

the Reporter

TMLT

TEXAS MEDICAL LIABILITY TRUST
January/February 2001

LEGAL IMPLICATIONS of VIDEOTAPING MEDICAL PROCEDURES

by Lynne Dakers, JD, Risk Management Representative

Although the “public relations” and educational benefits of providing patients with a videotape of an obstetrical ultrasound, a memento of childbirth, or recording of a surgical procedure are to be considered, there are certain risk management implications to take into account as well. Because they may be considered part of the medical record, videos should be identified with the patient’s name, identification number, and the date on which the recording was made and kept for the same period of time and at the same level of security that medical records are kept. Never allow the patient to retain the only copy. Consideration should also be given to the fact that videotapes may be admissible in a medical malpractice claim.

There’s no doubt about it — patients today are taking a more active role in their medical care. This is evidenced by the growing number of patients gathering information from the Internet prior to their doctors’ appointments. It can also be seen with patients who expect to be allowed to videotape certain medical procedures, most frequently childbirth. The tendency for parents to want to record the childbirth process may also be attributed to the demedicalization of the process (increased number of home births, alternative health care providers attending delivery, birthing rooms, broadcasting of childbirth on television and over the Internet).

Whatever the impetus, patients today are more likely to want certain procedures (especially obstetric procedures) videotaped and may even be inclined to seek another provider over this issue. A growing number of hospitals and doctors are instituting a “no recording” policy.¹ Such a ban, although perhaps not causing the patient to seek an alternate provider, may alienate her, causing a further breakdown in an already tenuous trust in the medical profession in general and in the physician-patient relationship in particular. Moreover, videotaped surgical procedures (e.g., laparoscopic surgery, where recording is quite simple) can provide an educational tool both for the

patient and for other physicians.

Why, then, are doctors, hospitals², certain specialty medical societies³ and some medical liability insurance companies⁴ advocating that videotaping be limited or abolished altogether? Undoubtedly, it stems from a fear of malpractice litigation.⁵ The question is, is this fear justified? There are varying opinions on this matter, but it seems to come down to a weighing of the patient’s wishes and expectations against the potential risk that a videotape may either increase the possibility of a lawsuit being filed⁶ or affect its defensibility⁷ (a ruling that a videotape is admissible being fairly certain).⁸

Perhaps the strongest argument against allowing videotaping of medical procedures is that the material would seem too graphic or confusing to a lay jury. Certainly, where there is obvious negligence involved, a videotape could prove inflammatory and result in larger awards.⁹ It could also provide more for experts to debate and attorneys to argue over, thereby prolonging trial.

Whether or not a tape can help or hurt the physician in his or her defense, there are certainly some precautions that anyone considering videotaping, whether in the delivery room or the surgical suite, should take.¹⁰ As with most medical risk management tips, these include a written consent by the patient, established policies and procedures, and adequate patient education and physician-patient communication.

Patients desirous of having a medical procedure videotaped must sign a written informed consent
continued on page 2



“However, practitioners must engage in a careful discussion of videotaping policies and procedures prior to the event.”

continued from page 1

in which he or she grants permission to be photographed. This consent must be included in the medical record. Beyond the written consent, however, practitioners must engage in a careful discussion of videotaping policies and procedures prior to the event. For instance, it should be explained to patients that the physician may choose to turn off the camera at his or her discretion if it becomes distracting to staff.

Patient education should not end with the termination of the procedure. Especially where there were complications, practitioners should take the time to review the tape with the patient so as to explain events and clarify confusion.

Policies and procedures should address:

- Consistency — practitioners and institutions must be consistent in the obtaining and/or retention of videos to avoid a charge of hiding evidence.
- Circumstances where photography or videotapes are allowed — including specific portions to be excluded, if any; camera positioning; circumstances where physicians can turn off the videotape at their discretion.
- Medical records issues — such as retention, storage, and release.¹¹

Other risk management suggestions include:

- Turn off the audio portion of the videotape.
- Discuss with staff the need to be aware of the video camera and review, if necessary, elements of professional conduct.
- In the delivery suite, tape from the head of the bed.
- Tape only a portion of the procedure rather than its entirety (allows for less misinterpretation) or send patients home with still photos rather than the video.
- Retain an unedited copy.

Hopefully, these suggestions and considerations will help practitioners when deliberating the use of videotapes in the delivery or surgical suite. Whichever route physicians decide to follow, either by choice or as dictated by the institutions where they practice, a candid, thorough discussion with patients which addresses their expectations and explains your and your hospital(s)' policies is a necessary step in maintaining a therapeutic physician-patient relationship.¹²

Notes

1. A growing number of hospitals and doctors are banning cameras from the delivery room. A University of Iowa study cited in the January 2000 edition of *JAMA* surveyed obstetricians and family physicians. Forty-one percent of the obstetricians and 19 percent of the family practitioners answered yes to the question

“would you ever prevent a patient from filming a medical procedure?” Of those who said yes, 80 percent cited legal concerns.

2. A recent *Houston Chronicle* survey of Houston hospitals found three with no-taping policies (one of which ranked in the top four area hospitals in number of deliveries) and three hospitals which had taping restrictions.

3. The American College of Obstetrics and Gynecology's Committee on Professional Liability released an opinion in September 1998 stating that it “strongly discourages any recording of medical and surgical procedures for patient memorabilia.”

4. Legal Implications of Birth Videos, *J Fam Pract* 1998; 46: 256-261.

5. *Ibid.* In September 1996, 35 members of the American College of Legal Medicine were polled on this issue. Respondents indicated that there were nine known cases where obstetric videos were used as evidence.

6. One physician who advocates against sending patients home with a memento video points out that less than 40 percent of iatrogenic injuries ever come to the attention of the patient. (*Laparoscopy Update*, March 1993.) But there is a competing argument that an available video may prevent needless litigation, since by chronicling the procedure it removes the need to infer what took place through reconstruction with oral testimony, expert witnesses, and the medical record. Or, if not preventing a suit from being filed, a video may at least save the time, expense, and emotional upheavals of a lawsuit by encouraging out-of-court settlement in cases where negligence has occurred.

7. However, another physician argues that the arguments against videotaping are akin to the old argument that supported minimalist charting. That is, they can't attack you about something you didn't document. Rather, a videotape of the procedure could provide evidence of conformity to the standard of care.

8. The Federal Rules of Evidence require for a finding of admissibility that the tape accurately represent the underlying events, that it be relevant to the issue at hand, and that its value as evidence outweighs the “danger of unfair prejudice, confusion of the issues, misleading of the jury, or by considerations of undue delay or needless presentation of cumulative evidence.” Rule 403.

9. *Houston Chronicle*, June 25, 2000. Report of a Houston case where a hospital agreed to an unprecedented \$15 million out-of-court settlement over videotape which shows that staff failed to appropriately respond to a hypoxic newborn for more than an hour, resulting in blindness and irreversible brain damage. In the video, one can hear the mother's cries and a medical attendant saying “Someone better get that tape and destroy it.”

10. See AHIMA practice brief re: patient photography, videotaping, and other imaging for sample written informed consent form and guidelines for use of patient photography in specific circumstances (research, education, law enforcement).

11. See, AHIMA web site, www.ahima.org for its current practice brief pertaining to patient photography and videotaping. The brief also contains a sample informed consent.

12. There is no statutory or case law addressing whether videotapes are part of the medical record, however it would be wise to keep tapes for the amount of time required for any other portion of the medical record. This would help defend a physician against a claim of spoliation of the evidence. Also, by retaining the unedited copy, the physician will be able to counter a plaintiff's offered video and give a broader perspective of the procedure. In addition, review of the tape prior to giving oral testimony and in preparation for cross-examination will likely bolster a physician's credibility on the witness stand.

from the president



Working together for medical liability reform in 2001

by Tom Cotten, President and CEO

The year 2000 has drawn to a close. At TMLT, we have been busy preparing for a challenging 2001. The medical liability industry remains volatile, with an escalating number of lawsuits and high damage awards across our state. TMLT ended the year with a record number of claims taken in and a record number of cases taken to court. Out of 91 cases taken to trial, TMLT won 74, and we closed more than 85 percent of claims with no indemnity payment. Claims frequency and severity continue to be at elevated levels.

In the face of these trends, medical liability carriers who continue to write coverage for physicians in Texas are increasing premium rates to help cover the costs of legal defense and claims pay-out. Some carriers are cutting back on services. Some out-of-state carriers have discontinued writing coverage in Texas until the trends improve. At TMLT, we reluctantly increased premium rates in 2000 and will be implementing another increase in January. The decision to raise rates was a difficult, but necessary, one for us and for our physician governing board. Unlike commercial carriers who have investors and must show a yearly profit, TMLT is a not-for-profit, physician-owned carrier. However, we must take all prudent steps to remain financially sound so that we can continue to provide medical liability protection for all our policyholders. At this time, this includes raising rates.

Although we have raised rates, we have not cut back on services. We are committed to maintaining the high level of quality products and services we offer you. This includes working toward solving the problems that have necessitated the rate increases. We believe that medical liability reform can have a strong impact on lawsuit abuse. We could place limits on damages that can be awarded in a malpractice suit. Class action reforms make up another potential area of medical liability tort reform. Carriers pay millions in defense of doctors in product-related mass litigation such as breast implant, Norplant, and Fen-phen. We should also take a hard look at cost bond and expert report reforms.

Although cost bond and expert report provisions were passed in 1995, they are not always enforced. Legislation eliminating judicial discretion regarding dismissal of the lawsuit when the timelines are not met under the cost bond provision could ensure that attorneys file bonds and provide expert reports on time.

However, setting the stage to effect meaningful medical liability reform takes time, money, and focused effort. For this 2001 legislative session, we must draw attention to the problems of lawsuit abuse, increasing claims frequency and severity, escalating premium costs and limited availability of affordable coverage. Physicians have a powerful, collective voice and now is the time to make your concerns known to those who can help.

At this time last year, we began sending policyholders an information kit called TMLT 2000. The kit contained letters, articles and other background resources to help you gain an understanding of the causes and effects of increasing claims frequency and severity. We also recommended you contact your state

legislators in the House and Senate with your concerns and we provided sample letters to help save you time in contacting them. In November, we sent all policyholders a copy of our press kit. This kit contained information on the TMA data study involving the three largest medical liability carriers in the state — TMLT, Medical Protective and API — and updated information on suggested medical liability reform. Both the TMLT 2000 kit and the November press kit were also posted on the TMLT web site for easy reference. If you haven't had time to read them yet, it would be worthwhile to do so now.

The kinds of change we believe will help curb the current medical liability trends will not happen overnight. Building awareness in the medical community and the legislative community is the first step, but only the first step. TMLT is working hard to solve these problems, but we need your help if we are to be successful. Please get involved in Citizens Against Lawsuit Abuse groups. Contact your state representative and senator. Contact your county medical society and the TMA. Help us work toward medical liability reform.

Risk Management Seminars for Office Staff

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\$45 TMLT insured
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Tuesday, April 10 Houston, Texas	Tuesday, May 1 McAllen, Texas
Tuesday, April 17 Dallas, Texas	Tuesday, May 8 Fort Worth, Texas

Seminar time:

1:30-4:30 p.m.

For additional information or to register, please call the Risk Management Department at (800) 580-8658 or send email to natalie-gilmore@tmlt.org.

Expert testimony on trial



By Laura Hale

These days, it is not uncommon for physicians to advertise their credentials and expertise to potential patients. Flip through the yellow pages and you'll see the words "Board Certified" and "FACS."

Pick up any law journal and flip to the back. You will see ads there as well. Only these ads are not intended for patients. These physicians are advertising their credentials, expertise and occasionally, their opinions, to attorneys.

Over the past several years, there has been increased concern at TMLT about the relatively unregulated activities of medical expert witnesses in the courtroom. The majority of expert witnesses are honest and are motivated by a desire to help judges and juries understand complex medical information. However, the potential exists, given the financial incentives involved, for experts to lose their objectivity and misrepresent medical theories in court. The intent of this article is not to share war stories or to broadcast the abuse of the system TMLT staff has witnessed over the years. This article will explore the importance of expert testimony in malpractice claims, discuss organized medicine's guidelines for medical testimony and focus on possible solutions to improving the quality of such testimony.

The importance of expert testimony

The testimony of medical expert witnesses is a key factor in malpractice claims. In Texas, current law requires a physician's expert report to maintain a lawsuit. At trial, a plaintiff's expert physician must define a particular standard of care and testify that the defendant violated the standard of care, in addition to explaining complex medical issues to a lay judge or jury. A defense physician expert will also explain the medical issues, define a particular standard of care, and testify that the stan-

dard of care was not breached. Without such testimony, a jury or judge would be unable to render a decision on the culpability or negligence of the physician.

Ideally, the medical expert should remain objective, testifying solely about the medical facts of the case. A witness should never be an advocate, and should realize the testimony is intended to inform rather than to improperly influence or prejudice the court or the jury.¹

"Unfortunately, the skillful, practiced expert witness often becomes a biased advocate . . . the expert's answers to questions during cross-examination become models of closing argument and are designed more for the purpose of persuasion than the conveyance of information."²

With a biased expert comes biased witness testimony. "Given the potential rewards it is hardly surprising that some physicians may seek to establish themselves as partisan experts who can be counted on to produce testimony designed to win cases rather than to communicate scientific truths."³ The medical and legal literature is full of commentary about medical witnesses who "develop theories of medicine or causation that are not sufficiently grounded in medical science,"⁴ and "who venture opinions they would not dare in an audience of peers."⁵

In dealing with medical malpractice issues, determining what constitutes “improper” expert witness testimony is not always easy. “Because medicine is both a science and an art with a dynamic body of knowledge, theories held by a minority of the medical community may not necessarily be ‘junk science’ and instead could be an evolving scientific consensus.”⁶ A well-credentialed expert who honestly believes in a minority opinion may not be offering “improper” testimony.

Despite the importance of medical expert testimony in malpractice litigation, there are currently no uniform standards for credentialing expert witnesses, nor are there truly effective ways to hold them accountable for their testimony.⁷ Witnesses enjoy a certain amount of testimonial immunity and cannot be sued for their medical opinions.⁸

Organized medicine oversight

Many medical professional organizations have focused on problems with expert witnesses. The 1998 AMA report on expert witness testimony summarizes organized medicine’s argument for a role in reforming medical testimony.

“Though many physicians who provide expert witness testimony do comply with these standards, others — seemingly motivated by financial gain — do not adhere to ethical or professional standards and, in fact, foster the introduction of ‘junk science’ into the judicial system. This practice not only harms the judicial system, but also reflects poorly on the medical profession itself. Though the admissibility and credibility of expert witness testimony clearly is the function of the judiciary, maintaining the integrity and quality of the profession and physicians, including those who provide expert witness testimony, is well within the purview of both organized medicine and licensing boards.”⁹

Most specialty societies, such as the American Pediatric Surgical Association, the American College of Cardiology, the Society for Academic Emergency Physicians and the American College of Obstetricians and Gynecologists, have adopted specific recommendations for their members who serve as medical witnesses, such as minimum qualifications for expert witnesses and requiring testimony be made available for peer review.¹⁰

While many specialty society guidelines do not include sanctions for members who fail to follow the guidelines, the American Academy of Neurosurgery has structured such a program design. The AANS maintains a file of depositions and trial testimony given by neurosurgical expert witnesses and have reviewed approximately 50 physician members over the last 15 years for unprofessional conduct in medical testimony. The review process involves substantial due-process and has resulted in censuring, suspending and expelling approximately 10 members from the AANS. Those who have been expelled or suspended have been reported to the National Practitioner Data Bank. This process has resulted in only one legal challenge.¹¹

In June 1998, AMA House of Delegates adopted the policy that physician expert witness testimony is considered the practice of medicine, subject to peer review. The AMA also studied ways in which such peer review could be conducted, and the organization will now be working with state medical societies and licensing boards to develop disciplinary measures against physicians who provide fraudulent testimony.¹²

Peer review

Physician’s groups, including the AMA, have proposed peer review of physician testimony as one way to improve the quality of such testimony. These groups believe it is physicians who are best qualified to evaluate the opinions expressed by other physi-

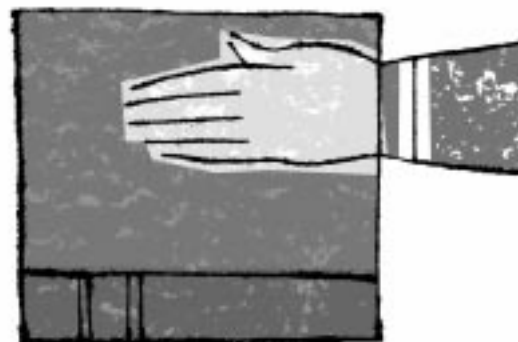
cians in the same specialty. “The process of peer review that typically has been suggested involves one or more ‘experts’ reviewing testimony and providing a ‘conclusion’ regarding its accuracy. The one who proffered the testimony would have an opportunity to reply.”¹³

However, due to practical and conceptual difficulties, peer review may be a less than perfect solution. Even the proponents of peer review admit there are many inherent obstacles to conducting peer review of expert witness testimony. “Several of those difficulties include assembling a true peer review panel, determining all the relevant facts, defining the standard of acceptable testimony, imposing meaningful sanctions and — most problematic — subjecting medical and specialty organizations and physicians conducting peer review to legal risk.”¹⁴

Other solutions

In addition to tort reform and specialty society oversight, the medical literature is full of commentary on additional changes that could be made to improve medical expert testimony, such as allowing independent court-appointed experts to testify, removing medical malpractice trials from the jury system, and the removal of “extraordinary financial incentive” from the expert testimony process.¹⁵

As the frequency of medical malpractice litigation in Texas continues to rise, so will the demand for medical expert witnesses. It is imperative for county medical societies, specialty societies and other physician groups to continue their efforts to reform the expert witness process.



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closed claim study

Alteration of medical records, failure to diagnose and treat

by Barbara Rose, RN, BSN, Risk Management Representative

Clinical presentation

A 37-year-old pregnant woman at 32+ weeks gestation reported to a new OB/GYN to continue her prenatal care, and for evaluation of swelling. (The patient was required to change physicians for insurance reasons.) The patient had a history of preeclampsia in her first pregnancy and her second delivery was without complications. She had 3+ pitting edema of her lower extremities, but her BP was 120/80 with normal deep tendon reflexes and 1+ proteinuria.

Physician action

The physician told the patient she might be developing preeclampsia. She ordered a preeclamptic lab study and directed the patient to absolute bed rest. The patient was to follow up for an ultrasound and re-evaluation of the edema.

The next day, the patient called the physician's office, complaining of cramps and pain in the pelvic area. When the physician saw the patient, her blood pressure was 120/80, urinalysis 1+ protein and 3+ edema in her extremities. Believing the patient had a urinary tract infection, the physician prescribed Ampicillin, and stressed the need for absolute bed rest. The patient did not comply with the instruction for bed rest.

Three days later, the patient presented to the emergency room at 12:45 a.m. with intolerable pain and BP of 219/117. She was seen by an obstetrical resident who diagnosed pregnancy-induced hypertension and preeclampsia. The resident was in her sixth month of residency, had one month obstetrics training, and had been involved in 29 deliveries. She was not yet licensed at the time. The resident contacted the OB/GYN on-call for the group by telephone at 1:20 a.m. to advise him of the patient. The patient was given Demerol and Phenergan at 1:54 a.m. At 2 a.m. the resident called the on-call OB/GYN, reporting continued elevated blood pressure

and abdominal pain. 20 mg of Labetalol was given over 2 minutes at 2:25 a.m. The resident and on-call physician spoke by phone at 2:30 and 2:42 a.m. At 3:10 a.m., the patient was treated with magnesium sulfate.

At 3:50 a.m., the patient was unresponsive. At 4 a.m., she developed a seizure and was treated with magnesium sulfate and Valium. The resident and on-call physician spoke again at 4:04 a.m., and the on-call OB/GYN arrived at the hospital at 4:40 a.m. The on-call OB/GYN cancelled the orders of magnesium sulfate and Valium. At 4:52 a.m., a Labetalol drip was started. The patient was taken to the operating room by the on-call OB/GYN, assisted by the resident, and a 4 lb 2-oz boy was delivered by c-section at 5:30 a.m. That evening, the patient was declared brain dead and was later removed from the ventilator. The autopsy showed acute massive intracerebral hemorrhage consistent with eclampsia.

Allegations

Allegations against the on-call OB/GYN:

- Failure to timely, properly, safely or adequately diagnose, assess, evaluate, recognize, care for and treat the patient's severe and/or critical preeclampsia and/or eclampsia and/or neurological condition and course
- Failure to adequately provide directions or instructions to the resident in appropriate anti-hypertension and anti-convulsion therapy
- Failure to arrive at the labor and delivery unit in a timely manner
- Failure to timely arrange and perform a cesarean section

Allegations against the patient's OB/GYN:

- Failure to timely, properly, safely and/or adequately diagnose, assess, evaluate and/or recognize that the patient's blood pressure condition required continued observation in the medical office or admission to a hospital for observation
- Failure to timely report to the on-call

physician concerning the patient's PIH or preeclampsia condition or course.

Legal principle

Negligence, according to the Texas Medical Jurisprudence, is defined as the "lack of ordinary care." Ordinary care is that degree of care that a reasonably prudent physician would have exercised under the same or similar circumstances.

TMLT consultants were divided in this case. There was strong opinion that the weakness in the on-call OB/GYN's care was in the delay in aggressively treating the patient within the first 2-3 hours after admission, specifically, initiating anti-hypertension therapy and controlling the patient's blood pressure. The consultants did agree that magnesium sulfate should have been given immediately but there was a delay from approximate arrival time of 12:45 to 3:10 a.m. in its administration. However, there may not have been much that could have been done to change the ultimate outcome. The patient had a violently deteriorating, pregnancy-induced hypertension syndrome. An earlier decision to perform a c-section would not have altered the course in this case.

The physician expert for the plaintiff had an opposing point of view that, when read, is quite convincing. Delay in treatment, not responding in a timely manner were described as failure to follow the reasonable, prudent and accepted standards of medical care expected of the on-call physician for the OB/GYN practice. This failure was labeled a direct and probable cause of the occurrence in this case, that is patient death.

Of further concern was the defendant physicians' alteration of the patient's medical records after her death. The on-call OB/GYN asked that the office chart be amended to include an entry about the call from the patient's daughter worried that the patient

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tmlt perspective



The year 2000 — managing policyholder defense

by Bob Fields, Executive Vice President, Claim Operations

In 2000, TMLT experienced another year of heavy malpractice claim intake.

Unfortunately, this statement is all too familiar to our policyholders — 1999 also saw record increases in claim intake. Claim intake has been increasing significantly throughout the 90s.

In the claim department, these increases mean more work for claim staff and defense attorneys. But what exactly does this mean for physicians? This article will serve as a review of malpractice claim activity for the year 2000 and to explain how lawsuit abuse and the current Texas legal environment affect the number of claims filed against Texas physicians.

Claim activity — by the numbers

When examining claim data, it is important to understand how malpractice carriers analyze claim activity. At TMLT, we track claim frequency and claim severity. Claim frequency, which is the number of claims filed per 100 policyholders, represents how many claims TMLT has received. Claim severity is how much it costs TMLT to resolve claims.

As stated previously, TMLT continued to see an increase in claim activity in the year 2000. As of December 31, 2000, TMLT had taken in more than 3,000 claims. This translates to a claim frequency of 30.8 percent, the second highest claim frequency ever recorded in the history of TMLT (next to last year's 34.6 percent). Texas physicians are being sued at unprecedented rates.

The 30.8 percent claim frequency includes two different types of claims — mass litigation claims and straight medical malpractice claims. Medical malpractice claim frequency was 22.1 percent and mass litigation claims made up the remaining 8.7 percent. Current mass litigation includes Fen-Phen and Valley Cardiovascular, which is a class action suit against a hospital for allegedly representing that a cardiovas-

cular surgeon was board certified when he was not. (The surgeon no longer works for the hospital, but more than 700 claims have been filed against the physician, his partner and referring doctors.)

When looking at the above numbers, many outside the insurance industry may be tempted to minimize the effect of mass litigation on claim frequency. In the past, mass litigation claims have been concluded with little or no indemnity paid on behalf of physicians. So, many believe they do not represent "legitimate" claims. It is tempting to think that claim frequency is really only 22.1 percent and to discount mass litigation's 8.7 percent. However, at TMLT, we look at the big picture. Mass litigation claims are still claims. While we have not paid any indemnity on these claims, we still pay legal expenses and court costs which have exceeded \$15 million in the 90s. TMLT also devotes staff time to handling these cases. Additionally, there is no guarantee that we will not have to pay indemnity on mass litigation cases in the future.

The current environment

Lawsuit abuse continues to plague the physicians of Texas. In 2000, TMLT closed more than 90 percent of claims with no indemnity payment. This translates into about 2,700 meritless claims and more than \$20 million spent in defense of these claims. Worse yet, the increase in the total number of lawsuits filed means your chances of being sued increased as well. Recent studies estimate that one out of every five Texas physicians will face a malpractice claim annually.

Why are physicians so often the targets of meritless litigation? In Texas, there are rarely any consequences for filing such a lawsuit. There is no frivolous litigation statute on the books. Plaintiffs' attorneys can allege whatever they want in lawsuits and in open court, and when it is all disproved, there is

no viable way for physicians to countersue the plaintiff for court costs, legal fees or damage to their reputation. Attorneys have nothing but their expenses to lose, but physicians must report every lawsuit, even the frivolous ones, on every credentialing form and malpractice insurance application they fill out for the rest of their careers. They are never compensated for the anxiety caused by this litigation.

Texas should provide recourse for physicians wrongly sued in malpractice litigation. This statute would serve as a deterrent by providing consequences for those who abuse the system. Faced with a possible loss of personal assets, a plaintiff or a plaintiff's attorney might think twice before filing a questionable suit.

The future

For the past 21 years, TMLT has been the physician's advocate in the courtroom. We will continue this advocacy at the state legislature this spring by serving as consultants to the Texas Medical Association. Medical liability reform measures, such as limits on attorney contingency fees, limits on non-economic damages or even a non-meritorious litigation statute, would reduce the number of lawsuits filed against Texas physicians. TMLT will be working with organized medicine to seek these long-term solutions. Absent such reform, we predict continued increases in claim activity and continued increases in malpractice premiums.

TMLT cannot win the battle for liability reform alone. The power and influence of the trial lawyers with the legislature and judiciary is far too strong for one company to succeed. We can achieve liability reform, however, with the commitment of thousands of doctors throughout the state. It's time to put an end to lawsuit abuse!

the Reporter

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closed claim study continued

was not at home. The patient's OB/GYN admitted to rewriting the chart to place the entry in the proper order and destroying the original. This testimony seriously damaged the credibility of both physicians and the entire medical record.

Disposition

The case was settled prior to trial for \$500,000 on behalf of the on-call OB/GYN and \$200,000 on behalf of the patient's OB/GYN. The on-call OB/GYN's failure to timely come to the hospital, his reliance on the resident to treat the patient, and the subsequent alteration of medical records were major factors in the settlement of this case.

Risk management considerations

With perfect hindsight it is easy to be critical of the physicians in this case. Management of risk when patients present late in pregnancy requires thoughtful, well-defined protocols that are followed by the practice. The attending physician informed the on-call physician that this patient was her only patient of concern and he might hear from her over the weekend. This was the right thing to do. Why then did the on-call physician not go to the hospital right away? This choice made defense of the physician difficult. Strict adherence to standards of care and "best practice" would include the expectation that a patient's primary physician or,

in this case, the on-call physician, would report to the hospital as soon as possible to manage the care of his/her patient.

Alteration of a medical record cannot be justified under any circumstance and all physicians understand this. A clearly labeled addendum or late entry may be written and that is the only protocol allowed in the medical record. Once it was discovered the office record had been altered, the credibility of both the attending and on-call physicians was seriously damaged. There is no reasonable explanation for this choice of action.



TEXAS MEDICAL LIABILITY TRUST

SPECIAL PHARMACEUTICAL ANNOUNCEMENTS

February 2001

PHENYLPROPANOLAMINE (PPA)

On November 3, 2000, the Food and Drug Administration (FDA) issued a letter to the manufacturers of phenylpropanolamine hydrochloride (PPA), requesting that they voluntarily discontinue marketing any drug products containing PPA. PPA is currently available by prescription and over-the counter (OTC) as a nasal decongestant and for weight control.

A report from Yale University School of Medicine, "Phenylpropanolamine and Risk of Hemorrhagic Stroke: Final Report of the Hemorrhagic Stroke Project," suggests that PPA increases the risk for hemorrhagic stroke. Scientists found an association between phenylpropanolamine use and stroke in women. The increased risk of hemorrhagic stroke was detected among women using the drug for weight control and for nasal decongestion, in the 3 days after starting use of the medication. Men may also be at risk. Following review of the report, the FDA Nonprescription Drugs Advisory Committee concluded that PPA could not be considered to be safe for continued use. On November 6, 2000, the FDA issued a public health warning concerning PPA, advising consumers to discuss alternative OTC and prescription medications with their health care provider or pharmacist.

Based on these recent developments, the FDA has significant concerns and intends to take action to remove PPA from prescription drug products and to initiate rulemaking to classify PPA as unsafe for OTC use. Many drug stores and pharmacies have voluntarily pulled OTC drugs containing PPA from their shelves.

To our physicians

- Advise patients against using drugs containing PPA they may have stored at home.
- Supply a list of OTC products containing PPA (see list below).
- Remove drugs containing PPA from your sample medication supply.
- Discuss alternative drugs with your patients.

Affected products

Note: These lists of over-the-counter products are informational only, and are not intended to include all products containing PPA.

ACUTRIM 16-HOUR TABLETS
ACUTRIM GUM
ACUTRIM MAX TABLETS
ALKA SELTZER + COLD/COUGH
ALKA SELTZER + COLD/SINUS
ALKA SELTZER PLUS CHILDRENS
ALKA SELTZER PLUS COLD
ALKA SELTZER PLUS COLD, CHERRY
ALKA SELTZER PLUS COUGH/COLD
ALKA SELTZER PLUS NT
ALKA SELTZER PLUS COLD, ORANGE
BC ALLERGY SINUS POWDER
COMTREM DEEP CHEST
COMTREM FLU DAY/NIGHT
CONTAC CAPSULES
CORICIDIN D TABS
CVS COLD & ALLERGY ELIXIR

CVS COLD & ALLERGY ELIXIR DM
CVS COLD & ALLERGY TABLETS MAX
CVS DAYHIST D
CVS DIET CAPLET
CVS DIET CAPLET WITH C
CVS EFFERVESCENT COLD TABS
CVS TRIACTING COUGH
CVS TRIACTING EXPECTORANT
CVS TRIACTING MULTI
CVS TRIACTING MULTI CHERRY
CVS TRIACTING SORE THROAT
CVS TUSSIN CF
DEXATRIM CAFFEINE FREE CAPLET
DEXATRIM CAPLET WITH C
DEXATRIM EX DURATION TABLET
DEXATRIM GELCAPS
DIMETAPP CHEW TABS

DIMETAPP DM ELIXIR
DIMETAPP ELIXIR
DIMETAPP EXTENTABS
DIMETAPP COLD & COUGH
NALDCN-DX ADULT SYR
NALDCN-DX CHILD SYR
NALDECON DX DROPS
PERMATHENE - 16 HR TABLET
TAVIST D
TAVIST D TABLETS
THINZ SPAN CAPSULES
TRIAMINIC COUGH
TRIAMINIC CHEST & CONGESTION
TRIMINIC COLD & ALLERGY
TRIMINICOL C&C

Previously discontinued items

Check your medicine cabinet to see if these products are there.

ALKA SELTZER PLUS FLU TABS
ALKA SELTZER PLUS SINUS
COMTrex ND LIQUIGEL
CONTAC CAPSULES
DEXATRIM EX DURATION TAB
DIMETAPP 4-HR LIQUIGELS
DIMETAPP QUICK TABS
TAVIST D
TAVIST D TABLETS

Items that may contain PPA

The following products have undergone a formula change and may contain PPA. Check the ingredients label to see if a product you have contains PPA.

ROBITUSSIN CF

Additional information on PPA, the Public Health Advisory and the results of the stroke study can be found on the FDA web site: www.fda.gov/cder/drug/infopage/ppa/default.htm.

LOTROX PULLED FROM MARKET

At the request of the U.S. Food and Drug Administration, Glaxo Wellcome Inc. voluntarily withdrew its prescription medicine Lotronex (alosetron HCl) for the treatment of persons with diarrhea predominant irritable bowel syndrome. The company has ceased distribution on Lotronex.

Glaxo Wellcome took this step after in-depth discussions with the FDA about gastrointestinal side effects that occurred in association with the use of Lotronex. There have also been rare reports of fatalities from complications of gastrointestinal events. For additional information, please visit Glaxo's web site at www.lotronex.com.

To our physicians:

- Have you prescribed Lotronex?
- Can you identify those patients, contact them and discontinue Lotronex?
- Is Lotronex among the sample medications you accept? If so, has it been removed from your practice?

PROPULSID (cisapride)

Early last year you received a letter from Janssen Pharmaceutica regarding Propulsid and the associated risk of serious cardiac arrhythmias and death. In consultation with the FDA, Janssen decided to discontinue marketing Propulsid as of July 14, 2000. Cardiac arrhythmias including, ventricular tachycardia, ventricular fibrillation, torsades de pointes and QT prolongation have been associated with the use of Propulsid. 341 such cases were reported between July 1993 through December 1999, including 80 deaths.

As of May 1, 2000, Propulsid is available only through an investigational limited access program. Specific treatment protocols have been developed for enrollment in the program.

Given the risks of the drug and available alternatives, we suggest that physicians continue to assess the need for Propulsid in each patient. For patients who fail other treatment options and meet the eligibility criteria for the limited access program, protocols for the investigational program should be strictly followed. Failure of previous standard therapeutic modalities and appropriate diagnostic evaluation, including radiological examinations and/or endoscopy should be thoroughly documented. The risks, benefits and alternative treatments should be thoroughly discussed and documented as well. It is important that your office notes document the essentiality of the treatment, disclosing all inherent risks of the treatment to the patient. **It would also be advisable to have the patient sign and date a statement verifying receipt and understanding of the informed consent information. The statement should be included in the patient's medical record.**

Additional information on Propulsid, including treatment protocols for the investigational limited access program, may be found on the FDA web site:

www.fda.gov/ohrms/dockets/ac/00/backgrd/3634b1a_tab4d.htm