A Publication From The Maryland Defense Counsel, Inc.

Winter 2009

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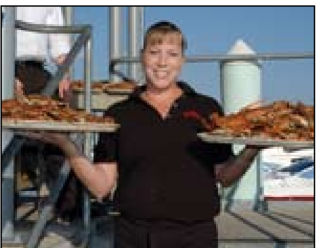

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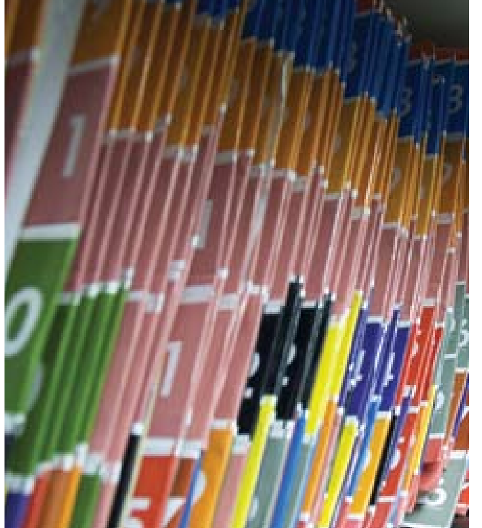
Challenging Plaintiff's Causation Theory

By John T. Sly and April Hitzelberger

A major frustration in Maryland medical malpractice cases has been the ease with which plaintiffs have been able to admit questionable expert opinions, especially on the issue of causation. We have had recent success in challenging plaintiffs in this regard. This article is a brief synopsis of the applicable law in Maryland on the issue of the admissibility of expert testimony and, as importantly, the process by which it can be challenged.



I. The Law

Expert testimony is admissible in Maryland only if: (1) the witness is qualified as an expert by knowledge, skill, experience, training or education; (2) the expert testimony is appropriate on the particular subject; and (3) there is a sufficient factual basis to support the expert testimony. Md. Rule 5-702[1]; *Wood v. Toyota Motor Corp.*, 134 Md. App. 512, 519 (2000). "Furthermore, the testimony must also reflect the use of reliable principles and methodology in support of the expert's conclusions." *Giant Food, Inc. v. Booker*, 152 Md. App. 166, 183 (2003) (citing Wood, 134 Md. App. at 523). "[W]hile Rule 5-702 does not specifically state that the expert testimony must be the product of reliable principles and methods (*i.e.*, phraseology taken from Fed.R.Evid. 702), Maryland case law interpreting Rule 5-702 requires such a foundation." *Id.*

While Maryland has not formally adopted the federal *Daubert* analysis, Maryland appellate courts appear to be moving in the direction of applying what might be called a "*Frye*-plus" test. In other words, Maryland will require a sufficient basis, a reasonable methodology and a conclusion that logically flows from the basis and methodology (the Daubert test) but will also continue to require that the methodology and conclusion be generally accepted before being admissible (an element lacking in *Daubert* but present in *Frye*)[2].

The decision as to the admissibility of an expert's opinion is firmly within the discretionary purview of the trial court. "'It is within the sound discretion of the trial judge to determine the admissibility of expert testimony' and that 'the trial court's action in the area of admission of expert testimony seldom provides a basis for reversal.'" *Buxton v. Buxton*, 363 Md. 634, 651 (2001) (*citing In re Adoption/Guardianship, No. CCJ14746*, 360

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[1] *Rule 5-702 provides:*
Expert testimony may be admitted, in the form of an opinion or otherwise, if the court determines that the testimony will assist the trier of fact to understand the evidence or to determine a fact in issue. In making that determination, the court shall determine (1) whether the witness is qualified as an expert by knowledge, skill, experience, training, or education, (2) the appropriateness of the expert testimony on the particular subject, and (3) whether a sufficient factual basis exists to support the expert testimony.

MD. R. Civ. Pro. § 5-702 (2007).

[2] *The appropriate analysis in Maryland is evaluation of the putative expert's opinions pursuant to* Frye v. United States, *293 F. 1013 (D.C. Cir. 1923) and* Reed v. State, *283 Md. 374 (1978) which require that the opinions be generally accepted in the particular scientific/medical community before they are admissible.*

(CAUSATION THEORY) *Continued from cover*

Md. 634, 647 (2000)). "It is well settled that the trial judge — not the expert witness — determines whether there exists an adequate factual basis for the opinion at issue." *Wood*, 134 Md. App. at 523.

II. Procedure

In *Clemens v. State*, 392 Md. 339 (2006), the Court of Appeals said: "Judges have discretion to defer a pre-trial ruling on a motion in limine and ordinarily do so where the issue can be better developed or achieve a better context based on what occurs at trial. Where evidence is subject to challenge under *Frye-Reed*, however, the issue should, whenever possible, be dealt with prior to trial. *Id.* at 349 n. 6 (emphasis added). Furthermore "[d]ealing with the issue pre-trial also avoids delays and diversions at trial that may inconvenience both witnesses and the jury." *See* Maryland Rule 5-104(c) ("Hearings on preliminary matters shall be conducted out of the hearing of the jury when required by rule or the interests of justice.") *Id.* The Court explained that:

> *Maryland Rule 5-103(c) also provides support for our conclusion that* Frye-Reed *examinations are better conducted in pre-trial hearings in its admonition that "[p]roceedings shall be conducted, to the extent practicable, so as to prevent inadmissible evidence from being suggested to a jury by any means, such as making statements or offers of proof or asking questions within the hearing of the jury." Conducting the hearing outside the presence of the jury would preclude its members from improperly considering evidence that is irrelevant to the task at hand and ensure that the verdict is derived from evidence properly before it.*
>
> *If the issue is to be dealt with at trial, it should be addressed, in its entirety, as a preliminary matter prior to admission of the challenged evidence, not, as here, by having the challenge made only to [the expert's] status as an expert during the State's case and then receiving most of the evidence bearing on whether the inferences sought to be drawn…are generally accepted in the relevant scientific community during the defense case, after the challenged inferences have already been admitted.* Id.

Because of these considerations, the *Clemens* Court found that an evidentiary hearing should be held on any *Frye-Reed* challenge to an expert's testimony, "[i]f a party raises a *Frye-Reed* objection, all evidence bearing on admissibility of the challenged evidence should be presented and considered ***before*** a ruling is made on the challenge." *Id.* (emphasis in original).

The Court of Appeals recently reaffirmed and expounded upon its reasoning in *Montgomery Mutual Ins. Co. v. Chesson*, 399 Md. 314 (2007). Additionally, the *Chesson* Court clearly stated that medical doctors are subject to the *Frye-Reed* analysis—a question previously left open by *dicta* in other cases.

In *Chesson*, the Court held that a pre-trial hearing is *required* in a case pursuant to *Frye-Reed* "when it is unclear whether the scientific community accepts the validity of a novel scientific theory or methodology" in order to demonstrate its reliability. *Id.* at 327. (emphasis added). In reaching its decision, the Court was particularly persuaded by the fact that appellee's expert offered no journal articles from reliable sources or other publications to shed light on the acceptance of his views and admitted that no other practitioners in the field shared his opinions. *Id.* at 327, 332-33, n.7. Without sufficient evidence of reliability, the expert's testimony must be excluded. *Id.*

III. *Booth v. University of Maryland Medical System (UMMS)*

In *Booth v. UMMS* (Baltimore City Circuit Court Case No. 24-C-06-5867) Plaintiff's anesthesia experts sought to link the attempt at regional anesthesia to profound neuropathy in an extremity. On behalf of UMMS, we argued there was no basis for Plaintiff's allegations and that her experts had failed to apply a reasonable methodology in developing their causation argument (analysis pursuant to Md. R. 5-702) and that their opinions were not supported by the medical literature (*Frye-Reed*). These issues were raised in multiple pretrial motions.

As a result of the pretrial motions challenging Plaintiff's experts' causation theories, and a formal request for a hearing on those motions, Plaintiff was forced to produce one

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Editor's Corner

The Editors are proud to publish this latest edition of *The Defense Line*, which features several interesting articles and case spotlights from our members. The lead article from John T. Sly, who is the co-chair of The Maryland Defense Counsel's Judicial Selections Committee, discusses Maryland's standard for the admissibility of expert testimony in medical malpractice cases. Kathleen Pontone, a partner at Miles & Stockbridge P.C. and the head of the firm's Labor & Employment Group, presents an article offering advice on how law firms should approach the evaluation of its lawyers in today's legal environment. In addition to these articles, Gregory M. Garrett, an associate in the Litigation Department at Tydings & Rosenberg LLP, highlights a recent Maryland Court of Appeals decision in which the court analyzed the learned intermediary doctrine under Maryland law.

The Maryland Defense counsel has had a number of successful events since the Summer 2008 edition of *The Defense Line*, including the always popular Past Presidents Reception. Mark your calendars now for Maryland Defense Counsel's Annual Meeting and Crab Feast, which will take place on June 4, 2009 at 5:30 at Bo Brooks in Canton! The Editors encourage our readers to visit the Maryland Defense Counsel website (www.mddefensecounsel.org/events) for full information on the organization's upcoming events.

The Editors sincerely hope that the members of the Maryland Defense Counsel enjoy this issue of *The Defense Line*. In that regard, if you have any comments or suggestions or would like to submit an article or case spotlight for a future edition of *The Defense Line*, please feel free to contact the members of the Editorial Staff.

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of her experts at a pretrial hearing. (Plaintiff declined to produce her second expert.) The pretrial hearing permitted extensive cross-examination in support of the *Frye-Reed*/Md. R. 5-702 motion and other motions filed on behalf of UMMS. The judge had the benefit of hearing the expert's testimony which lead, in part, to the court granting a related dispositive causation motion.

IV.Conclusion

The soft underbelly of most medical malpractice cases is causation. Plaintiff experts are adept at identifying alleged breaches in the standard of care and the alleged damages involved. What they often lack is a real scientific basis for their causation opinion. This is where the challenge to their admissibility must be focused. These are a few of the steps that can be employed in seeking to preclude unreliable expert testimony:

a. Question the expert closely at deposition with regard to supporting literature and follow-up with written discovery demands. A lack of literature supporting an opinion can be fatal in and of itself;

b. Ensure your expert has literature and can articulate a cogent rationale for why plaintiff's expert's causation theory is unsupported, *i.e.*, no scientific basis, no tests, and alternative causes;

c. Do not accept plaintiff's expert's effort to glance by the causation question. Demand the facts (study results, etc.) and how they demonstrate how the breach proximately caused the injury;

d. File a motion seeking a hearing with the judge assigned to the trial and support your motion enough to demonstrate its good-faith basis without providing all of your cross-examination material. This should be done at or around the dispositive motion deadline or at the deadline for motions in limine at the latest;

e. Be specific in requesting a hearing at which live witnesses will be called and contact the judge assigned to the motion to ensure it is understood that witnesses may testify;

f. **Be prepared for a live hearing. You must have witnesses and literature too.**

John T. Sly, Esq. is a partner at Waranch & Brown, LLC and is a member of the Board of the Maryland Defense Counsel.

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Micro-Evaluations Anyone?

By Kathleen Pontone

"Forty to fifty percent of new lawyers have been female for the better part of the last two decades. Despite honest efforts by most firms, the percentages of female partners continue to hover in the mid teens in most geographic areas. Thus, our failure rates with new lawyers are even higher for females than males."

Every time I get together with women lawyers, as I did this October at the DRI Women's Networking Luncheon at our annual meeting, I am forced to acknowledge that our profession still is not doing very well in the retention and promotion of women to partnership. The ABA's Commission on Women in the Profession has identified methods for evaluating associates as one way to improve retention and promotion rates. The ABA publication, "Toward Effective Attorney Evaluations" (2d Edition 2008) encourages the creation of elaborate models for associate evaluation and detailed recordkeeping on the mechanics of "each skill and ability" needed for success in the practice of law. I agree that our evaluation methods are failing our lawyers, but come to a different conclusion. My solution is quite different. I would not put more emphasis on yearly evaluations. I would make them irrelevant by putting more emphasis on project by project guidance — micro-evaluations.

The ABA's publication on evaluations does a superb job of stating the problem. First, the publication notes that 80% of new lawyers leave their firms within the first five years of practice. *Id.* at 13 The ABA publication goes on to note that the cost of replacing an associate ranges between $200,000 and $500,000. *Id.* You have to ask yourself why do we as lawyers, continue to do this? The only answer is "because we can," or more appropriately, given today's legal climate, "because *we could*."

The abundance of good work that could be billed out at high rates and a seemingly limitless pool of new talent coming out of law schools made this system workable for many years. Forty to fifty percent of new lawyers have been female for the better part of the last two decades. Despite honest efforts by most firms, the percentages of female partners continue to hover in the mid teens in most geographic areas. Thus, our failure rates with new lawyers are even higher for females than males.

The new economics of the practice is making this state of affairs unacceptable. Although most lawyers contend that the practice of law is a profession, not a business; it still must be carried out in a businesslike fashion. We now pay attention to what things cost and whether such costs provide value to our clients. We find clients increasingly impatient with a revolving lawyers, even if the billing rates are lower for the newer associates who replace the defectors. Clients are starting to ask what is wrong when they see new people being educated on their work rather than establishing lasting relationships with associates who know their business. Even if we write off fees, discount fees for new lawyers joining client teams, or forgoing billing at all for first year associates (as some firms have), many clients find this turnover distressing.[1]

Experience shows that a great percentage of these lawyers are simply discouraged that they are not progressing as far as they think they should. Child rearing responsibilities may factor in here, but the pressures to have a life outside the practice now fall on both sexes. Young lawyers are quite simply overwhelmed.

Pushed by labor lawyers and consultants, most firms have some formal yearly process for evaluating associates, as suggested by the ABA. There is a written form that must be filed, as well as a formal meeting. The most sophisticated firms have on line evaluation forms and standardized levels of grading the multiple skill sets and abilities deemed necessary to be a good lawyer. In addition to the research, analysis, and analytical skills, these systems measure compliance with deadlines, pro bono and community activity, compliance with firm administrative practices, and firm citizenship. And, of course, there is always someplace in the process to deal with the issues of "commitment" and value, measured by hours and collections.

Some evaluation systems now have a self analysis component in which the associate rates him or herself and some include a "three-sixty (360)" component where the associates get a chance to rate their supervisors. In an effort to be sure that young lawyers are learning what they need to know, some firms are now cataloguing core competencies of the different practice areas. These evaluation systems are necessary to defend in a discrimination case; however, they often prove devastating for those who are not instantly identified in the top group. Nothing in these systems encourages those who struggle at the outset, and many drift along and either sink or swim. This costs firms a great deal more than the money lost in the re-education of new associates, it saps morale in the firm, exhausts the evaluating lawyers, and shortchanges our clients. It has also had a very negative impact on firms meeting their diversity goals.

In point of fact, these evaluation systems were developed to address objections of the Courts to purely subjective evaluation tools used for promotion in race and sex discrimination cases. The Courts attacked the promotional systems based solely on the subjective judgment of the supervisor or hiring officer. For example, the United States Supreme Court attacked employer decisions based on subjugation standards in

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[1] *Indeed, many times senior lawyers evaluating the associates have similarly become disenchanted with pouring the intellectual and emotional energy to transition a practice to the next generation of lawyer only to have them move on. They decide it is easier just to do the work themselves, thus depriving the clients of a team approach that provides continuity and depriving the firm of succession planning for important relationships.*

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hiring of teachers by a Missouri school district. *See Hazelwood School District v. United States*, 433 U.S. 299 (1977). Subsequent cases continued that theme and cautioned lawyers to use similar criteria and focus on hours and billings as the tickets to success.

The generation of lawyers who are administering these systems are charitably referred to as "boomers," entering the practice of law in the 1970's and 1980's. This group of lawyers like systems and regularity but do not want to be controlled or regulated themselves. They just want to hear once a year that they are appreciated and are above average enough to justify more money and power.

Unfortunately, the associates receiving these reviews who entered practice just before or after the turn of the 21st Century, are not like the lawyers from the 1970's and 1980's who are administering the evaluation process. Although our society is by no means completely free of the issues that haunted us in that generation, the Courts have become a lot more comfortable with more subjective measures in professional positions. The attempt to characterize and codify all the traits that make a successful lawyer have instead convinced many young lawyers that they could not possibly measure up in all the categories that most evaluations encompass. Indeed, although virtually none of the partners in any firm excel at all these things, from *pro bono* to billable revenues, the standards we have set are a compilation of everything that a cadre of exceptional lawyers can do—just not all at one time.

The current associate pool find the yearly evaluation both overwhelming and too little too late. Sadly they are right. This growing disenchantment with the formal evaluation is popping up in other businesses as well. Indeed, a recent article in the *Wall Street Journal* by Samuel A. Culbert, urges us to "Get Rid of the Performance Review! It destroys morale, kills teamwork and hurts the bottom line and that's just for starters." Samuel A. Culbert, *Get Rid of the Performance Review*, *WALL ST. J.*, Oct. 20, 2008, at R4.

Basic information about generational differences between lawyers entering the profession now and those of us who manage them is now available and is a common topic of conversation among managers in industry as well as law. Ron Alsop's book "The Trophy Kids Grow Up: How the Millennial Generation is Shaking Up the Workplace" is but one insightful account of this group. Ron Alsop, *The Trophy Kids Grow Up: How The Millennial Generation Is Shaking Up The Workplace* (Jossey-Bass 2008). Certain themes continue to surface in what this group needs by way of evaluation, including constant, even daily, reinforcement, positive emphasis, precise guidelines, and/or defined rules and explanations of how mundane tasks affect the process.

The most senior lawyers, who entered the practice in the 1950's and 1960's want their performance critiqued when there is a problem but adopt the "no news is good news" philosophy. This is the way they were treated and they think it works just fine. They want little or nothing to do with the process, and rarely fill out the forms, which creates a compliance problem for the firm. Furthermore, although they tend to be the most astute observers of true legal ability, they rarely want to spend the time to participate in the full fledged evaluation process.

Those who entered the practice in the 1970's and 1980's compose the current management of most firms, like to think of themselves as cool and hip but are really quite set in their ways. As far as evaluations are concerned, once a year, whether they need it or not, is good for them. They are antiauthoritarian enough to want to minimize bureaucracy as they hate being subject to it. They do want to know, however, where they stand. Although this group will complain when the news in an evaluation is not good or at least above average, if they have survived long enough to be practicing at this point, their glass is usually half full. They fill out the forms but complain bitterly that they are too time consuming, and worry when their good people are subjected to what they see as unfair treatment by others who work with the associates on a sporadic basis.

The Gen X'ers (who entered the practice in the late 80's and 90's) came in seeking to shake things up and still do. Mistrustful and unsure of what they wanted when they arrived, many had the temerity to assert that they did not necessarily want to be partner. They want interesting work, good pay and fully intend to move on if they are not happy. Having entered the practice in the recession, they do not always think that firms have their best interest at heart and seek more reassurance that they are well thought of by their superiors. Although they certainly will move along for more money, they are not necessarily motivated by money alone, they want "lifestyle" concessions. Getting this group ready to take the reins of power has been challenging and rewarding. Many of them adamantly demand "less stress" and more personal time, which are two things that do not necessarily improve when management responsibilities increase. They can also be too blunt with the new associates, who are often more fragile then they appear to those who just left their ranks themselves.

And now of course we have the Gen Y (those who entered practice in the 21st Century) and what a difference. Although this group should be more familiar to those who started practice in the 1970's and 1980's because we raised others of the same vintage, they are completely alien to current firm managers as employees. Having grown up to expect a trophy for participation, these new lawyers seem to require almost constant reinforcement. These group of lawyers who endured "helicopter" parents programming their every minute with "activities," now expect the same kind of engagement from their supervisors. Some researchers tell us that the lawyers who began practice in the 21st century, want to be told how they are doing every day or at least several times a week. How can the 70's – 80's group be expected to do that and handle the hundreds of emails that we process every day? We have enough trouble evaluating associates once a year, business planning and budgeting, goal setting, core competency rankings, and, of course, doing legal work on the side.

Employment lawyers will argue that yearly performance evaluations are still necessary for defending discharge and failure to promote cases, but are evaluations the solution or the cause of associate dissatisfaction?

The elaborate yearly evaluation process simply does not work with the groups of lawyers who entered practice recently. They believe that they are being ignored on a daily basis and that their work is not important enough for comment by superiors. When faced with self-evaluation under the myriad of things the evaluation tells them they need to have mastered to make it, they become discouraged and mistrustful. They are skeptical enough to observe that few or none of

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the current partners excel in all these areas and think that these are just schemes to winnow down the ranks of the partnership. They fail to understand how they fit into the whole and, therefore, believe that they are just cogs in the wheel of billing. These feelings of frustration and self-doubt really come to a head in the critical 5th to 10th year of practice, when progress comes in fits and starts rather than in a linear progression of the early years. Rather than confront failure, something most of them have never done, too many junior lawyers leave before we have a chance to see if they are really "getting it" in terms of handling more difficult client matters or not.

Meanwhile, although the firms feel that they have expended huge sums in recruiting and evaluating these lawyers, many of those lawyers feel neglected in the only area they do care about-which is how their careers are progressing. If we treat them right, this group can be with us for the long haul. These associates are also surprisingly fragile, however, and get discouraged easily in the yearly model and will not wait around to fail. To the extent that some mechanism must identify areas for improvement, and it must, the once a year evaluation model scares them off. They get too discouraged by it.

The Solution — Get Back to Work

The solution is to set this whole process back where it should have been in the first place with the process of performing the client's work. Mature practitioners exist to do our client's work and to train the next generations of lawyers to do it without a break in continuity. The ideal, of course, is for us to speak to associates we work with as we work together, which is the way most of us learned to practice. We must act as colleagues working together. The most successful mentors continue to do just that.

Docketing

Assuming however, that we have all become so busy that we need some structure, a few suggestions are in order. By keeping track of what the associates are doing, supervising lawyers can figure out if they have enough work and how they are managing it. Associates with the help of their assistants, should be able to create a docket of the significant things they plan to do that month, what is completed last month and what will be coming up in a matter down the road. This tells a lot about what associates are doing and their beliefs about what is done, and what needs to be done next.

Talk to Associates

Talking about this, is the best way to give instantaneous feedback about how someone is doing and especially how they can do it better. Are they in fact taking "ownership" of the matter or are they just waiting for the next task? Are things falling through the cracks, either because it lingers month after month, or do they need help getting the client to respond so the matter or transaction does not languish? These are the things associates need to learn to move to the next level. If you want to see if someone understands, talk to them about the work. These task by task meetings are the place to give constructive criticism, not the yearly review. This also serves to focus the team on the client's matter, where it is and where it is going. Associates need to be encouraged to communicate this to our clients by watching more senior lawyers do it and doing it themselves.

Documenting Progress — Micro-Evaluations and Yearly Summary

Of course, there must be some documentation of this or the employment lawyers will argue that the firms are at risk in discrimination cases. This is, of course, true enough, but it risks mishandling our best associates in order to defend our actions against our worst performers. Yes, it is true that a Firm needs express written performance critiquing to justify a discharge, or failure to promote. That is what performance evaluations were designed for and they do it well. They have the unintended consequence, however, of discouraging some lawyers who would make it if they had more positive and less permanent records of their early failures and missteps. Firms put the emphasis in the wrong place if they comply with a process designed to justify discharge, rather than encouraging success.

Accordingly, rather than putting down the week to week feedback in the yearly evaluation, we should document these meetings in email which is the easiest and best way to ensure the notes are preserved. Lawyers can title the notes to be sure they are properly filed, and an up to the minute record can be maintained. This also gives associates time to respond if they want to clarify or expand on what was said, and how tasks fit together in the near and far terms. The result should be an interaction which helps associates to understand the best way to approach the issues. If it becomes a war of words, or dueling emails you may as well address the problem now before it gets to the point where it needs intervention.

There must, of course, still be something in writing on a yearly basis that summarizes progress for the year. This should facilitate the goal setting on a few discrete client management or development areas. Supervisors should encourage and recognize the results achieved during the year, rather than hours and billings. All firms have billing and collection targets which need to be achieved, however, this process should focus on the achieved results for clients, rather than hours as a goal in and of themselves. This second larger process should focus on interfirm cooperation which is a method of growth in all successful firms. Encouraging the concern for the community and real contribution should be the goal of this process. These are the issues that govern the partnership track in the end, and they should be the focus of the relationship early on. Is this person establishing the relationships and reputation they need to advance? How can the firm help them achieve those either at that firm or somewhere else? These should be less of a report card, and more of a method to encourage success.

The 21st Century lawyer is someone to whom clients will turn to for advice. These lawyers bring in clients by their skill, integrity and results achieved. The encouragement of the mind set needed to achieve that requires other skills which are equally important to the health and continuity of a Firm. We have to adapt to a faster, more immediate world if we want to achieve success in retaining our associates and our clients-hopefully benefiting both.

Kathleen Pontone is the practice group leader for Miles & Stockbridge P.C.'s Labor & Employment group. Her practice includes the defense of discrimination cases, with extensive experience in disability related claims, occupational safety and health cases, sexual harassment, and compensation and anti-competition disputes. The views expressed here are the personal views of the author herself and not those of the Firm.

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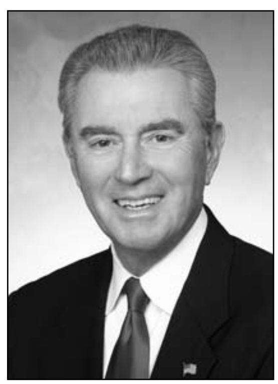

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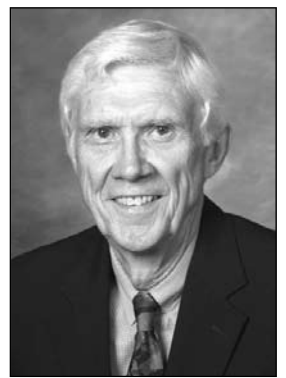

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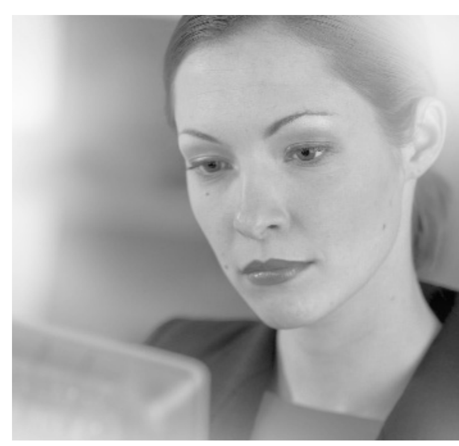

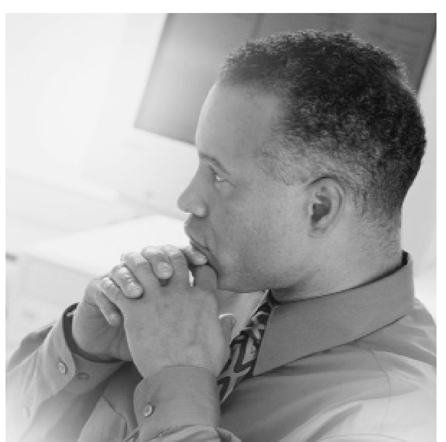

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SPOTLIGHTS

Court of Appeals Casts Doubt on Applicability of Learned Intermediary Doctrine

By Gregory M. Garrett

In *Gourdine v. Crews*, 405 Md. 722, 955 A.2d 769 (2008), the Court of Appeals upheld the grant of summary judgment in favor of a drug manufacturer, holding that the manufacturer owed no duty to a motorist that was killed by a driver who allegedly lost consciousness after using the manufacturer's product. Although the decision was a win for the defendant, the Court's discussion of the learned intermediary doctrine has injected a new level of uncertainty into Maryland products liability law.

The case arose when the patient, Ellen Crews, took a combination of drugs manufactured by the defendant, Eli Lilly & Co. ("Lilly"), which had been prescribed to Ms. Crews by her physician. While driving her car, Ms. Crews suffered a hypoglycemic reaction and lost consciousness. Her vehicle then struck another car, driven by Isaac Gourdine, causing Mr. Gourdine's car to crash into a tractor trailer. Mr. Gourdine suffered a mortal head wound as a result of the collision. His wife filed suit against, *inter alia*, Lilly in the Circuit Court for Prince George's County, bringing counts sounding in strict liability, negligence, and fraud, arising out of Lilly's failure to warn Ms. Crews that the drug combination could cause increased rates of hypoglycemia and drowsiness. The circuit court granted summary judgment in favor of Lilly, holding that (1) Lilly owed no duty to Mr. Gourdine or his survivors based on the learned intermediary doctrine; (2) the plaintiffs' failure to warn claim was preempted by federal law; and (3) because there was no duty and the alleged misrepresentations were not made to the plaintiff, the plaintiff's fraud claim failed. The Court of Special Appeals upheld the grant of summary judgment, relying on the learned intermediary doctrine and, in the alternative, ruling that Mr. Gourdine's death was not a reasonably foreseeable consequence of the allegedly wrongful conduct. *Gourdine v. Crews*, 177 Md. App. 471, 935 A.2d 1146 (2007).

The Court of Appeals first described the framework to be applied in failure to warn cases, holding that, regardless whether the theory of recovery is negligence or strict liability, duty is an essential element that must be alleged and proven. The Court disapproved, however, of the lower courts' reliance on the learned intermediary doctrine, which it defined as "impos[ing] on a manufacturer of prescription drugs or devices a duty to give adequate warnings to physicians, dentists, or other licensed health care professionals, including nurses, who may prescribe these products. Under the doctrine, a manufacturer which has adequately warned the physician, in almost every circumstance, has no duty to warn a patient."

In support of their findings that Maryland recognizes the learned intermediary doctrine, the lower courts relied on *Nolan v. Dillon*, 261 Md. 516 (1971). The lower courts ruled that, because the doctrine excuses the manufacturer from warning the end-user of dangers associated with the product, the manufacturer has no duty to a non-user of the product. The Court of Appeals, however, read the Nolan opinion narrowly, stating that the "case lacks the express adoption of the 'learned intermediary' doctrine undertaken by other courts." Accordingly, the Court found that it need not explore whether the doctrine is part of Maryland law, thereby ending its discussion of the issue.

Rather than relying on the learned intermediary doctrine, the Court turned to general principles of tort duty to inform its analysis. The Court focused its attention on the common law requirement that, to find duty, there must be "a close or direct effect of the tortfeasor's conduct on the injured party." The Court found that there was no connection between the lack of warnings on Lilly's product and Mr. Gourdine's death (and in fact, no relationship between Lilly and Mr. Gourdine at all), and consequently, Lilly owed Mr. Gourdine no duty in tort to label its drugs appropriately. In reaching its conclusion, the Court made clear that, absent truly exceptional circumstances, duty is not defined solely by the foreseeability of injury; rather, the court must also determine whether the imposition of a duty creates an obligation to "an indeterminate class of people." The Court also rejected plaintiffs' argument that the federal Food, Drug and Cosmetic Act imposed a tort duty on Lilly to refrain from placing a misbranded product into interstate commerce; instead, the Court held that the Act's purpose is to protect the public at large, and it cannot support a tort duty in favor of the plaintiffs.

Although the Court's ruling on duty is unsurprising in light of its earlier cases on the subject, its pointed refusal to apply the learned intermediary doctrine and limitation of the *Nolan* opinion casts serious doubt on whether manufacturers may rely on the doctrine in future cases. As Judge Raker wrote in a concurring opinion, the learned intermediary doctrine represents the majority view and would have provided "a clear, straightforward, and sensible" resolution to the case; the Court's refusal to rule on whether the doctrine is a part of Maryland law is therefore a troubling development for manufacturers. The uncertainty brought about by the *Gourdine* decision will affect not only drug companies, but manufacturers of all products in which warnings are typically provided to intermediaries rather than end-users. It likely will take a direct assault on the learned intermediary doctrine—such as a lawsuit by a patient, directly against a manufacturer, for failure to warn—before litigants know whether the doctrine is applicable in Maryland. Until the Court of Appeals provides a clear answer, however, defense counsel should expect trial judges to be more wary of applying the doctrine, and stronger arguments from plaintiffs' counsel (and counsel for physicians) that the doctrine is not part of Maryland law.

Gregory M. Garrett is an Associate in the Litigation Department at Tydings & Rosenberg LLP. He practices primarily in the areas of commercial and business litigation, health care and medical malpractice litigation, and antitrust law.

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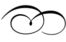
The Award Banquet will take place on Saturday, March 28, 2009, at the B&O Railroad Museum. All proceeds from the event benefit the MMTA Walter and Harriet Thompson Scholarship Fund, which provides financial support for students enrolled in trucking-related programs at member community colleges. We hope you will be able to join us.

Franklin & Prokopik represents a wide variety of motor carriers, private fleet operators, brokers, shippers, and their insurers. The Firm is a proud Allied Member of Maryland Motor Truck Association, Virginia Trucking Association, the American Moving & Storage Association, and National Tank Truck Carriers, and many of its attorneys are active in a number of other transportation related legal organizations.



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