MARTIN CLEARWATER & BELL LLP

DEFENSE PRACTICE UPDATE

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THE FRYE TEST: HAS "JUNK MEDICINE" MET ITS MATCH?

BY: PETER T. CREAN AND ELLEN B. FISHMAN

Both sides in the trial of a medical malpractice action, as in other cases involving scientific expertise, depend on opinion testimony from experienced practitioners. All too often, experts retained by injured parties express such outlandish opinions that their statements have been treated as "junk medicine" that has no place in the courts.

In New York, the "general acceptance" requirement of admissibility applies to expert testimony based on scientific principles or procedures. This standard is based on an 80-year-old federal decision, *Frye v United States*. When a *Frye* motion is made, the Trial Court decides the threshold issue of whether an expert should testify. That determination includes ascertaining that the expert's testimony meets accepted standards of reliability. If the expert's methodology has gained "general acceptance" by the relevant scientific community, it will be considered reliable and the jury may hear the expert's opinion.

Submission of a motion to preclude expert testimony entails preparation of a complex package of documents in order to make both the law and the medicine clear to the court. The party seeking to present the expert will oppose the motion with papers that often expand on the opinion in question. Not infrequently, the Court will hold an evidentiary hearing outside the presence of the jury to determine whether the challenged expert may testify.

The party seeking to present expert testimony has the burden of proving that the witness has qualifications that would make him or her an expert in the particular area in which testimony will be offered. An expert must possess the requisite skill, training, education, knowledge or experience from which it can be assumed that the information imparted or the opinion rendered is reliable. When a medical expert's testimony lacks a factual basis and is mere speculation, the opinion lacks probative valve.

Because there is a risk that lay jurors may credit unreliable opinion evidence, the *Frye* "general acceptance" test protects juries

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from being misled by expert opinions that may be couched in formidable scientific terminology, but that are based on fanciful theories. If the opposition objects, the jury may hear medical expert and other scientific testimony only after the *Frye* reliability test has been satisfied.

A series of United States Supreme Court decisions have cast doubt on this standard by holding that *Frye* no longer applies in federal courts. That trend started with *Daubert v Merrill Dow Pharmaceutical, Inc.* In *Daubert*, the Supreme Court held that the Federal Rules of Evidence (which have no New York counterpart) superseded the *Frye* "general acceptance" test. Under the *Daubert* standard, the admissibility of expert opinion testimony will depend on several factors including whether the expert's theory has been tested, the potential error rate of such testing, whether the expert's theory has been peer-reviewed and, like *Frye*, whether the theory has met with "general scientific acceptance".

Although some have described the *Daubert* standard as less rigorous than *Frye's* sole test of "general acceptance," that is not clearly so, as expert testimony must still demonstrate sufficient reliability to be admissible. For example, a federal court applying *Daubert* has precluded a physician from testifying about the etiology of a disease when the medical expert's proffered opinion on the causal relationship between a product and the plaintiff's condition was not shown to be sufficiently reliable to be admissible. Although no longer the exclusive test in federal courts, "general acceptance" still has a bearing on the inquiry made by the federal judge as "gatekeeper" in deciding whether to permit a scientific expert to testify.

A number of intermediate appellate and trial courts in New York have referred to *Daubert* and found its criteria useful in considering the reliability of expert testimony. New York's highest court has not yet resolved the question of whether the *Daubert* standard, which articulates criteria beyond "general acceptance," will apply in state cases.

In two significant decisions, New York's intermediate appellate court upheld the application of the *Frye* test to medical expert testimony, thus confirming its continuing validity in state cases involving novel theories about the cause of an illness. In 2002, the Appellate Division affirmed the grant of defendant's pre-trial motion in *Selig v Pfizer, Inc.* In *Selig*, defendant sought to preclude an expert's testimony that there is a causal link between use of Viagra and heart attacks in men with pre-existing coronary artery disease. While the expert's underlying methodology supporting his opinion was not novel in and of itself, his selective application of only those studies that supported his theory of causation did not find acceptance within the mainstream scientific community. Thus, applying the *Frye* rule often excludes not only the testimony of experts offering fanciful and novel scientific theories, but those who elect to disregard accepted scientific methods when presenting their hypotheses.

More recently, in *Lara v New York City Health and Hospitals Corp.*, plaintiff's neurology expert expressed the opinion that the infant-plaintiff had a hemorrhage at the time of his birth that eventually caused his cerebral palsy. Defendants' pediatric neurologist stated that he had never heard of such a theory in his 45 years of practicing medicine, it is not supported by medical literature and it is not an accepted theory in his field. Defendants thereby made a showing sufficient to put in issue whether plaintiff's theory is "generally accepted", i.e., reliable enough to present to the jury.

As it evolved at trial, plaintiff's theory of causation comprised a rapid second stage of labor/rapid decompression/intracranial bleeding/vasospasm/cerebral palsy, all in the absence of symptoms for over five months. Because plaintiff's neurologist had no personal knowledge of any cerebral palsy case in which the cause was found to be what he theorized had happened to plaintiff, it was necessary to consider whether his causation theory could be shown through the medical literature to have gained "general acceptance".

Ultimately, the trial court in *Lara* granted defendants' *Frye* motion, set aside a $10 million verdict and dismissed the complaint after a full trial. In 2003, the Appellate Division upheld that result, agreeing that plaintiffs' expert should never have been permitted to testify about the cause of the infant's brain damage. Absent that opinion, plaintiff had no case against the hospital.

This is in keeping with settled principles that to establish a medical malpractice claim, the injured party must prove that defendant departed from good and accepted medical practice and that the alleged deviation was a substantial factor in producing the injuries. No matter how grievous the injury or sympathetic the plaintiff, there can be no liability without competent medical proof of causation.

The Frye test for expert scientific evidence looks to "general acceptance" of the procedures and methodology as reliable within the scientific community.

New York courts regulate the use of medical expert testimony by examining the content of such testimony and its reliability. Generally, opinion evidence must be based on facts in the trial record or personally known to the witness. An expert may base an opinion on evidence outside the record only if it is of a kind "generally accepted" in the profession as reliable or if the evidence comes from a witness subject to full cross-examination at trial.

Thus, in New York courts, the customary admissibility test for expert scientific evidence looks to "general acceptance" of the procedures and methodology as reliable within the relevant scientific community. In the absence of a "generally accepted" basis in the scientific community for a medical opinion regarding causation, such opinion amounts to nothing more than personal speculation.

Martin Clearwater & Bell LLP trial and appellate attorneys will continue to monitor developments in both state and federal courts in order to make all appropriate arguments to keep "junk medicine" out of the courtroom.

The significance of analyzing a case for a potential *Frye* motion is reflected in the successful dismissal of a case handled by Martin Clearwater & Bell LLP partner, Thomas A. Mobilia, following a *Frye* hearing. Plaintiff's theory of causation that long thoracic nerve palsy was due to improper positioning of her arm during surgery under general anesthesia was challenged by the defendants' *Frye* motion as not "generally accepted" in the medical community. The court ordered an evidentary hearing in order to decide the motion and witnesses called on both sides included neurologists, a general surgeon and an anesthesiologist. It also included the submission of significant medical literature dating from the early 1900's to present.

The thrust of the hearing focused on such narrow medical issues as: (i) whether the long thoracic nerve (which emanates from cervical roots C5, C6 and C7) is considered, anatomically, to be part of the brachial plexus; and (ii) regardless of terminology, whether the alleged mechanism of injury, i.e., hyperabduction of an arm on an armboard attached to an operating table, in the absence of lateral flexion of the patient's head and without the patient's arm raised overhead (both being prerequisites discussed in the literature), can cause injury to either the long thoracic nerve or the brachial plexus. The defendants' motion to preclude plaintiff's experts' testimony was granted and, more importantly, the case was necessarily dismissed because not only was plaintiff's experts' testimony precluded, but so was plaintiff's theory of causation.

COURTROOM EXPERIENCE:
AN INSIDER'S VIEW

BY: JEFF LAWTON

A doctor is not liable for an error in judgment if (he/she) does what (he/she) decides is best after careful evaluation if it is a judgment that a reasonably prudent doctor could have made under the circumstances.

Although the February 2002 decision by the Court of Appeals in *Nestrorowich v Ricotta* limited the availability of the "error in judgment" jury instruction for a physician in a medical malpractice action, defense counsel can still obtain the invaluable jury charge provided that there is appropriate testimony in the record to support it.

New York Pattern Jury Instruction regarding error in judgment states:

"A doctor is not liable for an error in judgment if (he/she) does what (he/she) decides is best after careful evaluation if it is a judgment that a reasonably prudent doctor could have made under the circumstances."

The Court of Appeals ruling in *Nestrorowich* made clear, however, that this "error in judgment" charge is only appropriate in a narrow category of cases in which there is evidence that the defendant physician chose among severally medically acceptable treatment alternatives.

In October of 2002, MC&B partner, Jeff Lawton obtained a defense verdict in an elective breast implant case, brought by a 23-year-old single woman who worked for a public relations firm in New York City. Upon presentation to the defendant for breast augmentation, the plastic surgeon weighed various factors, including the plaintiff's wishes, which included "to be as big as possible", as well as her physical attributes, and made the choice to perform a sub-glandular, rather than sub-muscular, breast implantation. Over the next two years, the plaintiff sought additional treatments, including another procedure to further increase the size of her implants. Soon thereafter, the skin around her right breast began to thin, and the implant was in danger of extruding from the breast. Plaintiff commenced an action against the plastic surgeon claiming that the implant was excessive in size, that it was overfilled, and that it should have been placed under, and not over, the muscle.

At trial, the plaintiff's expert argued that the defendant plastic surgeon had used implants that were too large, and had overfilled them. The plaintiff's expert also claimed that a sub-glandular implantation technique was a departure from the standard of care.

On cross-examination, however, Mr. Lawton was able to elicit testimony from plaintiff's plastic surgery expert that the selection, location, and filling of the implant required a degree of judgment on the part of the defendant plastic surgeon. Plaintiff's expert also conceded that both sub-muscular and sub-glandular implants could be appropriate, depending on circumstances unique to each case.

The trial testimony of the defense's plastic surgery expert corrob-

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COURTS IMPOSE SANCTION FOR LOSS OF HOSPITAL AND MEDICAL RECORDS

BY: JEFFERY A. SHOR
AND NANCY A. BRESLOW

Although hospitals and physicians have long been responsible for maintaining patient records, several recent Court decisions have made it much more important that records now be meticulously preserved.

The Education Law of the State of New York defines professional misconduct of a physician as including the failure to maintain patient records for at least six years. Obstetrical records and records of minor patients (under age 18) must be maintained for a much longer period: at least six years, and until one year after the minor patient reaches the age of 18 years. New York State regulations impose similar requirements upon hospitals, adding that records must be maintained until at least six years after a patient's death.

Now, however, the loss of medical records can mean the loss of a medical malpractice case. The Appellate Division, Second Department in a case known as *Baglio v St. John's Queens Hospital* and the Appellate Division, First Department in *Herrera v Matlin* recently issued rulings that approved of striking the answer of a defendant in a medical malpractice case due to the loss of medical record evidence.

The striking of a defendant's answer is equivalent to a defendant's admission of full liability.

In the *Baglio* case, it was alleged that the infant plaintiff suffered brain damage due to a deprivation of oxygen during his delivery at the hospital. The fetal heart rate had been monitored during the labor and delivery, for the purpose of determining (among other things) whether there was fetal distress caused by a lack of oxygen, and a paper record ("fetal monitoring strips") was generated.

During the litigation, when plaintiffs learned that the Hospital could not locate the correct fetal monitoring strips for exchange in the discovery process, they asked the Court to strike the Hospital's answer due to spoliation of evidence. "Spoliation of evidence" is defined essentially as the destruction or loss of evidence, whether intentional or negligent. The trial court denied the motion.

On appeal, the Second Department reversed and ordered that the Hospital's answer be stricken due to the Hospital's loss of the strips.

The appellate court decided that the defendant's answer should be stricken because the plaintiffs had presented evidence, in the form of a physician's affirmation, that the fetal monitoring strips were "the most crucial evidence" to determine fetal well-being and to evaluate the obstetrical care rendered. Most significantly, the Court found that this spoliation of evidence deprived the plaintiffs of the means of proving their medical malpractice case.

A finding that the plaintiff was deprived of the ability to prove her case was also the basis of the decision of the Appellate Division, First Department in *Herrera v Matlin*. There, the defendant-physician retired approximately one year after his last treatment of the plaintiff, and left his patient records – including x-rays of the plaintiff's injured wrist – in a filing cabinet in the medical office where he worked; he never arranged to return the records to his former patients or transfer them to another doctor. During the litigation, the plaintiff was unable to procure the records from the medical office, and the physician was by that time deceased. The Court found that the deceased physician's professional misconduct in failing to maintain the patient's records for at least six years as required by the Education Law deprived plaintiff of "any means" of establishing a case and warranted the striking of defendant's answer.

It is extraordinarily difficult to defend a case where the medical records have been lost. For instance, where fetal heart monitor strips are missing but the hospital chart is

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MC&B NEWS

RECENT SEMINARS

"New York Appellate Practice"

MARTIN CLEARWATER & BELL LLP appellate counsel Ellen B. Fishman was invited by the New York State Bar Association to be a member of the faculty at a recent continuing legal education program for litigators. Ms. Fishman's lecture was presented on November 7, 2003, in Hauppauge, Long Island, as part of a program that emphasized practice in the Appellate Division, Second Department. This course, sponsored by the Bar Association's Committee on Courts of Appellate Jurisdiction, included distinguished appellate judges and chief court clerks on the same panel.

Ms. Fishman spoke from the perspective of an experienced practitioner on the nuts-and-bolts topics of "Raising Issues, Preservation of Error, Judicial Notice and the Harmless Error Rule." In particular, she stressed the need for attorneys at the trial level to raise key points in such a way as to lay the groundwork for a successful appeal. She offered tips for trial attorneys and urged them to consult with appellate counsel about making motions and taking other steps to assure that key issues are preserved for review by the appellate court.

Nurses and Allied Health Professionals in Disciplinary Proceedings"

MARTIN CLEARWATER & BELL LLP partner Kenneth R. Larywon co-chaired a New York State Bar Association program entitled "Representing Physicians, Nurses and Allied Health Professionals in Disciplinary Proceedings." In addition to co-chairing the program, Mr. Larywon also lectured on the subject of Hospital Disciplinary Proceedings Involving Physicians, both from a prosecutorial and defense standpoint. Mr. Larywon is the Co-Chair of the Health Law Section of the New York State Bar Association.

On October 31, 2003, Mr. Larywon co-chaired the same program in Manhattan for a group of approximately 100 lawyers. Martin Clearwater & Bell LLP partner Peter T. Crean participated and moderated a panel discussion involving the prosecution and defense of Office of Proffessional Misconduct proceedings. Mr. Crean was one of the three speakers including the Chief Counsel, Division of Legal Affairs and the Director of Investigations of the OPMC.

MARTIN CLEARWATER & BELL LLP partner Joseph L. DeMarzo also participated in the section of the program related to the hospital disciplinary process. Mr. DeMarzo discussed numerous hospital disciplinary topics including the effect of an adverse hospital disciplinary finding on subsequent disciplinary proceedings by the Office of Professional Misconduct.

CLE SEMINAR

Martin Clearwater & Bell LLP sponsored a morning CLE for clients on Thursday, February 5, 2004 at the UN Crown Plaza Hotel in Manhattan. Senior partners Bruce G. Habian and John L.A. Lyddane spoke along with a distinguished breast pathologist on ***Breast Cancer: The Defendant's Issues.*** The seminar covered an Overview of the Liability Issues, the Role of the Primary Care Physician/Gynecologist, Diagnostic Treatment/Recommendations, Liability Defenses - Causation, Evaluation of Exposure, and Sustainable Verdict Ranges & Causation. The seminar was approved by the New York State Continuing Legal Education Board for 3.5 CLE Hours.

ELLEN B. FISHMAN HEADS MC&B'S APPELLATE PRACTICE GROUP

MARTIN CLEARWATER & BELL LLP is proud to announce that Ellen B. Fishman has been appointed head of the firm's Appellate Department. Ms. Fishman is well known as an appellate advocate with particular expertise in healthcare matters. She was until recently, Senior Counsel in the Appeals Division of the New York City Law Department. Since her admission to the bar in 1979, Ms. Fishman's practice has included representation of all the facilities under the jurisdiction of the New York City Health and Hospitals Corporation, as well as the City's Chief Medical Examiner and the Department of Health and Mental Hygiene.

Ms. Fishman has handled hundreds of complex appeals at every level of the state and federal courts, including numerous cases of first impression in the area of medical malpractice defense.

The Court of Appeals decisions *Daniel J. v New York City Health and Hospital Corp.* and *Allende v New York City Health and Hospital Corp.* are two seminal cases briefed and argued by Ms. Fishman regarding the applicability of the continuous treatment doctrine to the filing of notices of claim. Ms. Fishman also handled the appeal of *Lara v New York City Health and Hospital Corp.* concerning the admissibility of medical expert testimony, discussed in our lead article this edition.

Ms. Fishman is a frequent lecturer on appellate practice and has served as Chair of the New York State Bar Association's Committee on Courts of Appellate Jurisdiction.

Ms. Fishman is well known as an appellate advocate with particular expertise in healthcare matters.

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orated the positions taken by the defendant. Specifically, the defendant showed that the choice of prostheses and the amount to which they were filled (to prevent a rippling of the skin the patient previously experienced), as well as the surgical plan of a subglandular technique (avoiding more extensive dissection of the tissue) were all reasonable considerations and choices made by the defendant plastic surgeon in treating this patient.

With the aforementioned testimony in evidence, the trial court granted Mr. Lawton's request that the jury be charged with the "error in judgment" instruction on the law. The *Nestrorowich* requirement that there be sufficient evidence that the defendant physician considered and chose among several medically acceptable treatment alternatives warranting an "error in judgment" charge had been well established from the trial testimony of the defendant, defendant"s expert plastic surgeon, as well as plaintiff"s own plastic surgery expert.

The jury returned a defense verdict, finding that although the defendant plastic surgeon's decisions during the implantation procedure may not have produced the best result, his decisions were the products of his informed judgment, based on his years of skill and experience.