ordered by the defendant caused the plaintiff to lose his hearing and there is absolutely no support in the medical literature that the drug is known to cause hearing loss, that would be a sound basis for a *Frye* motion. Conversely, if a defendant in a motor vehicle case is claiming that a car accident did not cause the plaintiff's injuries that will never get to a *Frye* hearing and will always be determined by the trier of fact. As Justice Saxe wrote in his concurring opinion in *Marsh v Smyth* 12 AD3d 307 (1st Dept. 2004): "…where the proposed expert testimony concerns a claim that the plaintiff's injury was caused by the actions taken by the defendants, the whole concept of the *Frye* analysis is of limited applicability."[8]

The 2006 decision by the *Court of Appeals in Parker v Mobil Oil Corporation* 7 NY3d 434, 824 NYS2d 584 (2006) is illustrative of the requirements for preclusion of so-called "junk science". In *Parker* plaintiff sued Mobil Oil Corporation, Island

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Transportation Corporation and Getty Petroleum Marketing, Inc., alleging that exposure to benzene in gasoline caused him to develop acute myelogenous leukemia (AML). Mr. Parker had worked as a gas station attendant for 17 years and had been exposed to benzene through inhalation of gasoline fumes and through contact with his skin. Mobil moved to dismiss the complaint on the ground that there was no medical causation. Mobil did not dispute that benzene is a known carcinogen. Rather, the defense argued that although there is an increased risk of AML for service station employees exposed to "large amounts" of benzene over an extended period of time, the low levels of benzene exposure resulting from gasoline service station work are "below the practical threshold for the dose necessary to initiate the leukemia process."[9]

In opposition to defendants' motion, Parker argued that his claim that benzene can cause AML was not novel and the scientific evidence in support of his claim should not be subject to Frye review. He also argued that that there is a difference of opinion in the scientific community as to what level of benzene exposure causes leukemia. To support his arguments, he produced reports from two experts who cited to case reports in the medical literature linking benzene to AML.

The Court of Appeals confined the issue on appeal to the admissibility of Parker's experts' opinions.[10] In affirming the dismissal of plaintiff's complaint by the Appellate Division Second Department[11], the Court of Appeals ruled that "…while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs"[12]

The Court of Appeals departed from the ruling of the Appellate division that Parker was required to specifically quantify the extent to which he was exposed to benzene.[13] According to Judge Ciparick "[t]he experts, although undoubtedly highly qualified in their respective fields, failed to demonstrate that exposure to benzene as a component of gasoline caused Parker's AML."[14] Basically, the Court concluded that the Appellate Division properly precluded plaintiff's experts and properly deemed them insufficient to defeat summary judgment but would not endorse the Appellate Division's determination that plaintiff had to actually prove how much benzene he was exposed to while working at the gas station.

Against the backdrop of *Parker* which prevented the admission into evidence of "junk science" consider the Second Department case of *Zito v Zabarsky* 28 AD3d 42 (2006) decided thte same year. Pamela Zito sued her internist, Dr. Gary Zabarsky, for prescribing 80 mg/day of Zocor, a statin drug used to treat hyperlipidemia.[15] Plaintiff claimed that the 80 mg/day dose of Zocor caused her to develop polymyositis, an inflammatory condition that causes muscle weakness. During the trial, the court conducted a Frye hearing and determined that the testimony of the plaintiff's expert witnesses, whose credentials were not disputed by either the trial court or the defendant, was inadmissible. The sole basis for the court's ruling was that the plaintiff failed to produce any medical literature that reported a causal nexus between an excessive dose of Zocor and the development of polymyositis.

In reversing the trial court, Justice Luciano authored an opinion that at first seems to be at odds with *Parker*. The Appellate Division ruled that a single case report published in the British medical journal *Lancet* describing the onset of polymyositis symptoms in a 43 year old patient on statins was enough to establish the possibility that Ms. Zito's symptoms were related to Zocor. The decision established the "synthesis of medical literature" rule which is that expert testimony on a novel theory of causation will be permitted where the expert is synthesizing his/her opinion from the medical literature. Trial courts are now encouraged to analyze expert opinions based on the principle that "general acceptance does not necessarily mean that a majority of the scientists involved subscribe to the conclusion. Rather it means that those espousing the theory or opinion have followed generally accepted scientific principles and methodology in evaluating clinical data to reach their conclusions."[16]. The opinion adds the following admonition:

> A strict application of the *Frye* test may result in disenfranchising persons entitled to sue for the negligence of tortfeasors. With the

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> plethora of new drugs entering the market, the first users of a new drug who sustain injury because of the dangerous properties of the drug or inappropriate treatment protocols will be barred from obtaining redress if the test were restrictively applied. *Zito* at 46.[17]

Fast forward five years. In 2011 the Appellate Division Second Department affirmed the trial courts dismissal of the complaint in *Ratner v McNeil-PPC, Inc.* 91 AD3d 63 (2011). Margalit Ratner attempted to advance the novel theory that she developed liver cirrhosis from long term use of Tylenol (acetaminophen). Her experts were prepared to testify that acetaminophen caused her liver cirrhosis because the drug is a known hepatotoxin and therefore her repeated exposure to acetaminophen caused chronic inflammation which lead to fibrosis of the liver, which may then cause liver cirrhosis. Not surprisingly the drug manufacturer argued that plaintiff's expert's opinion that acetaminophen can cause cirrhosis of the liver or contributed to the plaintiff's cirrhosis did not satisfy the standard for admissibility of scientific evidence, and should be excluded under *Frye*. McNeil proffered an expert affidavit in which it conceded that massive overdoses of acetaminophen could cause acute liver damage, but the theory that long term therapeutic doses can cause cirrhosis had not gained acceptance in the medical and scientific communities. McNeil's expert asserted further that plaintiff's expert's opinion was based on faulty conclusions on the nature of her diagnosis and the literature relied on consisted exclusively of case reports and animal studies.

The trial court (Ruchelsman, J., Sup. Court Kings Co.) granted the defendant's motion in its entirety and dismissed the complaint.[18] In affirming the decision, the Appellate Division, relying on *Parker* supra 7 NY3d at 447 ruled that "…where there is no novel or innovative science involved, or where the tendered scientific deduction has been deemed generally accepted as reliable, there remains a separate inquiry applied to all evidence. This inquiry is "whether there is a proper foundation—to determine whether the accepted methods were appropriately employed in a particular case" *Ratner* at 70-71. Citing to *Zito* the Court repeated the rule that "[g]enerally, deductive reasoning or extrapolation, even in the absence of medical texts or literature that support a plaintiff's theory of causation under identical circumstances, can be admissible if it is based upon more than mere theoretical speculation or scientific hunch." *Ratner* at 71. The remainder of the decision was spent on distinguishing *Ratner* from *Zito*. The distinction, according to the court, was manifest because, unlike the expert's opinions in *Zito*, the *Ratner* expert opinions were too speculative to be considered by the jury.[19]

What we are left with at present are variously created judicial approaches to the Frye hearing. Primarily we now have a judicial policy that that grants the court wide latitude in determining whether plaintiffs' experts can demonstrate that their theory of causation is reasonably permitted by a "synthesis" of the medical literature and whether there is a proper foundation for the opinion.[20] Nevertheless, it remains the rule that "[t]he court's job is not to decide who is right and who is wrong, but rather to decide whether or not there is sufficient scientific support for the expert's theory" (*Gallegos v. Elite Model Mgt. Corp.,* 195 Misc.2d 223, 225, 758 N.Y.S.2d 777 [2003]).

Cases in which the defendant has been successful in obtaining a Frye hearing and precluding plaintiff's expert from offering "junk science" opinions are always fact-specific and generally involve claims for which, at present, there is no support in the medical literature.[21] For example, *Selig v Pfizer* 290 AD2d 319 (1st Dept. 2002) [link between the use of Viagra and heart attack not established]; *Ratner v McNeil supra*, 91 AD3d 63 [link between long term therapeutic doses of Tylenol and cirrhosis not established]. Other cases in which there is a correlation but no scientific basis for causation between an event and an injury have also resulted in preclusion of expert testimony. *Melnick v Con Edison*, 39 Misc.3d 800 (2013) [prematurity does not cause Autism Spectrum Disorder]. *Styles v General Motors*, 20 AD3d 338 (1st Dept. 2005) [results of two-phase vehicle stress/crash test conducted by plaintiff expert were inadmissible where methodology of test performed had not gained acceptance in scientific community]; *Marso v Novak*, 42 AD3d 377 (2007) [Expert physician's testimony that stroke could have been avoided by placement of pacemaker in the year prior to patient's stroke, was not a conclusion

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generally accepted in the scientific community].

Obtaining the Frye Hearing

Most, if not all of those reading this article will be considering a Frye motion on the issue of causation. Although many lawyers move in *limine* for a Frye hearing this author continues to recommend moving to preclude the expert's testimony on the basis of *Frye* after the CPLR 3101 expert disclosure is received. *In limine* evidentiary motions often get you nowhere and are not appealable.[22] The trial court will frequently rule that your motion is premature because the court has not heard the testimony. You also run the risk that the trial court will interpret your motion as one for summary judgment and ask why you have made it now instead of within the applicable time period after the NOI was filed. Although you can always raise the issue again during trial, I find it best to have an appealable order that may be taken immediately to the Appellate Division under appropriate circumstances.

In support of the motion, counsel should provide the supporting affidavit of an expert stating that the plaintiff's expert's theory of causation has not gained acceptance in the particular medical field and specifically stating why. Articles from the applicable medical literature should also be attached as well as medical records of the plaintiff. In addition, wherever possible, the plaintiff's expert opinion should be attacked as speculative and lacking the appropriate foundation to get before the jury.

It is important to carefully map out the strategy of the request for preclusion under Frye. The first step is to review with the defense expert the issue of whether there is any support in the medical literature for the plaintiff's theory of the cause of an injury. A typical example is the case where plaintiff is claiming that a drug ordered by the defendant caused her injury. Having established that there does not appear to be a causal connection, is the plaintiff's expert following generally accepted scientific principles and methodology in evaluating clinical data?[23] This is the so-called "reasonable synthesis" test. In analyzing whether the plaintiff's expert has engaged in an appropriate synthesis of medical and clinical data, it is next necessary to determine what clinical data the expert has relied on, i.e. is the clinical data complete? Beware of the expert who only selects clinical data that supports his opinion and fails to consider other pertinent data that does not.[24]

The trial court is encouraged to follow the maxim that "general acceptance does not necessarily mean that a majority of the scientists involved subscribe to the conclusion. Rather it means that those espousing the theory or opinion have followed generally accepted scientific principles and methodology in evaluating clinical data to reach their conclusions"[25] It is therefore necessary to do as thorough a review of the medical literature as possible. Defense counsel must know in advance what studies or articles the plaintiff will rely on to establish that their expert has engaged in a "synthesis" of studies and case reports that reasonably support the conclusion under attack.

Seeing the forest for the trees

In cases where an expert offers a novel theory of causation your inquiry as well as the Court's starts with determining whether the opinion is properly founded on generally accepted methodology, not whether the causal theory is generally accepted in the relevant scientific community.[26] Therefore, you must look at the basis of the opinion not the opinion itself. We all agree that just because something can cause an injury does not mean that it did. But once your expert tells you that plaintiff's expert opinion on the cause of an injury is theoretically possible, your argument for preclusion under Frye may be lost. Your best chance is to appeal to the Court's inherent authority to determine that the gap between the studies and data relied on and the proffered opinion is simply too great. By contrast, the expert's theory of causation will be precluded where it is not supported by any case studies or data whatsoever. [27]

Conclusion

The *Frye* hearing remains a valuable tool for ferreting out and precluding expert theories of causation that have not gained acceptance in the particular field of medicine to which they belong. However, careful consideration must be given before making a *Frye* motion to ensure that the case is appropriate for preclusion of expert testimony where there is some basis grounded in accepted scientific methods and principles to support the expert opinion. As the case law suggests, trial courts

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are loathe to dismiss a complaint and would rather have a jury decide the issue whenever possible.

1 Justice Blackmun wrote: "General acceptance" is not a necessary precondition to the admissibility of scientific evidence under the Federal Rules of Evidence, but the Rules of Evidence—especially Rule 702—do assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand. Pertinent evidence based on scientifically valid principles will satisfy those demands. *Daubert* 113 S. Ct. 2786, 2799.\

2 New York CPLR §§ 4515 states:

Unless the court orders otherwise, questions calling for the opinion of an expert witness need not be hypothetical in form, and the witness may state his opinion and reasons without first specifying the data upon which it is based. Upon cross- examination, he may be required to specify the data and other criteria supporting the opinion. (emphasis added).

3 *People v Wesley*, at 423.

4 *People v Wesley*, at 422, (quoting *Frye*, 293 F. at 1014).

5 *People v Wesley* at 423 (quoting *People v. Middleton*, 54 N.Y.2d 42, 49).

6 *People v Wesley* at 435. Internal citations omitted

7 In general, expert testimony regarding "novel" theories must satisfy the court that it has gained general acceptance in the field in which it belongs. But, general acceptance by the relevant community does not mean that it must be unanimously endorsed (*People v Wernick*, 89 NY2d 111 (1996); *People v Wesley*, 83 N.Y.2d 417 [1994]).

8 12 AD3d 307, 310-311.

9 *Parker* at 442.

10 At issue in this case is the admissibility of Parker's experts' opinions. The parties dispute whether the opinions should be analyzed under Frye. The introduction of novel scientific evidence calls for a determination of its reliability. Thus, the Frye test asks "whether the accepted techniques, when properly performed, generate results accepted as reliable within the scientific community generally" Parker at 446.

11 The Appellate Division reversed the trial Court (Lally, J. Supreme Court Nass. Co.) who denied the motions to dismiss.

12 *Parker* at 447.

13 The Appellate Division ruled that "One expert's general, subjective and conclusory assertion that plaintiff had "far more exposure to benzene than did the refinery workers in the epidemiological studies" was insufficient to establish causation. Nor did the opinion of another expert that plaintiff was "frequently" exposed to "excessive" amounts of gasoline and had "extensive exposure ... in both liquid and vapor form" constitute a scientific expression of plaintiff's exposure level. Plaintiffs' experts were unable to identify a single epidemiologic study finding an increased risk of AML as a result of exposure to gasoline, and standards promulgated by regulatory agencies as protective measures were inadequate to demonstrate legal causation..

14 *Parker* at 450

15 The dose had been approved by the FDA and was the highest recommended dose.

16 *Zito* at 45

17 One might argue that that is the whole point of having a Frye hearing. What reason did Dr. Zabarsky have for stopping the drug if there was only a single report in a single medical journal of a single patient who possibly experienced an adverse reaction to the drug? Interestingly, the mytoxicity of statins is still a controversial subject. See, e.g. Law, M. & Rudnicka, A.R. Statin safety: a systematic review. *Am. J. Cardiol*. 97, 52C–60C (2006).

18 The Supreme Court stated that there were no studies or medical literature concluding that the ingestion of normal doses of acetaminophen caused cirrhosis, and that the plaintiff was attempting to draw a medical parallel between the ingestion of proper doses and excessive doses to conclude that acetaminophen caused cirrhosis. *Ratner* at 70.

19 The decision reads:

The plaintiff did not put forward any clinical or epidemiological data or peer reviewed studies showing that there is a causal link between the therapeutic use of acetaminophen and liver cirrhosis. Consequently, it was incumbent upon the plaintiff to set forth other scientific evidence based on accepted principles showing such a causal link. We find that the methodology employed by the plaintiff's experts, correlating long term, therapeutic acetaminophen use to the occurrence of liver cirrhosis, primarily based upon case studies, was fundamentally speculative (see *Lewin v. County of Suffolk*, 18 A.D.3d 621 [2005]), and that there was too great an analytical gap between the data and the opinion proffered. Ratner at 78.

20 *Lugo v NYCHHC*, 89 AD3d 42 (2nd Dept. 2011)

21 This was the problem with the Second Department's decision in *Zito v Zabarsky* 28 AD2d 42 (2006) where it was clear that there was rational line of scientific reasoning to conclude that the Zocor might have caused polymyositis but the theory had not yet been embraced in the medical literature. However, presently, in view of adverse reports the FDA recommends against 80 mg doses of the drug. That was not the case in 2005 so one might argue that the court was vindicated. FDA Consumer Update: fda.gov/For Consumers/ConsumerUpdates/ucm257884.htm

22 No appeal lies from an evidentiary ruling made before trial; such a ruling is reviewable only in connection with the appeal from the judgment rendered after trial. See, *Weatherbee Construction Corp. v Miele* 270 AD2d 182 (2000).

23 The Court must answer the question of whether "…,the proffered expert opinion properly relates existing data, studies or literature to the plaintiff's situation, or whether,

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DEFENDANT

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$450

Third Page (Square)
Width x Height
4 7/8" x 4 7/8"
$275

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Width x Height
7 1/2" x 4 7/8"
$375

Third Page (Horizontal)
Width x Height
7 1/2" x 3 1/8"
$275

Half Page (Vertical)
Width x Height
4 7/8" x 7 1/2"
$375

Frye Hearings: A Review Of Cases, Utility and Application

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instead, it is connected to existing data only by the *ipse dixit* of the expert" *Marsh v Smith* 12 AD3d 307, 310-311 (1st Dept. 2004).

24 See, e.g. *Ratner v McNeil supra..*

25 *Zito supra* at 45

26 *Ratner v McNeil* 91 AD3d 64,78.

27 See, e.g. *Cumberbatch v Blanchette* 35 AD3d 341 (2nd Dept. 2006): plaintiff's expert could cite to no relevant scientific data or studies to support his causation theory that fetal distress resulting from the compression of the infant plaintiff's head due to labor contractions, augmented by pitocin, resulted in ischemia, which, in turn, resulted in an infarction, and he could cite to no instance when this type of injury had previously occurred in that manner. The Second Department concluded that the opinion of the plaintiff's expert was scientifically unreliable.

Safety: A Common Ground For Plaintiff And Defense Medical Liability Attorneys

STEVEN E. PEGALIS*

In the disputed medical liability case, the adversarial system has been retained as the most effective way to ensure due process (e.g. a fair trial) and the most effective way to get to the truth. Within the framework of the law and subject to the rulings of the impartial presiding jurist we attorneys each advocate for our client.

The plaintiff alleges that a definable and provable patient injury was foreseeable and avoidable by the exercise of reasonable care. If this allegation is true that means that the health care services were not safe. Thus, the disputed case typically has issues of culpability. Plaintiff maintains one or more departures from accepted practice was (or were) a substantial contributing cause of injury. The defense often will maintain there were no departures from accepted practice and/or the injury is unrelated to the alleged departure(s).

We, on the plaintiff's side, should be carefully screening our cases to make sure that we are pursuing only meritorious and provable cases. I think we all know that the ethics of our legal profession is not to pursue any claim or any defense that as reasonable informed advocates we know lack merit. We also all know that zeal can lead advocates over lines they should not cross.

Still, all cases come to an end whether by settlement or otherwise. The adversarial process to resolve culpability and/or causation disputes is now over. Should the case be deemed dead and buried? Should we as advocates immediately plug ourselves into the next "battle." Regardless of which side we were on, what have we learned from the case? The end point goal of the Civil Justice System is to do justice. For the plaintiff with a meritorious case that means fair compensation and an accountability that promotes safer care for others. The justice sought by a plaintiff should not be for revenge or punitive action.

If good quality care truly was given then the defendant provider's justice should be reassurance that good quality is provable and sustainable under the rule of law. The health provider should be aware that our legal system is supportive of good quality care. Yet we all know that our clients on both sides and also members of the public too often expect a foolproof legal process that always dispenses pure justice. Pure justice can be defined in the mind of a litigant or a member of the public in a way that is disconnected from what our civil justice system actually contemplates and what our civil justice system actually can do.

I call to the attention of my legal colleagues on the defense side that some of us are working toward a process to use closed liability cases as anonymous teaching tools to try to help make care safer. If this process comes to your attention, I urge each of you to be as supportive as you can. The common ground we all have is that anything that can promote safer care is best for us and our families and best for the public.

The safety movement of 21st century medicine energized by the Institute of Medicine's landmark document[1] cited the work done by the Anesthesia Specialty[2] that importantly included a broad based study of closed medical liability cases as a basis to make anesthesia care safer. Could models for safety used in industries like the airline or nuclear industries work to make the healthcare industry safer? The Anesthesia Specialty using our closed liability cases proved that such safety approaches can work in medicine.

The motivated physicians of the American Society of Anesthesiology (ASA) proved that what they learned from closed medical liability cases could be used to make care safer. That dramatically increased safety which not only reduced liability costs but dramatically increased physician morale and peace of mind.[3]

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* *Steven E. Pegalis is a founding partner of Pegalis & Erickson, LLC. and an Adjunct Professor of Law at New York Law School.*

Safety: A Common Ground For Plaintiff And Defense Medical Liability Attorneys

More recently, similar approaches in other specialties have reduced the incidence of bad outcomes, reduced liability insurance cost and improved provider satisfaction.[4] For example, providers who were required by their hospital and liability insurance carrier to take certain safety steps, initially objected but later reported favorable perceptions toward a teamwork culture of safety.[5]

In discussing with a prominent member of the physician community concepts of attorneys and provider stakeholders working together I was asked [believe it or not] - "why include defense attorneys in the process?" My response was that defense attorneys are experts in identifying what was and what was not truly a preventable adverse outcome.

Once the case is closed why would we not wish to tap that expertise existing with defense attorneys, in a process that their medical clients would want to produce an even safer health care environment? If we can work together toward greater safety, we are then being consistent with our ethical obligations to our profession and to our clients who on each side want greater safety.

The standard of medical care does not require providers to formulate a foolproof system of care. The ethics of the medical profession does require providers to accept the fact that humans are fallible and sometimes errors that cause patient harm occurs. Our civil liability tort system cannot be a foolproof system that satisfies everyone that pure justice is always achieved. We attorneys do however have a role to promote a greater respect for our judicial system which system, though not perfect, is the best system ever created.

1 Kohn, L., Corrigan, J., Don Saldson. To Err is Human: Building a Safer Health System. Wash., D.C., National Academy Press, 2000

2 Ibid, #1

3 See e.g. David M. Gaba, Anesthesiology as a Model For Patient Safety In Health Care. 320 Brit. Med. J. 785 (2000)

4 See e.g. Pettker, CM, Thung, SF, Norwitz, ER, et al. Impact of a Comprehensive Patient Safety Strategy on obstetric adverse event. Am.J. OB-GYN 2009, 200:492 e1-492 e8

5 Ibid #4

We attorneys do however have a role to promote a greater respect for our judicial system which system, though not perfect, is the best system ever created.

THE DEFENSE ASSOCIATION OF NEW YORK

P.O. Box 950

New York, NY 10274-0950

DEFENDANT

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THE DEFENSE ASSOCIATION OF NEW YORK
P.O. Box 950
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I enclose my check/draft $_____

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Name _____

Address _____

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I represent that I am engaged in handling claims or defense of legal actions or that a substantial amount of my practice or business activity involves handling of claims or defense of legal actions.

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