"MEDICAL MALPRACTICE: Recent Developments"

TIM RILEY

RILEY LAW FIRM
1225 North Loop West, Suite 810
Houston, Texas 77008-1757
Phone 713.868.1717
Fax 713.868.9393
Mobile 713.703.7667
E-Mail: TDR@txtrial.com

JOELLE G. KENNEY

MCGEHEE & PIANELLI, L.L.P.
1225 North Loop West, Suite 810
Houston, Texas 77008-1761
(713) 864-4000
jkenney@lawtx.com

SOUTH TEXAS COLLEGE OF LAW
PERSONAL INJURY LAW CONFERENCE 2003

March 6, 2003 -- Houston

SECTION B: The Plaintiffs Perspective

TIM RILEY

RILEY LAW FIRM
1225 North Loop West, Suite 810
Houston, Texas 77008-1757
Phone 713.868.1717
Fax 713.868.9393
Mobile 713.703.7667
E-Mail: TDR@txtrial.com

&

Rio Grande Valley Office
(Meetings by appointment only)
845 East Harrison, Suite A
Brownsville, Texas 78520-7120
Phone 956.550.8825

RILEY LAW FIRM, an "AV rated" Texas law firm, was founded by Tim Riley. Mr. Riley has been practicing civil trial and personal injury trial law for more than 19 years. He has tried dozens of Texas lawsuits and settled hundreds of cases prior to trial. Mr. Riley is **BOARD CERTIFIED** by the Texas Board of Legal Specialization in Personal Injury Trial Law and Civil Trial Law.

In addition to his private law practice, Mr. Riley has also served as an Adjunct Professor of Law at the University of Houston Law Center, teaching a course in Evidence. In March 2002, Riley was elected, in a contested primary, as the Democratic nominee for the 22nd Congressional District of Texas. However, the 18 year Republican incumbent, Tom DeLay, prevailed in the November 5, 2002, general election.

His **POSITIONS IN PROFESSIONAL ORGANIZATIONS** include: Democratic Nominee United States Congress, 22nd Congressional District of Texas, 2002; Member, Texas Trial Lawyers Association; Member, Houston Trial Lawyers Association; Life Fellow, Texas Bar Foundation; Sustaining Life Fellow, Houston Bar Foundation; Houston Bar Association 1998-Present, Member, Attorney Fee Dispute Resolution Committee; 1990 Chairperson, Committee for Interprofessional Relations - Physicians; Litigation Section; Houston Law Review Alumni Association, Board of Directors, 1994-1997, Vice President, 1996. Additionally, he has written countless speeches, Publications, including both precedent-setting federal and state appellate briefs. His publications appear in journals such as; The National Publication DRI ADR; The Texas Lawyer, and Houston Law Review.

JOELLE GRACE KENNEY

McGEHEE & PIANELLI, L.L.P.
1225 North Loop West, Suite 810
Houston, Texas 77008-1761
(713) 864-4000
jkenney@lawtx.com

Joelle Grace Kenney, joined the "AV rated" law firm McGEHEE & PIANELLI, L.L.P., in January of 2002. Joelle is a former briefing attorney for Justice John S. Anderson on the Fourteenth District Court of Appeals where she drafted several, often complex, civil and criminal appellate opinions. Notably, Joelle was also a law clerk to Justice Eric Andell on the First District Court of Appeals. A graduate from South Texas College of Law, Joelle successfully competed in the national moot court program as an advocate and as a top brief writer. Joelle has studied law abroad at the University of London and Wales as well as the University of Malta.

Her **POSITIONS IN PROFESSIONAL ORGANIZATIONS** include: Texas Trial Lawyers Association; Texas Trial Lawyers Association, Houston Advocates; Houston Young Lawyers Association; and the Houston Bar Association, Appellate Division. Additionally, Joelle has written several speeches and Publications.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

United States Supreme Court Cases:

United States Court of Appeals Cases:

United States District Court Cases:

State Court Cases:

Federal Statutes:

Federal Legislative History:

Constitutional Provisions

State Rules and Codes:

State Statutes:

State Legislative History:

Secondary Authorities:

I. MEDICAL MALPRACTICE CAPS: Defining and Measuring the Problem

The impact of the November 5 election is felt not only on Capital Hill but also by plaintiff firms and associations across the nation. The political aftermath has brought the debate concerning medical malpractice to center stage. Not a day passes without extensive media coverage of this polarizing issue.

The House and Senate Judiciary Committees are expected to take another look at proposals to change the tort system, including legislation the American Bar Association opposes that would pre-empt state medical liability laws to limit compensation for parties injured by malpractice. The legislation passed the House in 2002 but did not garner support in the Senate.

The American Bar Association generally opposes federal legislation to govern tort law, and it specifically opposes caps on damages for pain and suffering that are proposed in the medical liability bills.

Nevertheless, seen both here in the Texas legislature and in Congress, is the ever present concern and excited debate regarding the current insurance crisis. A significant part of the problem, according to tort reform advocates, who support the limiting of plaintiffs' rights, are runaway jury awards, a system out of control, and that the insurance crisis jeopardizes patients' access to medical care. However, haven't we seen this argument before? What is a reasonable mechanism for obtaining affordable medical health care?

A. The Texas Legislature: Current Legislative Issues

Now that the Texas legislative session is underway, it is important to keep informed about what is happening at the Capitol and how it may affect your practice. Significant medical malpractice bills have been filed which contain provisions that would restrict plaintiff's rights in the event of a lawsuit. The following is a summary of such legislative proposals:

The House Civil Practices Committee, chaired by Rep. Joe Nixon (R-Houston), is set to begin hearings on broad-based liability reforms. Rep. Nixon, who has already filed a comprehensive medical liability reform, bill (H.B. 709), as well as a general liability reform (H.B. 3), and asbestos litigation reform.

This article attempts to highlight the most significant provisions of the House versions of the legislation, although the Senate companions are expected to be substantially the same, if not identical.

1. Medical liability House Bill 709

As filed, House Bill 709 contains the following major provisions (in summary form):

- an offer of settlement rule providing that, if the claimant rejects a reasonable settlement offer and the damages awarded are less than or equal to the offer, the court shall offset against the judgment the defendant's court costs, expenses, and attorney's fees;

- a prohibition on deposing a health care provider until suit is actually filed;

- admissibility of the claimant's past federal and state income tax payments to determine the amount of lost earnings and lost earning capacity;

- mandated jury instructions regarding the circumstances under which emergency care was provided;

- periodic payment of future damages if the present value of the award is equal to or greater than $100,000;

- a limitation on the recovery of medical expenses to those actually incurred by the claimant;

- admissibility of evidence of collateral sources of payment of the claimant's medical expenses, with abolition of non-federal third party liens and subrogation interests arising from the collateral sources being introduced into evidence;

- removal of a minor's disability to make the minor's limitation period enforceable under case law;

- inclusion of punitive damages under the existing $500,000 cap on damages contained in Art. 4590i, Sec. 11.02;

- a $250,000 cap on noneconomic damages if the health care provider maintains required levels of insurance;

- a 33.3% limitation on the claimant's attorney's fees;

- a lower sliding scale limitation on the claimant's attorney's fees if the $250,000 cap is struck down, either by the courts or by the voters in a constitutional amendment election;

- a clear and convincing evidence standard for proving negligence in connection with the provision of emergency care;

- a stay on discovery until the claimant files an expert report and the expert's CV (abolishes 90-day cost bond and makes the 180-day deadline for filing the expert report absolute with no discretionary extensions);

- mandatory dismissal of a claim with costs if no expert report is filed;

- a requirement that experts meet specified qualifications, including present practice in the same field, present knowledge, and training and experience standards;

- a requirement that, in a claim against a physician, only a physician may testify regarding causation;

- a $500,000 cap on all damages in a suit against a hospital;

- the inclusion of medical providers under the manufacturer's indemnity provision contained in Sec. 82.002, Civil Practice and Remedies Code;

- immunity for health care providers in a products liability suit if the provider followed accepted standards for the prescription of a drug or device; and

- specific statutory authority for a declaratory judgment action to determine the constitutionality of the Act.

2. General Tort Reform House Bill 3

This omnibus tort reform bill is equally comprehensive, and perhaps more controversial. The bill contains the following:

- a provision allowing the jury to allocate fault to nonparties exempt from the current joint and several liability scheme, including debtors in bankruptcy, immune employers, and criminal third parties (the so-called "empty chair");
- elimination of the 15% threshold for joint and several liability in toxic tort cases;
- repeal of the sliding scale settlement credit and substitution with a percentage credit;
- an interlocutory appeal to the supreme court of class certification orders an automatic stay of all proceedings in the trial court until appeal is determined;
- mandatory exhaustion of administrative remedies prior to filing a class action;
- implement the lodestar method for calculating fees awarded to class counsel;
- an interlocutory appeal to the court of appeals and supreme court of a trial court's venue ruling in multi-plaintiff cases;
- elimination of all statutory procedural barriers inhibiting trial judges from applying the common law doctrine of *forum non conveniens*;
- exclusion of subsequent remedial measures in a products liability action;
- a 15-year statute of repose for all manufactured products;
- statutory immunity for innocent retailers of manufactured products;
- a government standards defense for manufacturers who comply with specific rules or regulations governing product design, manufacture, or warnings;
- a $25 million ceiling on the amount of an appeals bond;
- elimination of the statutory floor on the judgment interest rate and a bar against the award of prejudgment interest on future damages;
- admissibility of seat belt use for purposes of proving causation and allocating fault;
- application of lodestar method to calculating attorney's contingent fees when private attorneys are hired by local governmental entities.

3. Proposed Constitutional Amendment House Joint Resolution No. 39

This joint resolution is more harmful to Texas consumers than House Bill 709 or House Bill 3. The resolution attempts to amend the Texas Constitution to allow the Texas legislature to limit liability concerning damages, other than economic damages, in medical or healthcare liability claims. The significance of this resolution is that it would act undermine Texas jurisprudence, which holds that statutory caps are unconstitutional as a violation of a victims right of access to "open courts," as well as a violation of the Equal Protection Clause. *See* Tex. Const., art. I, § 13; *Lucas v. United States,* 757 S.W.2d 687, 691 (Tex. 1988); and *Waggoner v. Gibson,* 647 F.Supp. 1102, 1106 (N.D. Tex. 1986).

In *Lucas v. United States,* The Texas Supreme Court decided that in the context of persons catastrophically injured by medical

negligence, it is unreasonable *and* arbitrary to limit recovery in a speculative experiment to determine whether liability insurance rates will decrease. 757 S.W.2d at 691. The Court continued by pointing out that the Texas Constitution article I, section 13, guarantees meaningful access to the courts whether or not liability rates are high. *Id.* As to the legislature's stated purpose to "assure that awards are rationally related to actual damages," under section 1.02(b)(2), that this is a power properly attached to the judicial and not the legislative branch of government. *See* Tex. Const. art. II, § 1. And, as a result, the Court held that it was unreasonable and arbitrary for the legislature to conclude that *arbitrary damages caps, applicable to all claimants no matter how seriously injured*, will help assure a rational relationship between actual damages and amounts awarded. *Id.* at 691.

To clarify its decision, the Court relied on a quote form the Florida Supreme Court in *Smith v. Department of Insurance*, regarding Florida's proposed legislation to place a $450,000 ceiling on noneconomic damages. *Id.* at 692. The Florida Supreme Court stated:

> [I]n decided that access to courts is granted for the purpose of redressing injuries. A plaintiff who receives a jury verdict for, e.g., $ 1,000,000, has not received a constitutional redress of injuries if the legislature statutorily, and arbitrarily, caps the recovery. Nor, we add, because the jury verdict is being arbitrarily capped, is the plaintiff receiving the constitutional benefit of a jury trial as we have understood that right. Further, if the legislature may constitutionally cap recovery at $ 450,000, there is no discernible reason why it could not cap the recovery at some other figure, perhaps $ 50,000, or $ 1,000, or even $ 1.

See Lucas, 575 S.W.2d at 692 (quoting *Smith v. Department of Insurance,* 507 So.2d 1080 (Fla. 1987)).

More importantly, however, the Court paused to recognize the legislature's concern in attempting to solve the health care problems it perceived during the middle of the 1970's. *Lucas,* 575 S.W.2d at 692. Nevertheless, the Court agree with the statement by the Supreme Court of New Hampshire: "It is simply unfair and unreasonable to impose the burden of supporting the medical care industry solely upon those persons who are most severely injured and therefore most in need of compensation." *See Lucas,* 575 S.W.2d at 692 (quoting *Carson v. Maurer,* 424 A.2d 825, 837 (1980)). Therefore, the Court held that the limitation on medical malpractice damages in Tex. Rev. Civ. Stat. art. 4590i, sections 11.02 and 11.03, is inconsistent with and violative of article I, section 13, of the Texas Constitution. *Id.* (relying on Tex. Const. art. I, § 13; and Tex. Rev. Civ. Stat. art 4590i, §§ 11.02, 11.03 (Vernon Supp. 2003)).

Interestingly, the *Lucas* Court decided not to address the additional certified question before the Court on whether the restrictions in sections 11.02 and 11.03 were reasonable when balanced against the purposes and bases of the statute. *See Lucas,* 757 S.W.2d at 691. Ultimately, the Court determined the question was moot. *Id.* at 692. However, the Northern District Federal Court of Texas in *Waggoner v. Gibson* had already determined that exact issue, two years earlier, and found that

statutory medical malpractice caps violated the Equal Protection Clause. *See* 647 F.Supp. 1102, 1106 (N.D. Tex. 1986).

In *Waggoner v. Gibson,* the District Court for the Northern District of Texas applied the traditional rational basis test: Whether there is a rational relationship between the legislation and the pursuit of a legitimate state interest. *See id.* The court held that the statutory cap violated the equal protection clause under both the state and the federal constitutions because the limitation of recovery for the most deserving victims of malpractice was not a legitimate state interest. *Id.* Further, the cap served no legitimate state interest because no corresponding societal quid pro quo existed to replace the victim's right of full recovery. *Id.* More importantly, the cap did not adequately compensate patients with meritorious claims and provided no means of eliminating frivolous claims. *Id.* at 1106-07. The court concluded that the detrimental effect of the cap on the most deserving victims was not vitiated by the existence of a medical malpractice insurance crisis. *Id.* at 1107. Thus, the statutory cap did not meet the rational basis test. *Id.*

In effect, Nixon's H.J.R. No. 39 proposal is outlined as follows:

- "economic damages" are defined as compensatory damages for any pecuniary loss or damage, but does not include any loss or damage, however characterized, for past, present, and future physical pain and suffering, mental anguish and suffering, loss of consortium, loss of companionship and society, disfigurement, or physical impairment;

- Notwithstanding any other provision of the constitution, the legislature may by statute determine the limit of liability for all damages and losses, however characterized, other than economic damages, of a provider of medical or health care with respect to treatment, lack of treatment, or other claimed departure from an accepted standard of medical or health care or safety, however characterized;

- The legislature may determine the limit of liability for all damages and losses, however characterized, other than economic damages, in any claim or cause of action;

- Meaning a claim or cause of action that arises under or is derived from common law, a statute, or other law, including any claim or cause of action based or sounding in tort, contract, or any other theory or any combination of theories of liability;

- The legislature may set limitations on liability within the statute, which would apply to each claim or cause of action, each claimant, each provider, or a combination of one or more claims or causes of action, claimants, or providers; and

- The legislature may limit all damages and losses, other than economic damages, sought with respect to such a claim or cause of action, an element of such damage or loss so sought, or a combination of such elements, which mat be subject to increase or decrease over time by a means or as otherwise specified by the legislative.

4. Asbestos Litigation

A third piece of the total package is an asbestos litigation reform bill that will

create a statewide inactive docket for unimpaired asbestos claims. Upon filing, a non-malignant asbestos claim will be placed on the inactive docket, where discovery is stayed and the statute of limitations is tolled. To remove the claim to the active docket, the claimant must demonstrate an asbestos-related illness that meets specific medical criteria, including chest x-rays of sufficient ILO grade and PFT testing performed on equipment that meets ATS certification standards and conducted by board-certified Texas physicians. The claimant must also have a detailed occupational history taken by the diagnosing physician. An independent expert will further review the claimant's medical records and tests to determine if the objective criteria have been met and make a recommendation to the trial judge.

5. Other issues

Other items that will likely be part of the package, either as part of the omnibus bill or in separate bills include:

- a statutory employer provision protecting contractors and premises owners from third party liability lawsuits where each party maintained workers' compensation insurance (whether this immunity will extend both vertically and horizontally is not yet known);

- a general offer of settlement rule similar to the one contained in the medical liability legislation; and

- a legal ethics bill that requires full disclosure of and consent to referral fees, allows the attorney general to prosecute lawyers for ethical violations, and requires disclosure of relationships between attorneys and judges.

Indications are that the bills will move fairly quickly through the House. The Senate has been slower to get started on liability issues and it is generally felt, because of the 21-vote rule, to be a harder nut to crack for the pro-reform groups. The opposition will probably make their stand in the Senate, hoping to peel off enough votes on any given issue to stall the entire package. This will undoubtedly raise pressure on the Senate to extremely high levels, as business groups, consumer advocacy organizations, and plaintiff's lawyers launch noisy public appeals through print and broadcast media. In the end, it would not be surprising to see the whole issue wind up in a highly charged conference committee towards the end of the session, with Governor Perry holding the hammer of a special session over the House-Senate negotiators.

B. The Real Question Is: Haven't We Heard This Before?

A medical malpractice insurance crisis occurred in the mid-1970's and mid-1980's, evidenced by escalating malpractice insurance rates and increasing numbers of malpractice claims. Daryl L. Jones, Fein v. Permanente Medical Group: *The Supreme Court Uncaps the Constitutionality of Statutory Limitations on Medical Malpractice Recoveries*, 40 U. Miami L. Rev. 1075, 1078 (1986). Insurance companies maintained that the increase in insurance rates was necessary because of the sharp rise in the number of malpractice lawsuits, astronomical damage awards, and ineffective mechanisms to prevent and to eliminate nonmeritorious claims. Physicians responded by forming their own insurance companies, canceling high-risk procedures, and orchestrating intensive legislative lobbying for tort reform. Insurance companies, physicians, and the

legislature collaborated efforts to resolve this medical malpractice crisis.

A national debate erupted regarding the proper way to address the medical malpractice insurance crisis. Michael J. Abramowitz, W. Va. Court Haults Insurers' Cancellations, Wash. Post, May 10, 1986, at D1. Insurance companies and physicians pressured state legislatures to reform liability laws that, in their opinion, permitted recovery of excessive damage awards by plaintiffs. *Id.* Consumer groups and lawyers suggested tighter regulation of the insurance industry. *Id.* State legislatures, in an attempt to remedy the perception that injured plaintiffs were overcompensated for their injuries, enacted "tort reform legislation," which included statutory caps on damages recoverable in medical malpractice actions. As a result of the extensive lobbying effort by physicians and insurance companies, twenty-seven states enacted statutes limiting recovery of damages in medical malpractice lawsuits.[1]

Lawyers responded by challenging state malpractice legislation on constitutional grounds, alleging violations of federal and state equal protection and due process clauses and the Seventh Amendment right to a jury trial. *See Moore v. Mobile Infirmary Ass'n,* 592 So.2d 156 (Ala. 1991).

Opponents of the cap also asserted violations of state constitution provisions such as the "open courts" provision or the "special legislation" clause. To date, ten state courts have held that statutory caps are unconstitutional.[2] Statutory caps and other tort reform measures are extremely important in light of proposed health care

---

[1] Ala. Code 6-5-544 (Supp. 1991); Alaska Stat. 09.17.010(a) and (b) (1991); Cal. Civ. Code 3333.2 (West Supp. 1992); Colo. Rev. Stat. 13-21-102.5 (1987 & Supp. 1991); Tort Reform and Insurance Act of 1986, ch. 86-160, 1986 Fla. Laws 160 (repealed 1991); Act of June 1, 1981, ch. 162, 1975 Idaho Sess. Laws 1-13 (repealed 1981); Act effective Nov. 11, 1975, ch. 79-960, 4, 1975 Ill. Laws 960 (repealed 1979); Ind. Code Ann. 16-9.5-2-2 (Burns 1990 & Supp. 1992); Kan. Stat. Ann. 60-3402 (Supp. 1991); La. Rev. Stat. Ann. 40:1299.39 (West 1992); Md. Cts. & Jud. Proc. Code Ann. 11-108 (1989 & Supp. 1991); Mass. Gen. Laws Ann. ch. 231, 60H (West Supp. 1992); Mich. Comp. Laws Ann. 600.1483 (West Supp. 1992); Act effective May 4, 1990, ch. 455, 1986 Minn. Laws 88 (repealed 1990); Act effective 1983, ch. 189, 1983 Mont. Laws 675 (repealed 1983); Neb. Rev. Stat. 44-2825 (1988); N.H. Rev. Stat. Ann. 507-C: 7, 508: 4-d (1983 & Supp. 1991); N.M. Stat. Ann. 41-5-6 (Michie 1989 & Supp. 1992); N.D. Cent. Code. 26.1-14-11 (1989 & Supp. 1991); Ohio Rev. Code Ann. 2307.43 (Anderson 1991); S.D. Codified Laws Ann. 21-3-11 (1987 & Supp. 1992); Tex. Rev. Civ. Stat. Ann. art. 4590(i) 11.01-11.05 (West Supp. 1992); Utah Code Ann. 78-14-7.1 (1992); Va. Code Ann. 8.01-581.15 (Michie 1984), as amended by Va. Code Ann. 8.01-38.1 (Michie Supp. 1992); Wash. Rev. Code Ann. 4.56.250 (West 1988 & Supp. 1992); W. Va. Code 55-7B-8 (Supp. 1992); Wis. Stat. Ann. 655.27 (West 1980 & Supp. 1991).

[2] Moore v. Mobile Infirmary Ass'n, 592 So. 2d 156, 171 (Ala. 1991) (cap violates right to a jury trial and equal protection clause of the state constitution); Smith v. Department of Ins., 507 So. 2d 1080, 1089 (Fla. 1987) (cap violates state "open courts" provision); Wright v. Central Du Page Hosp. Ass'n, 347 N.E.2d 736, 744 (Ill. 1976) (cap violates "special legislation" clause and equal protection clause of state constitution); Kansas Malpractice Victims Coalition v. Bell, 757 P.2d 251, 260, 264 (Kan. 1988) (cap violates right to a jury trial and "open courts" provision of state constitution); White v. State, 661 P.2d 1272, 1275 (Mont. 1983) (cap violates equal protection guarantees), rev'd on other grounds, Meech v. Hillhaven West, Inc., 776 P.2d 488 (Mont. 1989); Carson v. Maurer, 424 A.2d 825, 838 (N.H. 1980) (cap violates equal protection clause of the state and federal constitution); Arneson v. Olson, 270 N.W.2d 125, 135 (N.D. 1978) (cap violates equal protection clause of state constitution); Morris v. Savoy, 576 N.E.2d 765, 7771 (Ohio 1991) (cap violates due process clause of the state constitution); Lucas v. United States, 757 S.W.2d 687, 690 (Tex. 1988) (cap violates "open courts" provision of state constitution); Sofie v. Fireboard Corp., 771 P.2d 711, 723 (Wash. 1989) (cap violates state constitutional right to a jury trial).

legislation entitled the Health Care Liability Reform and Quality of Care Improvement Act of 1992 the "Health Care Bill". *See* H.R. 3037, 102nd Cong., 1st Sess. (1991).

1. The medical malpractice crisis of the 70's & 80's

The medical malpractice crisis of the 1970s and 1980s can be attributed to a combination of factors. During the early 1970s, and again in the 1980s, medical malpractice claims increased, damage awards escalated, and amounts paid under insurance policies rose. Insurance companies argued that the rising number of frivolous claims, coupled with high and erratic jury verdicts, decreased the predictability of the rate structure, forcing the insurance companies to raise premiums. Critics of the insurance industry suggested that these increases in malpractice claims and damage awards were not reflected in insurance premiums in a timely fashion. *Williams v. Kushner,* 549 So.2d 294, 306 (La. 1989). Initially, investment gains in the stock market obscured the inadequacy of premiums and rates. *Id.* at 306. When the stock market gains declined, the insurance companies' surpluses suffered massive losses. *Id.* Consequently, the insurance companies' approach to medical malpractice insurance changed: premiums escalated and certain coverage was reduced or eliminated. *Id.* Many insurance companies went bankrupt. *Id.* As a result, the cost and availability of insurance nationwide was significantly impacted. *Id.* Some commentators suggested that other factors, including lack of patient trust, increase in public litigiousness, increase in medical error due to advanced technology, and lawyers' contingency fees contributed to the malpractice crisis.

This is not unlike the current medical malpractice debate we face today. The 2003-2004 medical malpractice crisis, like the medical malpractice crisis of the 70's and 80's, can be attributed to a combination of factors. Those of us that live in Texas, and particularly Houston, are all too well aware of how the "from Boom to Bust" of the Enron Corporation has affected our State and the state of the national economy, not to mention consumer confidence. The stock market has consistently declined. Consequently, insurance companies' surpluses have suffered massive losses. And, as we have seen in the past, the end result is that the cost and availability of insurance nationwide is significantly impacted.

2. The Health Care Liability Reform and Quality of Care Improvement Act of 1992

On July 2, 1992, former President George H. W. Bush submitted the Health Care Liability Reform and Quality of Care Improvement Act of 1992 ("the Health Care Bill"), to Congress for enactment. H.R. Doc. No. 84, 102nd Cong., 1st Sess. (1991). The stated purpose of the bill was to stem the cost of health care caused by medical malpractice. *See id.* President Bush noted the need for such an act because: "the access to quality care for significant portions of the population has been threatened." 138 Cong. Rec. H5976-07 (July 2, 1992); 138 Cong. Rec. S9772-02 (July 2, 1992) (Message from President Bush to the Senate and the House of Representatives). The Health Care Bill set forth the following significant findings: (1) The rising cost of malpractice insurance, litigation, and liability were escalating the cost of health care; (2) the malpractice crisis was creating tensions between the medical and legal professions as well as between the insurance industry and consumers; and (3) doctors were practicing

unnecessary defensive medicine and canceling high-risk procedures and specialties due to fear of malpractice suits. H.R. 3037, 102nd Cong., 1st Sess. 101(b)-101(d) (1991).

The Health Care Bill suggested that health care reforms would reduce the incidence of medical malpractice and would improve the effectiveness of the civil system. *Id.* 101(d)-101(e). In turn, frivolous claims of health care malpractice would decrease and meritorious claims would be more fairly compensated. *Id.* 101(f).

Title II of the Health Care Bill outlined health care liability reforms. *Id.* 201-210. Section 204 placed a limitation on noneconomic damages. *Id.* 204. The limit of $ 250,000 was to be applied to all health care actions. *Id.* 204(c). The cap was to be imposed against all plaintiffs and defendants whose cause of action arose out of, or was caused by, the same personal injury or death. *Id.* 204(a)-(b). The most significant provision was that the Secretary of Health and Human Services, for good cause, could waive the statutory cap requirement. *Id.* 204(a). The waiver authority was limited and was intended to be used sparingly. 137 Cong. R. E2716 (July 25, 1991) (statement by Rep. Bill Archer).

The Health Care Bill, and in particular its caps on noneconomic damages, was criticized: "It's a plan to protect malpractice insurers. It will have little, if any, effect on health care costs." 137 Cong. R. E2716 (July 25, 1991). Caps were further criticized as a stale approach to the crisis because their constitutionality had already been questioned and rejected at the state level. *Id.* Moreover, little evidence exists that showed that statutory caps would lower insurance rates. *Id.* Critics argued that rates are more accurately and closely tied to the insurance industry's investment income performance rather than to actual payout risks. *Id.* Washington's Insurance Commissioner, Dick Marquardt, concluded that the procedures of rate review and the reporting of investment income would stabilize the insurance market more effectively than tort reforms. *Id.* "Bush's proposal is five years late and a proven failure to boot." *Id.*

Lawyers and legal commentators criticized the caps because they were considered unfair and unnecessary, and tended to punish the most severely injured people whose quality of life was destroyed by negligence. Legal commentators asserted that it is a totally regressive form of tort reform. Additionally, these kinds of proposed legislative changes had mixed success on the state level: Caps produced an insignificant impact on insurance premiums. States with caps continued to experience smaller increases in their malpractice premiums.

Consumer groups such as the National Insurance Consumer Organization argued that the inherent privilege granted health care providers in comparison to other tortfeasors was unfair. They suggest that the problem lay with the doctors who should bear the burden of reform, instead of the victims whose rights are taken away.

Interestingly, critics suggested that the actual decline in the medical malpractice insurance crisis was misleading because the medical malpractice crisis is a ten-year boom and bust cycle. Critics suggested that a new wave of litigation in medical malpractice was possible as a result of the present financial troubles of the insurance industry and the slight increase in the frequency of claims in 1990. Walter

Wadlington, Medical Injury Compensation A Time for Testing New Approaches, 265 JAMA 2861 (1991).

C. Whose Interest Should We Favor?

The Health Care Liability Reform and Quality of Care Improvement Act of 1992 aimed to ease the medical malpractice insurance crisis. As outlined above, however, the Health Care Bill failed to address the problems within the medical profession and insurance industry that contributed to the malpractice insurance crisis. The Bill did not regulate the insurance rate structure nor did it provide a mechanism to eliminate or reduce frivolous claims.

In order to ultimately resolve medical malpractice crisis, the burden of attaining affordable health care for the public must not be placed on the most severely injured victims of medical malpractice. The medical malpractice crisis is not a single problem created by the legal community. It is a series of problems spanning the legal and medical profession as well as the insurance industry. The medical profession and the insurance industry now must take the initiative to resolve the medical malpractice crisis.

Do we favor the interests of business over the interests of those harmed thereby, or vice versa? Because the interests are for the most part so diametrically opposed, the solution will always be, at best, a compromise. But it must be a compromise; we must admit that both sides' interests are important and we must strike a balance. Medical Malpractice and Tort Reform legislation should be no exception.

II. THE FEDERAL LEGISLATIVE PROPOSAL: Preemption Legislation Regarding Medical Devices

Consider the following situation: Imagine that you have been diagnosed with heart disease and upon the recommendation of your doctor, you decide to have heart valve replacement surgery. However, upon recovery, you note that your body feels fatigued, begins to retain limitless fluids, and that you experience shortness of breath. Concerned, you contact your doctor. Is this, in fact, part of the recovery process? What if it isn't? Is something wrong with the mechanical heart valve that was implanted into your body? Are your physicians informed about recent mechanical heart valve complications? What serious effects would a mechanical heart complication cause your body? Hopefully, such an experience will never happen to you, yet, it has happened to thousands, and consumers in Texas must be protected against defective medical devices.

A. The Medical Device Amendments of 1976

The heart of the Medical Device Act (MDA) is a regulatory scheme that allows for prospective evaluation. The rationale underlying the proposal for the MDA of 1976 was "the need to overcome deficiencies in the existing Federal Food, Drug, and Cosmetic Act, which allowed the FDA to initiate regulatory action against a hazardous medical device only after it was in commercial use and after it was demonstrated to be misbranded or adulterated." 21 U.S.C. § 301-395 (1994). Thus, the 1976 amendments broadened the FDA's regulation of consumer and medical products with the hopes of increasing consumer protection and thus furthering the

federal objectives of public health and safety.

The three goals of the MDA are to: "(1) assure public protection against unsafe and ineffective devices; (2) ensure that health practitioners can be confident about the medical equipment they use or prescribe for their patients; and (3) provide market protection for pioneers of new medical technologies." 43 Food Drug Cosm. L.J. 495, 496 (1988). In other words, the MDA strives to protect innovation and advancement of certain medical devices from severe governmental restrictions while concurrently protecting consumers against unsafe and ineffective products. *Id.*

B. Preemption as Relating to Medical Devices

When Congress significantly expanded federal regulatory control of medical devices by the MDA in 1976, it expressly preempted competing state requirements. Thus, this paper focuses on express preemption rather than implied preemption. The pertinent part of the MDA relating to preemption is section 360k(a) which provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

See 21 U.S.C. § 360k(a) (1994); *see also Medtronic, Inc. v. Lohr,* 518 U.S. 470 (1996).

Some potential relief, however, is afforded to the states. The statute permits states to petition for an exemption in certain circumstances. *Id.* § 360k(b). The exemption requirements are set forth in section 360k(b):

> Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if --
>
> (1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
>
> (2) the requirement --
>
> (A) is required by compelling local conditions, and
>
> (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

See id.

The exemption applies to both state and local statutes and regulations, and the FDA regulations provide specific examples of state and local medical device provisions not preempted by the FDA for twenty-one states. 21 C.F.R. §§ 808.1; 808.53-98 (1995).

Congress left no question that its intent was to allow the MDA to have a broad preemptive effect with regard to regulation of medical product approval. 49 Food & Drug L.J. 183, 185 (1994). One reason offered for this broad language is that interstate commerce must not be unduly burdened. *Id.* (citing *Massachusetts v. Hayes,* 691 F.2d 57, 60-61 (1st Cir. 1982). An additional justification for the wide scope of the preemption provisions is that Congress strongly suspected that potential state or local requirements pertaining to medical devices, in addition to existing federal controls, would cause an undue burden that could severely interfere with technological innovations. *Id.* at 185. Thus, the preemption of additional state requirements was fundamental for Congress to achieve its objective of fostering research and development, which is tied to its goal of protecting the health and safety of the people. This desire not to restrain growth in the medical device industry relates back to Congress' intent to protect the public from dangerous and ineffective devices with the minimum amount of control by the federal branch of government.

The applicability of preemption for product approval is also grounded in the FDA regulations. Section 808.1(b) states:

> [The MDA] prescribes a general rule that ... no State or political subdivision ... may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

See 21 C.F.R. § 808.1(b) (1994).

The intended preemptive effect on states approving or regulating the manufacturers marketing of medical devices has somehow been perverted into an argument that the MDA was intended by Congress to preempt product liability suits brought under State Law. *Worthy v. Collagen Corp.,* 967 S.W.2d 360 (Tex. 1998). The dubious rationale is that, by imposing liability on a manufacturer for a defective product that was "approved, "i.e., found "safe and effective" by the FDA, is as much regulation by the state as if the state were re-examining whether the product should be approved for sale within that state. *Id.* at 374-75. As questionable as the logic is, the argument has found support in a number of court decisions. *Id.* Accordingly, plaintiffs lawyers handling product liability suits for defective medical devices have no choice but to address the preemption argument head on.

Thus, when determining whether preemption is applicable, three elements must be present. First, the state must

"establish or continue in effect with respect to a device intended for human use any requirement." *See* 21 U.S.C. § 360(k). Next, the requirement must be "different from, or in addition to, any requirement applicable" to a device under the MDA. *Id.* Finally, the state requirement must pertain "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device" under the MDA. *Id.*

C. The Current Split in Authority Among the States Regarding Medical Device Preemption.

Advocates favoring preemption often argue that FDA standards should not be considered minimum standards that need to be complemented by state laws. FDA standards are the result of extensive research and testing. Thus, the argument continues, courts should not allow juries to undermine the FDA's judgment as to scientific evidence, since holding a manufacturer liable after it has complied with FDA standards effectively second-guesses the FDA's judgment. Since the FDA is considered the expert on medical devices, the states and courts should defer to the FDA's insight on this subject. *Premo Pharmaceutical Labs., Inc. v. United States,* 629 F.2d 795, 804 (2nd Cir 1980) (offering the opinion that the FDA, because of its expertise, is generally in a stronger position to make decisions regarding medical devices than the courts).

1. Public safety

Certainly a much stronger, if not the strongest, argument in opposition to preemption is that holding manufacturers liable for state tort claims will encourage them to develop products that are safer for consumer use. *Graham v. Wyeth Labs,* 666 F.Supp. 1483, 1493 (D. Kan. 1987) (holding that a state tort action viewed as actually enhancing the national goal of optimum vaccine safety). Opponents of preemption argue that the federal government's interest in the protection of the public would be badly served by preempting the state's power to protect its citizens. If the manufacturer knows that preemption will protect him as long as he meets FDA standards, he may very well stop there.

On the other hand, if faced with the risk of potential liability claims, the manufacturer may be more inclined to maximize safety and effectiveness to an even higher degree. Furthermore, such a risk imposed on the manufacturer would most likely induce that manufacturer to continue trying to improve the product after it has entered the marketplace. But manufacturers not faced with such a risk would feel protected against tort claims and could find it more cost-effective to stop trying to improve the product. The manufacturer relying on preemption may attempt to continue maximizing a product's safety after its entry into the market only if it would be profitable for it to do so. Therefore, fundamentally, the argument is that liability provides an incentive for manufacturers to produce safer products.

Additionally, the FDA provides protection to manufacturers who pioneer devices that pose a certain amount of risk due to the need for more testing by classifying such devices as experimental or investigatory devices. 21 U.S.C. § 360j. Such devices fall outside of the general category of medical devices because they are presented to consumers as experimental, and a consumer must provide explicit consent that he understands the risk involved with such a product before it may be used. *Id.* § 360(g)(3)(D); 21 C.F.R. § 812.1. An

example of a plaintiff's claim being preempted because of a device's experimental status is illustrated in *Slater v. Optical Radiation Corp.* 756 F.Supp. 370 (N.D. Ill. 1991), *aff'd,* 961 F.2d 1330 (7th Cir. 1991), *cert. denied,* 113 S.Ct. 327 (1992). In *Slater*, the device, an intraocular lens, was an experimental product, and Mr. Slater signed a consent form indicating that he understood the device to be in the experimental stages and that its safety and effectiveness were not thoroughly proven. *Id.* Such devices labeled as experimental can be used by consumers only with their consent and understanding of the limitations of the product; thus, the risk of using such a product falls on the consumer rather than on the manufacturer.

2. Injured consumers need a remedy

One criticism of preemption of state law claims relating to medical devices is that injured plaintiffs have no remedy available to them since they are denied recourse in state courts and no federal remedy exists. To injured plaintiffs, this lack of any remedy whatsoever seems *extremely unjust.*

The basic justification for the exercise of preemptive powers by Congress is the solution of major public problems in the most effective and efficient manner. Is preemption a near-perfect solution to major problems involving medical device regulation? Or would something be gained by permitting states to impose additional guidelines without compromising the entire federal strategy concerning medical device regulation, which includes the encouragement of the marketing and development of new products and the need for some sort of uniformity across the country? Is it possible for such state standards to work in conjunction with those imposed at the federal level? These are the questions at the heart of the preemption debate, and it is these questions that must be considered when evaluating how medical devices should be regulated in the United States.

The basis of the argument, addressed in this article, is that the preemption doctrine should not be so readily invoked concerning medical devices because the MDA is far from perfect in achieving the federal objective of public health and safety. The MDA has been criticized for serious shortcomings. One commentator stated that, "[d]ue to the overwhelming complexity of the classification scheme, as well as inertia on the part of the FDA, the MDA of 1976 never accomplished their intended goal." H.R. Rep. No 808, 101st Cong., 2d Sess. 13-14 (1990), reprinted in 1990 U.S.C.C.A.N. 6305, 6311.

Thus, the fact that flaws are present in the pre-market approval process for medical devices, express preemption is not only inherently unjust, in that it leaves the injured without a remedy, but also it should not be applicable across the board, under a blanket preemption defense, since it is possible for the system to be manipulated or perverted by manufacturers.

D. Current Federal Preemption Legislation: A potential light at the end of the litigation tunnel

On September 18, 2002, the House of Representatives approved, by voice vote, bill H.R. 4600. *See* H.R. 4600, 107th Cong. (2002). The bill, entitled The Help Efficient, Accessibility, Low Cost, Timely Health Care (HEALTH) Act of 2002, makes changes to the health care liability system, including compensation for injured patients and other issues arising out of health care law suits. *Id.* at § 2. Interestingly, the bill

allows for any health care liability claim concerning health care goods or services *against a manufacturer*, regardless of the theory of liability on which the claim is based. *Id.* at § 9. Further, the bill allows for a health care liability action to be brought in a *state or federal Court* against a manufacturer, regardless of the theory of liability on which the claim is based. *Id.*

Significantly, field preemption against FDA approved medical devices is not found within the four-corners of the bill. Instead, the bill sets forth requirements and permissible recovery amounts for compensating patient injury, including: (1) the full amount of economic loss without limitation; (2) non-economic damages as specified; and (3) a fair share rule. *See id.* at § 4. The only section of the bill that specifically addresses medical products, FDA standards, or FDA approval is a singular section that categorically prohibits *punitive damage awards*[3] for products that comply with the Food and Drug Administrations standards. *See id.* at § 7. Despite this, the bill consciously shreds this enumerated protection and allows a plaintiff to still seek a *punitive damage award* where a manufacturer makes a material and knowing misrepresentation to the FDA concerning a products approval or clearance information. *Id.*

Therefore, a blanket preemption defense proffered by medical device manufacturers does not exist. As shown, this pending federal bill, as well as the identical bill before the Senate, clearly and unequivocally recognizes health care liability claims by injured patients against manufacturers for ***actual damages***. *See id.* at § 4. With respect to preemption for FDA approved products, both bills carve out a protection for manufacturers against an injured patient's claim for punitive damages. *Id.* at § 7. Unquestionably, though, even this statute would not completely insulate corporations or manufacturers from liability when their products are defective.

III. THE SUFFICIENCY OF THE 4590i REPORT

The Medical Liability and Insurance Improvement Act was passed in 1977 to address what the legislature perceived as a "medical malpractice insurance crisis in the State of Texas." Tex. Rev. Civ. Stat. Ann. art. 4590i (Vernon Supp. 2003). The Texas Legislature used this legislation as a tool to curb and eliminate what it believed were frivolous medical malpractice lawsuits filed by the plaintiffs' bar. *Horsley-Layman v. Angeles,* 968 S.W.2d 533, 537 (Tex. App.--Texarkana 1998, no pet.). In its effort to achieve this result, the legislature implemented both substantive and procedural guidelines into article 4590i, including expert report provisions, notice provisions, statute of limitations provisions, limits on liability provisions, discovery procedure provisions, and computation of prejudgment interest provisions. *See* Tex. Rev. Civ. Stat. Ann. art. 4590i, §§ 13.01; 4.01; 10.01; 11.02; 13.02; 16.02. In addition to these provisions, the legislature has also restricted the use of res ipsa loquitur and enacted specific requirements for informed consent cases. *See id.* at §§ 6.01; 7.01.

One of the most important areas that the legislature has decided to regulate is the plaintiff's production of expert reports under article 4590i, section 13.01. This section was originally "enacted to address the perceived problem that litigants were filing

[3] The bill requires a plaintiff to show, by clear and convincing evidence, malicious intent to injure or a deliberate failure to avoid substantially certain, unnecessary injury, to prevail on a punitive damage claim. *Id.* at § 7.

unmeritorious claims against medical practitioners which were not adequately investigated in a timely manner" which "led doctors to settle such suits, regardless of the merits, and also to expend great amounts of money on defending against ultimately "frivolous claims.' " *See Horsley-Layman,* 968 S.W.2d at 537. However, as originally enacted this section did not achieve the goal of the legislature, as the act required only that plaintiff's counsel submit an affidavit stating that he had obtained a written opinion from an expert who had knowledge of accepted standards of care for the diagnosis, care, or treatment of the illness, injury or condition involved in the claim and that the acts or omissions of the physician/healthcare provider were negligent and a proximate cause of the harm claimed. Medical Liability and Insurance Improvement Act, 75th Leg., R.S., ch. 140 1, 1977 Tex. Gen. Laws 2039 (amended 1995). The legislature thus recognized a need for change in this area of article 4590i. In 1995, the legislature implemented a significant change in the Act, making it mandatory that a claimant produce an expert report on or before the 180th day from the date of the filing of the claim. Tex. Rev. Civ. Stat. Ann. Art 4590i, § 13.01(d) (Vernon Supp. 2003).

The legislature designed the expert report requirements of section 13.01 in such a way as to require plaintiffs either to substantiate their claims with a written report or, failing to do this, have their claims dismissed with prejudice. *See id.* 13.01(e)(3).

A. What Constitutes an Expert Report?

As a threshold matter, there is often an issue of whether the document the plaintiff produces is sufficient to bring it under the scope of the definition of "expert report" provided for in the Act.

"Expert report" is defined in subsection 13.01(r)(6) as:

> [A] written report by an expert that provides a fair summary of the expert's opinions as of the date of the report regarding applicable standards of care, the manner in which the care rendered by the physician or health care provider failed to meet the standards, and the causal relationship between that failure and the injury, harm, or damages claimed.

See id. at 13.01(r)(6).

When a document, submitted as an expert report, does not define a) the applicable standards of care, b) how that particular defendant is alleged to have breached that standard of care, and c) "the causal relationship between that failure and the injury, harm or damages claimed," the plaintiff runs a serious risk of having the court determine that the document does not comply with the statutory requirement of an expert report. *See Wood v. Tice,* 988 S.W.2d 829, 831 (Tex. App.--San Antonio 1999, pet. den.) (quoting Tex. Rev. Civ. Stat. Ann. art. 4590i, § 13.01(r)(6) (Vernon Supp. 2003)).

B. Section 13.01(d): The Mandated 180 Day Expert Report

Article 4590i section 13.01(d) controls the mandated 180 day expert report. It provides:

> Not later than the later of the 180th day after the date on

> which a health care liability claim is filed or the last day of any extended period established under Subsection (f) or (h) of this section, the claimant shall, for each physician or health care provider against whom a claim is asserted:
>
> (1) furnish to counsel for each physician or health care provider one or more expert reports, with a curriculum vitae of each expert listed in the report; or
>
> (2) voluntarily nonsuit the action against the physician or health care provider.

See id. at 13.01(d).

There is no question that the provisions of article 4590i are mandatory with regard to the production of expert reports. Subsection (d) requires that the plaintiff "shall" produce (not necessarily file) an expert report for each physician or health care provider against whom a claim is filed on or before the expiration of the 180th day from the date on which suit was initiated. *Id.*

Although the parties are allowed to enter into Rule 11 type agreements extending the time to file expert reports, in many instances this is not done. As a direct result of parties not entering into these written extension agreements, judicial interpretation of article 4590i section 13.01 deals primarily with the issue of plaintiffs' failures to timely file the mandatory expert report in the absence of a section 13.01(h) request to the defendant. *See, e.g., Nguyen v. Kim,* 3 S.W.3d 146, 151-52 (Tex. App.--Houston [14th Dist.] 1999, no pet.); *Tibbetts v. Gagliardi,* 2 S.W.3d 659 (Tex. App.--Houston [14th Dist.] 1999, pet denied). These situations present cause for the plaintiff to assert the two other exceptions provided for in sections 13.01(g) and (f). *See* Tex. Rev. Civ. Stat. Ann. art. 4590i, § 13.01(f), (g) (Vernon Supp. 2003). When asserted by the plaintiff, these exceptions involve an analysis of what constitutes "good cause" under section 13.01(f) and "accident or mistake" under section 13.01(g). *See id; see also Nguyen,* 3 S.W.3d at 151-52 (discussing the meaning of accident or mistake under section 13.01(g)).

In sum, although section 13.01(d) is mandatory, the Texas Legislature has provided plaintiffs with favorable provisions providing them the alternative remedies of either extending their expert report deadline by agreement or by court order after failing to meet the requirements of section 13.01(d). *See id.* at 13.01(h), (f), (g).

C. Section 13.01(e): The Defendant's Remedy Upon Plaintiff's Failure to Meet Section 13.01(d)'s Requirements

When a claimant fails to produce the report mandated by section 13.01(d), the affected physician/health care provider has significant recourse. The sanctions for a claimant's failure to comply with section 13.01(d) are set out in section 13.01(e):

> If a claimant has failed, for any defendant physician or health care provider, to comply with Subsection (d) of this section within the time required, the court shall, on the motion of the affected physician or health care provider, enter an order awarding as sanctions against the claimant or the claimant's attorney:

(1) the reasonable attorney's fees and costs of court incurred by that defendant;

(2) the forfeiture of any cost bond respecting the claimant's claim against that defendant to the extent necessary to pay the award; and

(3) the dismissal of the action of the claimant against that defendant with prejudice to the claim's refiling.

See id. at 13.01(e).

This section requires the defendant to take an affirmative step to get relief by filing a motion to dismiss upon the plaintiff's failure to provide an expert report within the required time period. This pleading can be in the form of a motion to dismiss or can simply be in the form of a responsive plea to the plaintiff's motion for a deadline extension. *Nguyen,* 3 S.W.3d at 150 (holding that the substance of the plea controls over the form; thus a response to plaintiff's motion for an extension of statutory deadline, which included arguments for dismissal under section 13.01(e), clearly gave notice and was intended as a dismissal notice).

D. Section 13.01(f): The Good Cause Exception

Section 13.01(f) allows a claimant to seek a thirty day extension upon motion in which the claimant shows "good cause." It provides:

> The court may, for good cause shown after motion and hearing, extend any time period specified in Subsection (d) of this section for an additional 30 days. Only one extension may be granted under this subsection.

See Tex. Rev. Civ. Stat. Ann. art 4590i, § 13.01(f) (Vernon Supp. 2003).

This exception has been described by the courts as "intended for use when a plaintiff "needs a little extra time to comply with the 180-day deadline." *See Roberts v. Medical City Dallas Hosp., Inc.,* 988 S.W.2d 398, 402 (Tex. App.--Texarkana 1999, pet. denied). Granting relief under this subsection is discretionary with the court, and the appellate courts will only review this decision for an abuse of discretion. *Id.*

There remains some question as to whether the extension provided for in section 13.01(f) may be sought at any time. One possible interpretation of this subsection is that a claimant may request the court to extend the 180 day deadline to 210 days. In that instance, the argument is that such an extension must be requested within the 180 day deadline, and the expert report(s) filed within 210 days of filing suit. *Id.* at 402 (noting that section 13.01(f) should not be read "to require the filing of the motion to be within the 180-day period under section 13.01(d)"). However, because the language of this subsection is ambiguous, it might also be argued that a claimant may, at any time, ask the court for thirty days from the date the court rules on the request to produce the expert report. In Roberts, the court held that the motion was timely, notwithstanding the fact that it was filed after the 180 day deadline. *Id.*

E. Section 13.01(g): The Mistake or Accident Exception

Subsection (g) is the brightest "light at the end of the tunnel," so to speak, when the claimant has failed to produce the expert report within the 180 day deadline established in subsection (d). Subsection (g) states:

> Notwithstanding any other provision of this section, if a claimant has failed to comply with a deadline established by Subsection (d) of this section and after hearing the court find that the failure of the claimant or the claimant's attorney was not intentional or the result of conscious indifference but was the result of an accident or mistake, the court shall grant a grace period of 30 days to permit the claimant to comply with that subsection. A motion by a claimant for relief under this subsection shall be considered timely if it is filed before any hearing on a motion by a defendant under Subsection (e) of this section.

See Tex. Rev. Civ. Stat. Ann. art. 4590i, § 13.01(g), (f) (Vernon Supp. 2003).

Subsection (g) gives a claimant a second chance despite the failure to comply with the mandatory requirement for the timely production of an expert report. The language of subsection (g) mandates a thirty day grace period to produce the required expert report where the failure to produce a report was the result of accident or mistake. *See id.* Neither "accident" nor "mistake" are defined in the statute. *See id.*

Section 13.01(g) is undoubtedly the most addressed subsection in the limited number of appellate cases addressing the timeliness of expert report production, as required in section 13.01(d).

The majority of the appellate court decisions discussing the appropriateness of a trial court's decision to grant or deny an extension for filing an expert report focus on whether the appellate record reveals any evidence that plaintiffs' failure to file an export report on time resulted from an accident or mistake on the part of the plaintiff. *Nguyen,* 3 S.W.3d at 151-152.

Therefore, while there are mechanisms to overcome failure in the timely production of the required expert report, the substantive changes to article 4590i, section 13.01 enacted in 1995 have affected the prosecution and defense of medical malpractice claims by promoting reasonably prompt dismissals, either voluntary or non-voluntary, of suits where expert reports had not or could not be timely obtained. Additionally, as a practical matter, despite the prohibition of the use of article 4590i reports as summary judgment evidence, the production of these mandatory reports has significantly reduced the number of summary judgments sought by physician/health care provider defendants.

As a practical matter, the most efficient method of article 4590i, section 13.01 compliance, both financially and procedurally, is to produce the mandatory expert report at the time of the filing of the petition or at least by the ninetieth day after the filing of the suit.

IV. THE DAUBERT CHALLENGE: Facts and Trends

"By a preponderance of the evidence" is the burden on the offering party to prove that expert evidence is admissible and demonstrate the expert's qualifications, methodological reliability, connective reliability, and foundational reliability. *See, e.g., E.T. du Pont Nemours & Co. v. Robinson,* 923 S.W.2d 549 (Tex. 1995). The burden is not necessarily on the party with the ultimate burden of proof; it is on the party who offers the expert testimony. *Merrell Dow Pharmaceuticals, Inc. v. Havner,* 953 S.W.2d 532, 720 (Tex. 1997). A defendant challenging causation testimony, however, has a lower burden of proof since a defendant may present evidence of mere possibilities. Although the defendant must still prove the reliability of proffered expert testimony, it does not have to prove that another alternative cause is the most likely cause; the defendant simply must demonstrate that the other alternative cause is possible.

A. Raising the Reliability Challenge

How a party should raise a reliability challenge is an open procedural question. *Maritime Overseas Corp. v. Ellis,* 971 S.W.2d 402, 411 (Tex. 1998). Some parties make blanket reliability challenges to all of an expert's opinions, hoping to use the burden of proof placed on the offering party to obtain a preview of the full basis of the expert's opinions. Conversely, they hope for a failure to establish some link in the chain of proving reliability in order to exclude the testimony.

The evidentiary polices underlying *Daubert's* competing rationales, efficiency and fairness concerns, and the structure of the discovery rules, all dictate placing a burden on the opponent of the evidence to make a prima facie showing that the proponent's evidence suffers from the deficiencies identified in *Daubert*, before the court has any obligation to undertake an admissibility determination.

Texas has not addressed the proper method of raising a reliability challenge, but it appears that a conclusory motion would be improper. The party opposing the evidence must make a specific objection to a specific offer of expert evidence. *Robinson,* 923 S.W.2d at 557. A general objection to evidence is normally insufficient. *See, e.g., United States v. Arteaga-Limones,* 529 F.2d 1183, 1190 (5th Cir. 1976); *Sandow v. State,* 787 S.W.2d 588, 596 (Tex. App.--Austin 1990, pet ref'd); and *Carona v. Pioneer Life Ins. Co.,* 557 F.2d 477, 480 (5th Cir. 1966). In *Robinson*, the motion to exclude detailed the basis for the motion with specificity. *See* 923 S.W.2d at 557. "At that point," the offering party bears the burden of proof. *See id.*

Just as it is improper to make conclusory, no-evidence summary judgment motions without identifying the specific elements that are lacking evidence, it is improper to make conclusory reliability challenges without specifying the opinions that are challenged. *See* Tex. R. Civ. P. 166a, cmt. (stating that the motion must be "specific" and forbidding motions that are "conclusory" or "general"). Thus, there are strong arguments for suggesting that Texas requires specific objections to specific opinions. *See* Tex. R. App. P. 33.1(a)(1)(A).

Moreover, the federal courts have yet to explicitly address the burden on the movant seeking to strike expert testimony. *Kumho Tire Co. v. Carmichael* found that the objecting party had called the expert's testimony "sufficiently into question." 119

S. Ct. 1167 (1999). In addition, the Fifth Circuit recently concluded that the issue was sufficiently raised "by providing conflicting medical literature and expert testimony." *See Tanner v. Westbrook,* 174 F.3d 542, 546 (5th Cir. 1999).

B. The Timing of the Challenge

Another open question is whether a party must file a *Daubert/Robinson* challenge before trial. Neither the United States Supreme Court nor the Texas Supreme Court has set forth a procedure for challenging the expert. There are two fundamental options: require a pretrial motion or permit the challenge during trial by formal objection. *Maritime,* 971 S.W.2d at 425. It appears the Texas Supreme Court wants to give the trial courts an opportunity to experiment with different procedures before determining which procedure is best, but suggests that such challenges should normally be made pretrial. *Id.* at 414. No Texas appellate court has required the challenge to be raised in a pretrial motion.

Trial courts are using a number of different procedures for the timing of *Daubert* challenges. Some courts require the challenge to be made long before the trial. *Hose v. Chicago N.W. Transp. Co.,* 70 F.3d 968, 973 n. 3 (8th Cir. 1995) (expressing a desire for early *Daubert* hearings). Some courts may even state explicitly that a late filing is deemed a waiver of a *Robinson* objection. *Maritime,* 971 S.W.2d at 415. These courts normally allow a party to file the motion earlier if they desire. For these courts, the challenge still must be made after sufficient time for discovery has been allotted because each side needs "an opportunity to depose the other side's experts" in order to develop strong critiques and defenses of the experts' methodologies. *See In re Paoli R.R. Yard PCB Litig.,* 35 F.3d 717, 739 (3rd Cir. 1994). The advantage (some would say disadvantage) to this procedure is that it allows a party the opportunity to cure the striking of their expert by hiring a new expert. *See, e.g., Summers v. Missouri Pac. R.R. Sys.,* 132 F.3d 599, 605 (10th Cir. 1997) (amending scheduling orders so that the plaintiff could locate new experts after the first were struck).

Other courts require the motion to be heard no later than shortly before trial. *See, e.g., Gier v. Education Serv. Unit No. 16,* 845 F. Supp. 1342, 1343 (D. Neb. 1994) (following *United States v. Martinez,* 3 F.3d 1191 (3rd Cir. 1993), and holding a *Daubert* hearing after a motion in limine was filed). The advantage to this latter procedure is that all of the discovery will have been conducted and the court will have all of the necessary information to make a ruling. Additionally, the court avoids an "advisory ruling," which would allow a party a second opportunity to locate a new expert. Deferring the matter until shortly before trial may avoid a prolonged Rule 104(a) hearing because most cases settle before such motions are heard. Requiring the motion before trial avoids jurors waiting out in the hallway or judges rendering quick decisions without adequate reflection, research, or both.

Still other courts hear the issues during a motion in limine. *In re Paoli,* 35 F.3d at 738-39. One potential problem here is that a jury may have already been ordered before the hearing on the motion in limine begins. Therefore, a court may lack the time to thoroughly review the motion before the commencement of trial. On the other hand, because the case is at its most ripe at this point, the court may have a better understanding of the issues. Moreover, a motion in limine preserves nothing for

appellate review. *Maritime,* 971 S.W.2d at 425 (Hecht, J., dissenting).

Some courts prefer to hear the motion in trial. *See, e.g., United States v. Johnson,* 28 F.3d 1487, 1496 (8th Cir. 1994) (finding no error in the trial court's choice of determining admissibility during trial). This procedure ensures that the court will have the best understanding of the case and the significance of the testimony. It also avoids unnecessary hearings because most cases settle, and it adds an additional element of risk that works to increase the likelihood of settlement. Additionally, this procedure minimizes the discovery advantage that both parties obtain in a *Daubert* hearing. A pretrial *Daubert* hearing is an opportunity for the offering party to learn part of the attack on its expert and an opportunity to better prepare the expert for trial. It also gives the challenging party an opportunity to obtain additional information that the other side will use to qualify its expert and show a reliable basis for the opinion testimony.

Ultimately, Rule 104(a) hearings during trial help minimize the expense of bringing experts to the court twice - once for the hearing and a second time for trial - at least for the party that offers the expert (the opposing side's expert may still need to testify both at the hearing and a second time in front of the jury).

In addition to the disadvantages of jurors waiting (which some judges minimize by late night hearings or reviewing the evidence such as depositions, affidavits, and articles during the trial) and quick rulings, challenges in the middle of trial inflict a two-fold prejudice upon a party whose expert is struck. Not only does the party lose the expert, the attorney also loses credibility with the jury because presentation of the expert may have been promised or referred to during voir dire or opening statement. Additionally, judicial resources, taxpayer money, and juror time may be wasted because the striking of an expert will in some cases be tantamount to a directed verdict. Even if the expert is not necessary for a party's case to survive a motion for directed verdict, key strategic decisions that depend upon the expert for jury persuasiveness may be irrevocable in the middle of trial. Moreover, presenting rebuttal evidence at a *Daubert* hearing in the middle of trial can also have practical difficulties.

Deferring *Daubert* challenges until trial also creates problems when an expert's deposition is used at trial. If the proffering attorney did not anticipate a *Daubert* objection or issues of concern to the trial judge, it will be difficult to address these issues without the witness testifying live at trial. Conceivably, the objection could be cured by an affidavit or by testimony from the expert over the telephone, but time makes these remedies impractical in the middle of trial. On balance, courts should normally require parties to make reliability challenges at least thirty days before trial. *Maritime,* 971 S.W.2d at 414-15.

C. Reliability Challenges in Motions for Summary Judgment

Whether trial courts should allow an evidentiary hearing on the admissibility of expert testimony in the context of a summary judgment motion is another open question. Both the Texas and federal rules prohibit oral testimony during a summary judgment hearing. *See* Fed. R. Civ. P. 56; Tex R. Civ. P. 166a. The federal courts have indicated that the trial court may consider a *Daubert* challenge before a summary judgment and if the party prevails in striking an expert, may grant a summary

judgment. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993); *Cortes-Irizarry v. Corporacion Insula De Seguros*, 111 F.3d 184, 188 (1st Cir. 1997). The same result will probably occur in Texas courts, although this issue is more theoretical than real because parties normally file a motion to strike or make an objection to the expert's testimony in connection with a "no-evidence" motion for summary judgment. *See, e.g., Weiss v. Mechanical Assoc. Servs., Inc.*, 989 S.W.2d 120, 123 (Tex. App.--San Antonio 1999, pet. denied); *Lampasas v. Spring Ctr., Inc.*, 988 S.W.2d 428, 434-35 (Tex. App.--Houston [14th Dist.] 1999, no pet.). The court first hears the motion to strike or the objection to the expert testimony under Rule 104(a). In most causation summary judgment motions, if the plaintiff's expert is struck, the summary judgment motion will be granted. *In re Paoli*, 706 F. Supp. At 376. In some cases, fairness may require a continuance of the summary judgment hearing to allow the party whose expert is struck an opportunity to designate a new expert. If the expert is not struck, the denial of the summary judgment is not reviewable on appeal and the motion to strike will have to be reurged at trial. *See Black v. J.I. Case Co.*, 22 F.3d 568, 569 (5th Cir. 1994) (refusing to review a pretrial denial of a motion for summary judgment).

D. Rule 104(a) Hearings

A trial court has discretion on whether to grant the parties an evidentiary hearing on a *Daubert* challenge. *Kumho Tire Co. v. Carmichael*, 199 S.Ct. 1167, 1176 (1999). Before *Kumho Tire*, this issue was open, with some courts definitively requiring evidentiary hearings and others stating that no right to an evidentiary hearing existed. *Kumho Tire* granted trial courts wide latitude "to decide whether or when special briefing or other proceedings are needed to investigate reliability." *See* 119 S. Ct. at 1176. If an evidentiary hearing is conducted, judges should "freely ask questions" during the hearing. *Robinson*, 923 S.W.2d at 720. Parties should also request a record of any hearing on an expert challenge.

E. Appellate Review

Trail courts have broad discretion in determining whether the expert testimony satisfies the helpfulness standard, whether a witness is qualified to offer expert testimony, and the scope of the expert testimony. A trial court's ruling as to whether an expert is qualified can only be reversed for abuse of discretion. *Moore v. Ashland Chem., Inc.*, 126 F.3d 679, 700 (5th Cir. 1997); *Broders v. Heise*, 924 S.W.2d 148, 151 (Tex. 1996). Appellate courts also apply an abuse of discretion standard when reviewing the exclusion of evidence under Rule 403, although they afford such exclusions "particular deference." *See In re Paoli*, 113 F.3d at 453; *Montgomery v. State*, 810 S.W.2d 372 (Tex. Crim. App. 1990). Similarly, the standard of review on appeal for reliability challenges in both state and federal courts is abuse of discretion. *General Elec. Co. v. Joiner*, 522 U.S. 136, 139, 141, 143 (1997); *Robinson*, 923 S.W.2d at 558. In conclusion, whatever the basis for its ruling, a trial court enjoys wide latitude in its determination of whether expert testimony is admissible. *Id.*

A failure to object to the reliability of an expert's testimony at trial (or, at minimum, before trial) waives the claim to any error concerning the testimony on appeal. *Havner* suggested that it might not be necessary to object to unreliable expert evidence to preserve error because unreliable scientific evidence is "no

evidence." *See* 953 S.W.2d at 714. The Texas Supreme Court directly addressed the waiver issue in *Maritime Overseas Corp. v. Ellis*. *See* 971 S.W.2d at 402. The court had two choices: On one hand, the court could have followed the "no-evidence" reasoning of *Havner*, which would, under a technical legal analysis, result in a decision that the failure to object does not waive error. In the alternative, the court could have adopted a pragmatic approach that a failure to object waives any error.

Maritime Overseas adopted the pragmatic approach. *See id.* at 411. The case suggests that the failure to object waives any error in all cases and directly held that the appellant waives error if, on appeal, he or she only raises a factual insufficiency point of error. *See id.* at 409. In other words, if the appellant does not raise a no-evidence point of error, any error by the trial court in admitting the expert evidence is waived if the proper objection was not made at trial. Therefore, *Maritime Overseas* holds that it is too late to object to the reliability of expert evidence after a verdict; it also arguably indicates that it may be, at least in some circumstances, sufficient to object before trial, as occurred in *Havner*. *See id.*

F. Daubert and Justice

It has also been argued that *Daubert* and *Robinson* will result in less justice. Injustices will occur when some theories that are now viewed as unreliable ultimately become accepted principles. Also, evidence may be excluded that, with time, could prove to offer authentic insights. At the risk of over-simplification, it was at one time generally accepted that the world was flat, but the rejection of the round-world view did not make it false. Based upon this rationale, one circuit liberally permitted unreliable scientific evidence addressing the ""frontier of current medical and epidemiological inquiry'" if the expert used sound methodology. *See Ealy v. Richardson-Merrell, Inc.*, 509 U.S. 579, 596-97 (1993). On the other hand, many new scientific ideas are often proven to be wrong.

The United States Supreme Court did not duck this difficulty; it conceded that injustices may occur, but commented that the quest for truth in the courtroom is very different than the quest for truth in the laboratory. *Daubert,* 509 U.S. at 596-97. Discovery in a lawsuit has certain time deadlines, but discovery in the scientific process has no deadlines. The resolution of legal disputes requires finality; the resolution of scientific disputes involves perpetual revision of hypotheses and rounds of testing. *See* John Schwartz, Only Good Science to Keep on Debating "*Junk Science,' Hous. Chron.*, March 28, 1999, at 5C. Evidentiary rules are not designed to achieve "cosmic understanding" but only to resolve particularized legal disputes. *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1320 n.13 (9th Cir. 1995) (upon remand).

The Texas Supreme Court has also rejected the argument that courts should not wait for reliable scientific studies because waiting will cause early claimants to be denied recovery and a "core policy" recognized by tort law requires risk-spreading and deterrence. *See Havner,* 953 S.W.2d at 728. "We expressly reject these views . . . The law should not be hasty to impose liability when scientifically reliable evidence is unavailable. *See id.* As Judge Posner has said, "law lags science; it does not lead it.' " *See id.* The Fifth Circuit has also observed that "the law cannot wait for future scientific investigation and research. We must resolve cases in our courts on the

basis of scientific knowledge that is currently available." *Ashland Chem.*, 151 F.3d at 276. On the other hand, courts should not unnecessarily rush into trial cases that involve novel scientific issues while important studies are ongoing and while other, less "novel," cases are available for trial. *See, e.g., In re Ethyl Corp.*, 975 S.W.2d 606, 620 (Tex. 1998).

G. The Final Analysis

A similar, although often unstated, criticism of *Daubert* and *Robinson* is that the cases place too heavy a burden on the plaintiff. Indeed, it can be argued that the result is inequitable because a defendant has a lower burden of proof for causation - a defendant does not need to disprove causation by a reasonable degree of medical probability and thus is permitted to offer proof of other potential causes. If, however, the defendant's expert testifies that another possible cause is the most likely cause, the expert's opinion would have to meet the same burden of proof as that of the plaintiff's expert. A related criticism is that the expense will become so great that recovery will be denied for deserving plaintiffs in products liability litigation who cannot afford to conduct testing to meet the new reliability standards, thus permitting unsafe products to remain in the market.

The other side of the argument is that the failure to require reliability may result in undeserving plaintiffs receiving a windfall, defendants paying monies for which they are not responsible, and defendants refusing to place products on the market for fear of liability.