Pharmaceutical Litigation and Pederal Preemption

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canons?



assist in preventing the unauthorized practice of law.

Canon 2. A paralegal shall not perform any of the duties

rules); the paralegal shall

Canon 2. A paralegal shall not perform any of the duties that attorneys only may perform or do things which attorneys themselves may not do.

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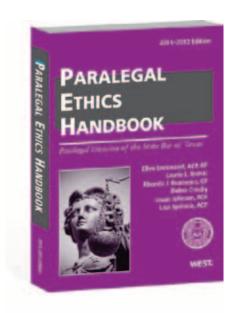
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CORRECTIONS

Christine R. Cook (paralegal for John Lane & Associates) was a co-author on the 2011 Legislative Update that was published in the last issue of the TPJ.

The original papers written from which the last issue's Legislative Update article was based were by Norma Bazan and Gary Nickelson.

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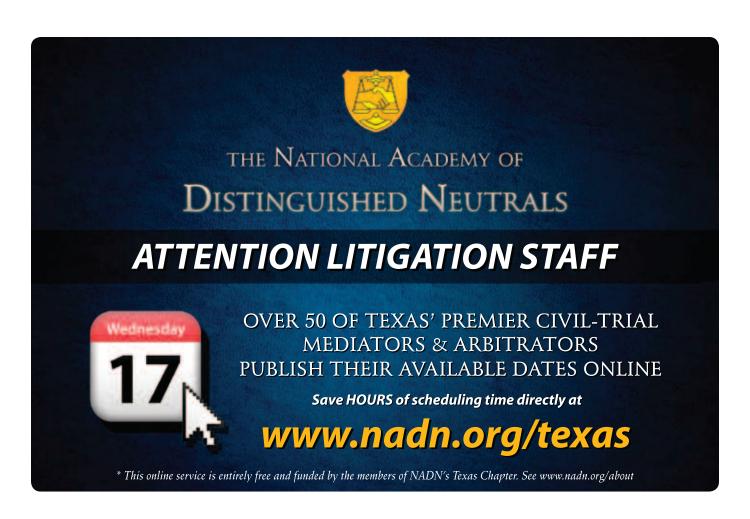
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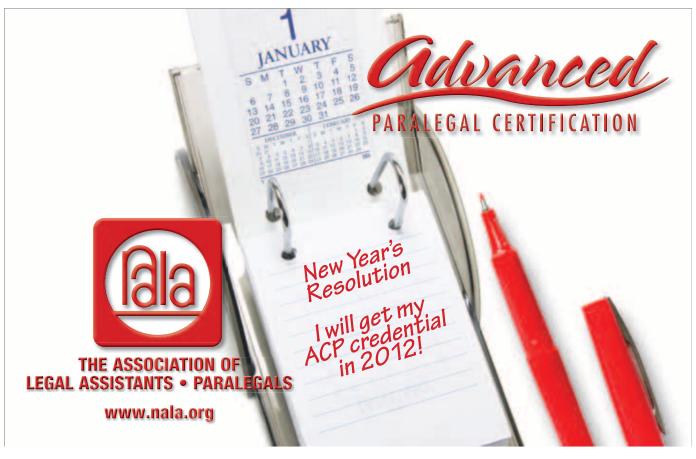
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EDITOR'S Mate

by Heidi Beginski

"I believe in professionalism, but playing is not like a job. You have to be grateful to have the opportunity to play."

Wynton Marsalis

"Gratitude is not only the greatest of virtues, but the parent of all the others."

Cicero

or many, the New Year symbolizes the beginning of a better tomorrow. The beginning of a page 1 to 1 ning of a new calendar year is a great time to take stock in where we are in our lives, and our profession is certainly a huge aspect of what we do and, for some, how we define ourselves. Whether you are a new paralegal or one who has many years of experience, ask yourself what your job means to you. I am grateful to be able to provide whatever work product (I don't claim any talent) and knowledge I have to help others. Sometimes I only see that I am helping my boss, but other times I can see that my efforts are truly helping his clients. Either way, it is an honor to be able to do so, and I am grateful for the opportunities to do so.

For the last two days, I've been struggling with my computer because I can't see the icons on the bottom of the screen for all the sticky notes I've got pasted there. How lucky I am! There is something to be learned every day. It may not be anything life-changing or slap-you-in-the-face monumental, but it is there. There is always something for which to be grateful. I am grateful for the people I have met, and the lessons I have learned from my affiliation with the Division. The only way I can think to reflect my gratitude for these experiences is to learn from my fellow PD members and work to become a better paralegal.

"Any man's life will be filled with constant and unexpected encouragement if he makes up his mind to do his level best each day."

Booker T. Washington

"Gratitude unlocks the fullness of life. It turns what we have into enough, and more. It turns denial into acceptance, chaos into order, confusion into clarity.... It turns problems into gifts, failures into success, the unexpected into perfect timing, and mistakes into important events. Gratitude makes sense of our past, brings peace for today and creates a vision for tomorrow."

Melodie Beattie

Texas Paralegal Journal (ISSN# 1 089-1633) is published four times a year in Summer, Fall, Winter, and Spring for \$15 set aside from membership dues for a 1-year subscription by the Paralegal Division of the State Bar of Texas, 3505 Black Mesa Hollow, Austin, Texas 78739. Periodical Postage Paid at Austin, TX. POSTMASTER: Send address changes to the Texas Paralegal Journal, P.O. Box 13 75, Manchaca, Texas 78652

Circulation Fall 2011: Total Printed: 1,700; Paid or Requested: 1,644; Mail Subscriptions: 1,644; Total Paid and/or requested circulation: 1,644; Free Distribution: 25; Total Distribution: 1,669; Office Use or Leftover: 31

Publications: Heidi Beginski, TBLS, Editor Susan Wilen, R.N., President

Norma Hackler, CMP, Coordinator Sunnie Palmer, Board Advisor

Art Direction

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The Texas Paralegal Journal is published four times a year as a service to the paralegal profession. A copy of each issue is furnished to the members of the Paralegal Division as part of their dues.

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Pharmaceutical Litigation and Federal Preemption

by Justin Ryan Vatter, ACP

I. INTRODUCTION

Federalism is the relationship and distribution of power between the national and regional governments within a federal system of government. In the United States, federalism is the evolving relationship between sovereign state governments and the federal government. The Tenth Amendment to the United States Constitution addresses federalism by providing that powers not granted to the federal government (nor prohibited to the states) are reserved to the states or the people.² Therefore, the federal government only has those powers clearly or expressly granted by the Constitution, making it one of limited powers. This narrow interpretation of the Tenth Amendment does not imply a total disregard of the federal government's authority, but there are limitations in certain circumstances.

Sometimes federal law supersedes or supplants any inconsistent state-law or regulation.³ This concept is known as preemption. The Supremacy Clause of the United States Constitution provides:

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any state to the Contrary notwithstanding. The Supremacy Clause clearly grants Congress the power to enact statutes that can supersede state laws, as long as they are constitutionally authorized. Congress is also able to create agencies through enabling acts that define the scope of an agency's authority. These agencies, which have some degree of independence from the President and Congress, sometimes use federal authority in attempt to preempt state-law and state tort remedies. In the context of pharmaceutical litigation, preemption refers to a defense in a federal court where a drug manufacturer argues federal law or regulation supplants a state tort claim.

The following article provides an overview of pharmaceutical litigation, concentrating on pro-preemption arguments pursued by drug manufacturers against product liability and failure-to-warn claims. The article will address preemption defenses and the potential liability of drug manufacturers in the context of prescription drugs, medical devices, and warning labels approved by the Federal Drug Administration ("FDA"). First, the article will define the agency and give a brief history of the FDA. An examination of the FDA's drug approval process will follow, concentrating on the New Drug Application phase through final approval for commercial sale and marketing. This section will specifically focus on the role of the reviewers at the Center for Drug Evaluation and Research. Next, an examination and discussion of liability theories, specifically focusing



on the Restatement (Third) of Torts⁵ and its application to the potential liability of drug manufacturers when their products cause harm to consumers. An overview of the main categories of preemption will follow. Attention will then turn to key pharmaceutical cases, concluding with the most recent decision in Wyeth v. Levine⁶, which considered the scope of federal preemption in the pharmaceutical industry when applicable federal regulations contain no express preemption clause.⁷ The purpose of the article is to define and review pharmaceutical litigation as it relates to preemption defenses, drug manufacturers, and the FDA.

II. BACKGROUND

A. The History of the FDA

The FDA is a scientific, regulatory, and public health agency. Its jurisdiction encompasses most food products (other than meat and poultry), drugs, therapeutic agents of biological origin, medical devices, cosmetics, animal feed, and radiation-emitting products for consumer, medical, and occupational use.⁸

In 1848, Lewis Caleb Beck was appointed to the Patent Office to carry out chemical analyses of agricultural products. This appointment marked the beginning of what is presently known as the FDA. In 1906, with the passage of the Pure Food and Drugs Act, the agency's modern regulatory functions were established. The act prohibited interstate commerce of contaminated and misbranded food or drugs and provided basic elements of protection that consumers had never known before that time.⁹

According to the FDA's website, the agency grew from that single chemist in 1848 to a staff of approximately 9,100 employees and a budget of \$1.294 billion in 2001. The agency consists of chemists, pharmacologists, physicians, microbiologists, veterinarians, pharmacists, and lawyers. The agency has over 150 field offices and laboratories, including five regional

offices and twenty district offices. The FDA monitors the manufacture, import, transport, storage, and sale of most consumable products. ¹⁰ The agency also employs scientists who evaluate applications for new drugs. This comprehensive assessment before approval is called a New Drug Application ("NDA"). ¹¹B. New Drug Application: Individual Benefit versus Population Risk

The NDA is how drugs are formally proposed to the FDA for approval for commercial sale and marketing. The goals of the NDA are to provide enough information to permit FDA reviewers to establish the safety and effectiveness of a drug (i.e., insure insuring adequate warning labels and inserts are included) and to examine methods used in manufacturing. 12 The required documentation included in a NDA tells the drug's whole story; including what happened during the clinical tests, ingredients of the drug, how the drug behaves in the body, and how it is manufactured and packaged. Current law requires that all new drugs demonstrate "substantial evidence of the drug's efficacy for a marketed indication, in addition to the existing requirement for pre-marketing demonstration of safety."13

The Center for Drug Evaluation and Research ("CDER"), a division of the FDA, oversees the NDA process. Throughout the life cycle of a drug, reviewers in the CDER weigh information regarding risks and benefits. Reviewers then make decisions based on a risk-benefit profile. The reviewers' final approval, based up on this risk-benefit profile, has life-or-death consequences. For instance, a drug can be life-saving for an individual patient but may pose substantial risk when viewed in the context of the general population.¹⁴ This tension between individual benefit and population risk reflects the complex decisions the FDA must routinely make. Before final approval by the CDER for commercial use and sale, the drug is turned over to the Office of New Drugs ("OND") and the Office of Drug Safety

("ODS") for further review. The OND holds the responsibility for final drug approval and is involved in post-market safety reviews. If necessary, the OND has the duty and ability to take regulatory actions. The ODS serves primarily as a consultant to OND and does not have any independent decision-making capabilities.¹⁵

After final approval of a NDA, the manufacturer must continually evaluate a drug and report any adverse effects to the FDA. Any serious or fatal events must be reported within fifteen days and any other on a quarterly basis. ¹⁶ In finding any adverse effects, the FDA has the ability to require the manufacturer to conduct additional clinical trials. In severe cases, the FDA can require risk management plans that may provide for other kinds of studies, restrictions, or post-market safety surveillance.

III. CONTEXT FOR PREEMPTION
ISSUES ON PHARMACEUTICAL
LITIGATION: FDA DRUG APPROVAL
VERSUS STATE-LAW CLAIMS,
CONGRESSIONAL INTENT, AND
PRODUCT LIABILITY

A. Failure-to-warn Litigation and Pharmaceutical Drug Approval

Even though the FDA approves and evaluates drugs and warning labels based on information provided by the manufacturers, it is not an investigative agency. Like other regulatory agencies, the FDA does not actively seek out information; it relies on information brought to its attention and must react retroactively. Historically, the FDA took the position that its product-approval process and state tort liability operated independently.¹⁷ The FDA reasoned that regulatory efforts could coexist with state-law claims because failureto-warn litigation did not interfere with the agency's regulatory duties. Recently, though, this attitude changed, and the FDA now argues the tort litigation system is an avenue that needs to operate concur-



rently with a regulatory system that does not have authority to require the regulated industry to engage in efforts to obtain or report all adverse risk information.¹⁸ The FDA also argues that the Federal Food, Drug, and Cosmetic Act (FDCA) impliedly preempts failure-to-warn claims based on product labeling approved by the agency. The agency formalized this position in the preamble to a 2006 rule that revises requirements for drug labeling.19 This change was based on the FDA's concerns over the "growing propensity of bad scientific reasoning" that was seeping into court cases involving FDA-regulated products.²⁰B. Congressional Intent: the "Ultimate Touchstone"

The Supreme Court has addresses preemption and has held that the intent of Congress is the ultimate touchstone regarding preemption²¹ and

1.) "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated ... in a field which the States have traditionally occupied,' ... we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.' "22

The Supremacy Clause of the Constitution addresses preemption and provides that any federal law, even a regulation of a federal agency, trumps any conflicting state law.²³ Federal law may expressly or impliedly preempt state-law. When Congress chooses to expressly preempt state-law, the only question for a court is whether the challenged state law²⁴ is one the federal law is intended to preempt. On the other hand, implied preemption presents more complicated issues. The court has to look beyond the express language of federal statutes to determine whether Congress has occupied the field in which the state is attempting to regulate, or whether

a state law directly conflicts with federal law, or whether enforcement of the state law might conflict with federal purposes. Federal "occupation of the field" occurs, according to *Pennsylvania v Nelson*²⁴, when there is "no room" left for state regulation. Courts are to look to the pervasiveness of the federal scheme of regulation, the federal interest at stake, and the danger of frustration of federal goals in making the determination whether a challenged state law can stand.

B. The Restatement of Torts (Third): Framework for a Cause of Action

Federal laws concerning the FDA are part of the Food, Drug and Cosmetic Act,²⁵ but most product-liability causes of action are determined at the state level. Accordingly, most lawsuits involving pharmaceutical drugs are filed in state courts, opening a door for preemption arguments and defenses. Product liability is the area of law in which those who make products available to the public (manufacturers, distributors, suppliers, and retailers) are held responsible for the injuries their products cause.

Because each type of product-liability claim requires proof of different elements for a successful claim, it is useful to examine the Restatement of Torts (Third) before an examination of relevant case law. This Restatement examines the liability of commercial sellers, manufacturers, and distributors for harm caused by products. The Restatement also covers liability of product sellers not based upon defects at the time of sale, including liability for post-sale failure to warn, and successor liability.²⁶ The Restatement furnishes extensive guidance to all who practice in the area of products liability law and develops special rules for component parts, prescription drugs, medical devices, food, and used products.²⁷

The following sections of the Restatement, though not exclusive, pro-

vide definitions and guidelines regarding liability of commercial sellers and manufacturers. The sections lay out theories and principles concerning liability, which the courts have used to decide these cases.

Section 2, Categories of Product Defect, declares a product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings.²⁸

Section 4, Noncompliance and Compliance with Product Safety Statutes or Regulations, provides two ways liability for defective design or inadequate instructions or warnings can occur:

- (a) a product's noncompliance with an applicable product safety statute or administrative regulation renders the product defective with respect to the risks sought to be reduced by the statute or regulation; and
- (b) a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation.²⁹

Regarding liability of drug manufacturers, Section 13, Liability of Commercial Seller or Distributor for Harm Caused by Defective Products, provides: "One engaged in the business of selling or otherwise distributing products or who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect." Section 6, Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices, provides greater detail of a manufacturer's liability regarding prescription drugs and medical devices. 1

The Restatement (Third) of Torts lays out the framework for causes of actions regarding product liability actions and provides guidelines for consumers to allege



claims in state court. Judges consider the Restatement as secondary authority and make a decision as to how to apply to the case at hand. While under no formal obligation to adopt Restatement sections as law, judges often do because such sections accurately restate the already established law in that jurisdiction, or they believe the rule is appropriate in a case of first impression. Preemption arguments emerge as defenses to these causes of action.

IV. ANALYSIS OF RELEVANT CASE LAW

The central argument regarding preemption in federal courts is the proper distribution of judicial power between the states and the federal government. For example, in a case based on preemption of a state law claim by federal law, both the states and the federal government have interests in asserting jurisdiction, furthering their own policies, and interpreting laws. The following cases have been decided on consumers' product liability causes of action versus the manufacturers' preemption defenses.

A. Cipollone v. Liggett Group, Inc.: Labeling and advertising do not preempt claims based on express warranty, intentional fraud and misrepresentation, or conspiracy.

In 1992, the Supreme Court addressed the issue of preemption regarding state litigation and the tobacco industry. The court held the Cigarette Labeling and Advertising Act of 1969 pre-empts certain failure-to-warn and fraudulent misrepresentation claims, but does not pre-empt other such claims or the claims based on express warranty or conspiracy.³²

Rose and Thomas Cipollone brought a state civil action against cigarette manufacturers after Rose was diagnosed with lung cancer. Thomas, Rose's spouse, continued the action after she died. After the jury returned a verdict for Rose on express warranty claims, the U. S. District Court for the District of New Jersey denied the

manufacturer's motions for judgment notwithstanding verdict and for new trial; the manufacturers appealed.³³ The Court of Appeals for the Third Circuit allowed the case to be retried in district court on the condition that no claims regarding advertisement and promotion could be made. The District Court, affirmed in part, reversed in part, and remanded. The Supreme Court granted certiorari.

The Supreme Court's majority opinion held: (1) the Federal Cigarette Labeling and Advertising Act, before being amended by the Public Health Cigarette Smoking Act of 1969, did not preempt state law damages actions; (2) the amended Act preempted claims based on failure to warn and neutralization of federally mandated warnings to the extent those claims relied on omissions or inclusions in manufacturers' advertising or promotion; and (3) the amended Act did not preempt claims based on express warranty, intentional fraud and misrepresentation, or conspiracy.³⁴

The Cipollone ruling also limited future litigants to smokers who developed disease prior to 1969. The opinion did not exclude claims for fraud and conspiracy or express warranty, if the plaintiff could prove the industry conspired to hide evidence concerning the harms of smoking or lied to the public. The opinion also held if express warranties were breached, then a new case could be filed, since there was no discussion of tort litigation or damage claims in the Federal Cigarette Labeling and Advertising Act.

B. *Medtronic, Inc. v. Lohr*: Preemption clause of MDA does not preempt state requirements equal to requirements imposed under federal law

In 1996, the issue of preemption was again addressed, but this time in the context of the Medical Device Amendments Act ("MDA"). Lora Lohr was dependent on a pacemaker for the proper functioning of her heart. She was implanted with a Class III medical device the FDA approved for marketing under the MDA. The device

failed, and she brought an action in state court against the manufacturer asserting claims of negligence and strict liability. The action was removed to federal court, and the manufacturer moved for summary judgment based on preemption under the MDA. The U.S. District Court for the Middle District of Florida granted the motion. On appeal, the Court of Appeals for the Eleventh Circuit affirmed in part, reversed in part, and remanded. The Supreme Court granted certiorari.³⁵

The main issue presented was whether Congress had clearly intended to preempt state law. Medtronic's defense argued all of Lohr's product liability claims were preempted because the tort laws on which they were based necessarily created requirements different from, or in addition to, the federal requirements imposed by the FDA. The majority held that Congress had not expressed a clear intent to preempt state common-law theories since they were similar to the federal laws; claims based on allegedly defective labeling and marketing were not preempted under this fact pattern.³⁶

The Court reasoned it need not go beyond pre-emptive language to determine whether Congress intended the MDA to pre-empt at least some state law. This interpretation was guided by the assumptions that the States' historic police powers cannot be superseded by a Federal Act unless preemption is Congress' clear and manifest purpose, and that any understanding of a preemption statute's scope rests primarily on an understanding of congressional purpose.

The Supreme Court concluded that nothing in the Food Drug & Cosmetic Act's preemption provision denied a traditional damages remedy for violations of common-law [product liability] duties when those duties parallel federal requirements:³⁷ The Court emphasized this conclusion was at "an early stage in the litigation," leaving open the possibility that such claims could be preempted under other facts in other cases,³⁸ as seen in the following. As result, the opinion



significantly restricted federal preemption of claims asserting regulatory violations regarding product liability.

C. Riegel v. Medtronic, Inc.: Preemption clause of MDA expressly preempts state common-law claims and manufacturers of FDA-approved devices are protected from liability under state laws.

In 2008, the Supreme Court again looked at and applied the MDA to state litigation, this time holding that federal law preempted a state law claim that a device was designed, labeled, and manufactured in violation of New York common law. The holding in this case barred state common-law claims that challenged the effectiveness or safety of a medical device that received premarket approval from the FDA. The holding also reasoned that manufacturers of FDA-approved devices are protected from liability under state laws.³⁹

Charles Riegel, a cardiac patient, sued the manufacturer of a balloon catheter used in his angioplasty, alleging state-law claims of strict liability, breach of implied warranty, and negligent design, testing, sale and manufacturing. Medtronic filed a motion for summary judgment claiming immunity based on the FDA's pre-market approval of the device. The U.S. District Court for the Northern District of New York granted the manufacturer's motions for summary judgment; Reigel appealed. The United States Court of Appeals for the Second Circuit affirmed, and the Supreme Court granted certiorari. 40

In an eight-to-one decision, the Supreme Court held the MDA preemption meant exactly what it said: (1) premarket approval imposed federal requirements on medical device manufacturers, and federal law preempted state laws or actions that sought to impose requirements different from or in addition to those requirements in question, and (2) the asserted claims were based on state requirements "that are different from, or in addition to the federal ones, and that relate to safety and effectivenss." "41

This decision effectively overruled *Lohr* and reaffirmed the preemption clause of the MDA does bar state common-law claims that challenge the effectiveness or safety of a medical device marketed in a form that received premarket approval from the FDA.

D. *Wyeth v. Levine*: State law tort claims are not preempted by the FDA approval process.

In Wyeth v. Levine, 42 the United States Supreme Court directly addressed the issue of federal preemption in the context of FDA approval of a New Drug Application, holding that state law tort claims are not preempted by the FDA approval process. The FDA first approved injectable Phenergan in 1955. In 1987, the FDA suggested stronger warnings regarding the risk of arterial exposure. In 1988, Wyeth submitted a revised warning label incorporating those changes. The FDA though did not respond until 1996, when it requested a new warning label from Wyeth, without addressing the previously revised 1988 label. After a few additional changes to the labeling (not related to intra-arterial injection), the FDA approved Wyeth's application, instructing that Phenergan's final printed label "must be identical" to the approved package insert.43

Diana Levine, a professional musician, sought treatment for a migraine headache at a clinic in Vermont. Normally she received the drug Demerol for pain relief, along with an injection of Phenergan to relieve the nausea that accompanied her migraines. The physician's assistant used an alternative method for administering Phenergan approved by the FDA. Called intravenous push, the drug was injected directly into a vein in the arm. As a result of the injection, she lost her hand to gangrene. She brought action against Wyeth alleging failure to warn of dangers relating to the IV-push method of drug administration.

Wyeth argued that permitting state law tort claims to require stronger warn-

ings would interfere with Congress' intent for the FDCA. Wyeth also argued that it could not have modified a warning label placed on a drug once it had been approved by the FDA and that it would have been impossible for the manufacturer to comply with both state law and federal labeling duties. Although a manufacturer generally needs FDA approval before changing a drug label, the manufacturer may take certain unilateral labeling changes that improve drug safety. Wyeth's interpretation of this regulation was based on the misunderstanding that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling. Justice Stevens noted:

State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulatn.44

Since Congress has placed the burden on the manufacturer to monitor the market and not the FDA, the Supreme Court, in a turn around from *Riegel*, now reasons that state tort actions are one of the best ways to ensure adequate monitoring of the safety and efficacy of prescription medications.

V. SUMMARY AND CONCLUSION

It makes sense that the Supreme Court would hold that drug manufacturers are not immune from tort actions, as they have an ongoing duty to monitor the



effects of their products on human health and disclose known risks. Generally, the Supreme Court has rejected implied federal preemption in a state failure-to-warn pharmaceutical lawsuit absent "clear evidence" the FDA would not have permitted a stronger warning of the risk. With that said, the *Wyeth* holding seemed to directly contradict the preemption case decided a year earlier in *Riegel. Riegel*, though, involved the MDA, which contains an express preemption provision, whereas the FDCA at issue in *Wyeth* contains no such express preemption provison. 46

Riegel held that states may provide a damages remedy for claims that parallel federal requirements under the MDA; in other words, a state-law claim may proceed, in theory, as long as it does not interfere with the federal regulatory scheme. But the Supreme Court provided no guidance regarding which state-law claims are parallel. Consequently, plaintiffs have continued to bring product liability claims against manufacturers of FDA-approved devices, arguing that such claims do not add to or conflict with FDA requirements. Lower courts are now left with the challenging task of sorting out which state-law claims parallel FDA regulations and which ones interfere. Not surprisingly, courts have disagreed on where to draw the line. As result of the broad interpretation most courts give Riegel, product-liability plaintiffs are now left with few options for redress against medical device manufacturers.

Following the *Wyeth* decision, some members of Congress have now sought to revoke the express preemption provision in the MDA, specifically trying to eliminate section 360(k) preemption for suits seeking damages for injuries by plaintiffs. These lawmakers charge that eliminating section 360(k) would align drug and medical-device manufacturer liability, because under the current system, drug makers can be sued in state courts under *Wyeth* while medical device makers cannot under *Rieel.*⁴⁷

There is no doubt the ruling in *Wyeth* will empower consumer advocates to

more actively pursue state-court suits over defective prescription drugs and medical devices. There will be an increase in pharmaceutical litigation in the coming years. Consumers, though, do not have the same lobbying power that manufacturers have with Congress. So if Congress is truly concerned with consumer protection, it must expressly word acts or amendments with preemption clauses going forward with Justice Stevens' op which reasoned that drug companies are responsible for keeping warning labels up to date and complete. Specifically, the FDA needs to monitor the industry more closely. Both opinions noted that recently the FDA had abandoned its long-standing view that state-law offers an additional, and important, layer of consumer protection that complements FDA reguation..⁴⁸ The courts, Stevens wrote, should defer to the FDA only when it can point to either a specific federal law that puts it solely in charge, or only when the agency writes a binding regulation that has "the force of law."49 The FDA must understand, however, that if these regulations or amendments are too rigorous, and the ability to recover for personal injury is hampered, consumers will no longer be able to sue drug manufacturers, even if the manufacturers are clearly responsible for the consumers' injuries. As a result, juries will not have the opportunity to hear the issues, as the decisions will have already been made by experts in government agencies. Congress and the FDA's main concern going forward should be to find a balance between consumer protection and federal sovereignty without limiting consumer's ability to recover for injuries sustained by drug manufacturers.

NOTES

- ¹ Black's Law Dictionary 277 (2nd Pocket ed. 2001).
- ² U.S. Const. amend. X.
- ³ Black's Law Dictionary, supra note 1, at 545.
- 4 U.S. Const. amend. VI 6 2.
- ⁵ Restatement (Third) of Torts: Product Liability (2009).
- ⁶ Wyeth v. Levine, 129 S. Ct. 1187(2009).
- ⁷ Id at 1187.
- ⁸ FDA What We Do, http://www.fda.gov/AboutFDA/

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⁹ FDA What We Do/History, http://www.fda.gov/ AboutFDA/WhatWeDo/History/default.htm (last visited September 2010).

¹⁰ FDA What We Do/History/FDA's Origin & Functions Origins, http://www.fda.gov/AboutFDA/ WhatWeDo/History/Origin/ucm124403.htm (last visited September 2010).

11 Home/Drugs/Development & Approval Process (Drugs)/How Drugs are Developed and Approved http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm.

¹³ Food, Drug, and Cosmetics Act Amendments, Pub. L. 87-781, 76 Stat. 780 (Kefauver Harris Amendment 1962).

¹⁴ The Future of Drug Safety: Promoting and Protecting the Health of the Public, The National Academies 1 (2007), http://www.nap.eduicatalo-11750.html.

¹⁵ U.S. Gov. Accountability Office, GAO Report to Congressional Requesters, DRUG SAFETY, Improvement Needed in FDA's Postmarket Decision-making and Oversight Process, Introduction (March 2006).

¹⁶ 21 C.F.R 6 314.80 (2010).

¹⁷ Mary J. Davis., The Battle Over Implied Preemption: Products Liability and the FDA, 48 B.C. L. Rev. 1089, 1094 (2007).

¹⁸ Id. at 1153.

¹⁹ David Kessler & David Vladeck, A Critical Examination of FDA's Efforts To Preempt Failure-To- Warn Claims, ⁹⁶ Geo. L. Rev. 461, 462-64 (2008).

²⁰ Davis, supra note 17, at 1095.

²¹ Medtronic, Inc. v. Lohr, 518 U. S. 470, 485 (1996).

 22 Id. (quoting Rice v. Santa Fe Elevator Corp., 331 U. S. 218, 230 (1947).

²³ U.S. Const. amend. VI 6 2.

 24 Pennsylvania v. Nelson, 350 U.S. 497 (1956).

²⁵ Food, Drug, and Cosmetics Act Amendments, Pub. L. 87-781, 76 Stat. 780 (Kefauver Harris Amendment 1962).

²⁶ Restatement (Third) of Torts: Product Liability, available at http://www.ali.org/ali_old/Tortpl.htm (last visited September 2010).

²⁷ Id.

²⁸ Restatement (Third) of Torts: Product Liability 6 2 (2009).

²⁹ Id. 6 4. ³⁰ Id. 6 13.

³¹ Id. 6 16.

³² Cipollone v. Liggett Group, 505 U.S. 504, 504

³³ Id. at 509-11.

³⁴ Id. at 530.

³⁵ Medtronic, Inc. v. Lohr, 518 U.S. 470, 480-82 (1996).

³⁶ Id. at 470.

³⁷ Id. at 495.

³⁸ Id. at 496.

³⁹ Riegel v. Medtronic, Inc., 552 U.S. 312, 313-14 (2008).

⁴⁰ Id. at 320-21.

⁴¹ Id. at 313.

42 Wyeth v. Levine, 129 S. Ct. 1187 (2009).

⁴³ Id. at 1222-24.

⁴⁴ Id. at 1202.

- ⁴⁵ Federal Preemption in the Non-Drug Context After Wyeth v. Levine, Drug Litigation Conference: Pharmaceutical Law and Preemption in Post-Levine World 1 (June 2009).
 - ⁴⁶ Id.

⁴⁷ Id. at 8-9.

⁴⁸ Wyeth v. Levine, 129 S. Ct. 1187, 1202 (2009).

⁴⁹ Id. at 1190.

Lowering the Cost of Health Care

Craig Hackler, Financial Advisor, Raymond James Financial Services, Inc., Member FINRA/SIPC

merica's spending on health care is growing faster than the rest of the economy. What are the reasons for this, and what can you do to lower your health-care costs?

Why is the cost of health insurance rising?

The main reason for premium increases is the growing cost of health care itself. On average, 90 cents out of every premium dollar is paid back in benefit payments for health-care services. Several factors are contributing to the rise in health-care costs:

- Increase in the average age of the population
- New medical technology
- High administrative costs
- · More government regulation
- Oversupply of health-care facilities
- Overuse and misuse of medical ser-
- Prescription price increases and their increased use
- Tougher medical provider negotiations with health plans
- Consumer demands for easier and broader access to care
- The medical needs and demands of 77 million baby boomers
- Investors putting pressure on insurance companies to be profitable

What can you do to lower the cost of health insurance? Obviously, there are areas you have no control over. But there are some things you can do.

Become an informed consumer

Group insurance is less expensive than individual health insurance. If you can't get group coverage from your employer, investigate buying insurance through another group such as a fraternal or professional association.

If individual coverage is the only alternative, look at different types of plans. For

example, if you need insurance for just you and your spouse, individual policies may be less expensive than a family plan. Research the benefits and options. Find out which best suit you and your family. Don't buy more insurance than you need. Many on-line resources are available to help you purchase health insurance.



However, an insurance agent or financial advisor may save you both time and money.

You may be able to save money by self-insuring against routine medical expenses (i.e., paying routine medical expenses out of pocket) and buying major medical insurance to cover only costly illnesses or emergencies. If your cash reserve is large enough to pay for minor medical expenses, you should consider choosing a higher deductible. For example, increasing your deductible from \$250 to \$500 could significantly lower your insurance premiums.

Other ways to reduce premiums

- Avoid purchasing single disease policies
- Avoid duplicating any coverage your spouse may have from his or her employer
- Ask how much you can save by paying premiums annually

After you determine what you need, compare at least three companies for the best deal. Remember that the lowest price does not necessarily mean the best plan.

Ask questions such as:

- What is the plan's history of premium increases?
- How much notice is given before a premium increase?
- How are deductible and out-of-pocket costs figured?
- What are the co-payment levels, and when are they charged?
- What is excluded?
- How long is the free-look period?
- Is the insurance company financially healthy?

Avoid plans that exclude pre-existing conditions. You may end up paying for a policy that doesn't cover you. If you have

no choice, try to get one that covers the condition within six months or less.

Try to get quality and accreditation reports on the plans you are considering. Quality reports contain consumer ratings that outline how satisfied consumers are with the doctors in their plan and how well a health-care organization prevents and treats illnesses. Accreditation

reports give information on how accredited organizations meet national standards, and often include clinical performance measures. Most employer groups can provide this information. Talk to your plan's administrator or customer service department.

Don't lie

Be truthful on the insurance application. If you make a minor error, such as your month of birth, there shouldn't be a problem. However, if you fail to report that you are a smoker, benefits could be denied for smoker-related problems that you might later develop. Worse yet, your policy could be rescinded, leaving you with no coverage at all

Control your out-of-pocket costs

Avoid unnecessary surgery. Ask questions. If it's not an emergency, find out if there are alternative treatments. It is your responsibility to make sure that you are covered for certain procedures. If you choose an elective surgery, make sure that your policy will cover it. Do the benefits include hospital and doctor's fees? Some

plans pay only one or the other.

Does the plan pay a percentage of the actual costs, or does it pay based on a set fee schedule? A plan that pays 80 percent of a fee schedule instead of 80 percent of the actual costs can end up costing you more out of pocket. Ask your doctor if he or she will agree to accept the insurance company's set fee. And ask about home health care for your recovery. Home care would be less expensive than a nursing home or hospital stay, and you'd be able to recover in the more comfortable environment of your own home.

Take advantage of tax deductions

Medical expenses are generally deductible to the extent that they exceed 7.5 percent of your adjusted gross income.

Deductible expenses can include:

- · Insurance premiums
- · Prescriptions
- · Doctors and dentists
- · Hospitals and clinics
- · Lab and X-ray fees
- · Glasses and contact lenses
- Transportation for medical reasons

Note: Starting in 2013, the threshold to deduct medical expenses will be raised

from 7.5 percent of adjusted gross income to 10 percent. The threshold increase will be delayed until 2017 for those age 65 or older.

Work to continually save money

- Live a healthy lifestyle. For example, a smoker who quits can usually receive a premium reduction.
- Ask your insurance company about other discounts.
- Take advantage of free health screenings at local clinics, hospitals, and health fairs.
- · Avoid the overuse of antibiotics.
- Watch your co-payments and outof-pocket expenses to make sure that you don't overpay.

Each year, check the coverage of your policy. Make sure that it's keeping up with the changing needs of you and your family. Check rates when your lifestyle changes, such as moving to a new part of the country or getting married. When your children go off to college, look into college health plans. Some are subsidized by tuition and might save you money.

Reducing the amount of care you require will pay off. You will save money in

out-of-pocket costs, insurance premiums, and lost time from work. But the greatest payoff will be a longer and healthier life.

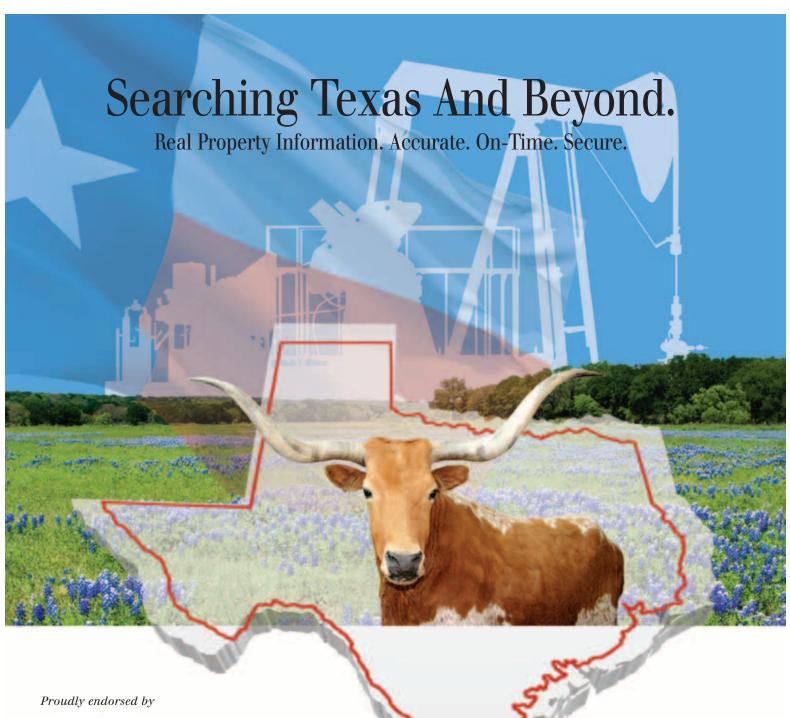
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Publication Title TEXAS PARALEGAL JOURNAL		 Publication Number 14295 	ISSN 10891633	3. Filing Date 10/05/2011
4. Issue Frequency QUARTERLY; SPRING, SUMMER, FALL, WII		5. Number of Issues Pu 4	blished Annually	6. Annual Subscription Price \$ 15.00
7. Complete Mailing Address of Known Office of Publica 3505 BLACK MESA HOLW		ation		Contact Person NORMA HACKLER
AUSTIN, TRAVIS, TX 78739-7533	Telephone (512) 280-1776			
8. Complete Mailing Address of Headquarters 3505 BLACK MESA HOLW AUSTIN, TX 78739-7533	or Genera	I Business Office of Pu	blisher	
9. Full Names and Complete Mailing Addresse	es of Publi	sher, Editor, and Manag	ing Editor	
Publisher (Name and complete mailing address PARALEGAL DIVISION PO BOX 12487 AUSTIN, TX 78711-2487	5)			
EL PASO, TX 79902-4305				
Managing Editor (Name and complete mailing a NIA NIA Owner (Do not leave blank. If the publication	n is owned t	by a corporation, give the	name and address	of the corporation immediately followed
N/A	is owned to	holding 1 percent or more	e of the total amour	nt of stock. If not owned by a corporation
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13. Publication Title TEXAS PARALEGAL JOURNAL			14. Issue Date for Circulation Data Below 10/01/2011		
TEXAS PAR	HAL	EGAL JOUHNAL		1	
15. Extend ar	nd N	lature of Circulation	Average No. Copies Each Issue During Preceding 12 Months	No. Copies of Single Issue Published Nearest to Filing Dat	
a. Total Numbers of Copies (Net press run)		of Copies (Net press run)	1675	170	
	(1)	Mailed Outside County Paid Subscriptions Stated on PS Form 3541 (Include paid distribution above nominal rate, advertiser's proof copies, and exchange copies)	1386	146	
(By Mail and Outside the Mail)	(2)	Mailed In-County Paid Subscriptions Stated on PS Form 3541 (include paid distribution above nominal rate, advertiser's proof copies, and exchange copies)	175	18	
	(3)	Paid Distribution Outside the Mails Including Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Paid Distribution Outside USPS	C		
	(4)	Paid Distribution by Other Classes of Mail Through the USPS (e.g. First-Class Mail)	C		
c. Total Paid I	Dist	ribution (Sum of 15b (1), (2), (3), (4))	1561	164	
	(1)	Free or Nominal Rate Outside County Copies included on PS Form 3541	C		
Distribution (By Mail and Outside the Mail)	(2)	Free or Nominal Rate In-County Copies included on PS Form 3541	C		
	(3)	Free or Nominal Rate Copies Mailed at Other Classes Through the USPS (e.g. First-Class Mail)	C		
	(4)	Free or Nominal Rate Distribution Outside the Mail (Carriers or other means)	75		
e. Total Free	or I	Nominal Rate Distribution (Sum of 15d (1), (2), (3), (4))	75	5	
f. Total Distribution (Sum of 15c and 15e)		tion (Sum of 15c and 15e)	1636	169	
g. Copies not Distributed		stributed	39		
h. Total (Sum of 15f and 15g)		15f and 15g)	1675	170	
i. Percent Paid ((15c / 15f) times 100)		((15c / 15f) times 100)	95.42 %	97.05	
X If the p	ubli	f Statement of Ownership cation is a general publication, publication of this statemer / 2011 issue of this publication.	nt is required. Will be printed	Publication not required.	
17. Signature	and	d Title of Editor, Publisher, Business Manager, or	l'itle	Date	
NORMA HACKLER		KLER	MANAGER	10/05/2011 02:53:26 PM	
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Who Would Own Software Created by an Employee of a Software Company on an Employee's Personal Time?

by Matt Hartley

wnership-assignment clauses are inserted into contracts to ensure that employee creations are owned by the company. What limits exist for these clauses? Similar clauses such as non-competes do not have unlimited scope, and this article attempts to draw some considerations for what might be expected for ownership-assignment clauses to remain valid. This article will look at the enforceability of ownership-assignment clauses, and then intellectual property law as it would apply to works created outside the scope of employment.

I. Issues and Brief Answers

- May a Texas employer enforce an ownership-assignment clause in an at-will employment contract against a former at-will employee for the former employee's creations made outside the scope of employment with the employer?
 - This issue remains unclear. However, research into an analogous area of contract law suggests that an employer's attempt to enforce such a contract clause may be unreasonable in the eyes of Texas courts.
- Does intellectual property law give an employer a valid claim to ownership of an employee's creations made outside the scope of employment with the company?

While a company has a valid claim to ownership of the employee's creations made in the scope of employment, there is a strong argument that the work created by the employee on his own is his sole property.

II. Discussion

· Contract Issues in Texas

Employment contracts in an at-will state may seem like something of a misnomer, but they allow companies to protect their intellectual property. At this point in time, absent a clause in the contract not to terminate employment, merely signing a contract does not change the at-will nature of employment. "The mere fact that an employment contract is in writing . . . is insufficient to rebut the presumption of employment at-will; an employment contract must directly limit in a "meaningful and special way" the employer's right to terminate the employee without cause." Massey v. Houston Baptist Univ., 902 S.W.2d 81, 83 (Tex.App.-Houston [1st Dist.] 1995, writ denied) (relying on Lee-Wright, Inc. v. Hall, 840 S.W.2d 572, 577 (Tex. App.-Houston [1st Dist.] 1992, no writ)). Maintaining atwill status allows both parties to keep their mobility if the relationship is not working out, or if there are better offers elsewhere. However, the at-will nature of employment can



make it difficult for employers to show that the promises made by employees are given sufficient consideration. Employment contracts can include non-compete covenants, which will be discussed below, and which may provide a good analogy to ownership-assignment clauses. Such covenants also have an interesting history in Texas, and can be used to make some predictions on the sort of facts and tests that would be applicable to ownership-assignment clauses.

In evaluating contracts, Texas courts "consider the entire writing and attempt to harmonize and give effect" to the whole contract. Frost Nat'l Bank v. L&F Distrib., LTD., 165 S.W.3d 310, 312 (Tex. 2005). This four-corners doctrine will be used to interpret the contract and determine how "the particular business activity sought to be served." Id. The court must also look to avoid a construction that is unreasonable and oppressive, before deciding whether the contract is ambiguous or not. Id. The issue of what the contract says is a fact question that the court will determine before considering any other claims in a suit. If a plaintiff attempts to enforce the contract against the defendant, the court will apply these general concepts. The defendant must be prepared to show the contract is ambiguous. If unsuccessful, the defendant must demonstrate that the con-

tract is invalid. As there is no case law regarding ownership assignment contracts in Texas, the defendant must look to non-compete covenants to gain insight in how to show an ownership assignment contract invalid.

• Non-Compete Covenants in Texas

Non-compete covenants are governed by Chapter 15 of the Texas Business & Commerce Code. Tex. Bus. & Com. Code Ann. 615.52 (Vernon 2001). Non-compete covenants have not always been enforced in Texas, but with the Texas Supreme Court's *Sheshunoff* decision, discussed below, they have become acceptable in the eyes of the Texas courts. Because Texas courts have not issued any rulings on ownership-assignment clauses, it is prudent to look at the history of non-compete covenants in order to predict how they might treat an ownership-assignment clause.

Sections 15.50 and 15.510f the Texas Business & Commerce Code

Originally passed in 1989, the statutory provisions in sections 15.50 and 15.51 establish the criteria that must be met to have a valid non-compete covenant. The statute was initially passed after the Texas Supreme Court made some rulings unfavorable to covenants not to compete, and has been amended several times. See generally Crystal L. Landes, The Story of Covenants Not to Compete In Texas Continues, 33 Hous. L. Rev. 913 (1996) (detailing the history of non-compete agreements in Texas). Several of these amendment attempts were subsequently struck down by the Texas Supreme Court. As written today, the statute provides that

a covenant not to compete is enforceable if it is ancillary to or part of an otherwise enforceable agreement at the time the agreement is made to the extent that it contains limitations as to time, geographical area, and scope of activity to be restrained that are reasonable and do not impose a greater restraint than is necessary to protect the goodwill or other business interest of the promisee.

Tex. Bus. & Com. Code Ann. 615.50 (Vernon 2001). Non-compete covenants may not promote monopolies, restraints of trade, or other things made illegal by section 15.05. *Id.*

Despite the approval of these agreements by the legislature, Texas courts sometimes rejected them. A hint of hostility in the courts' stance came in the 1994 decision, *Light v. Centel Cellular*, 883 S.W.2d 642 (Tex. 1994). In *Light*, the Texas Supreme Court rejected a covenant not to compete on grounds that it did not meet the requirement that the covenant be "ancillary to or part of an otherwise enforceable agreement at the time the agreement is made." *Id.* at 648. However, the court mused in a footnote,

[S]uppose an employee promises not to disclose an employer's trade secrets and other proprietary information, if the employer gives the employee . . . specialized training and information during the employee's employment . . . [I]f the employer accepts the employee's offer by performing . . . a unilateral contract is created in which the employee is now bound by the employee's promise.

Id. at 645. This sort of open musing led many companies to update their employee agreements, and caused some debate as to when an employer should disclose confidential information to make the non-compete enforceable. See Eliot P. Tucker & Roy L. Barnes, Covenants Not to Compete In a Post-Sheshunoff World, in 15th Annual Advanced Employment Law Course Chapter 7.1 (2007). The Austin Court of Appeals heard a case in which it declared that the confidential information needed to be provided the exact moment that the contract was signed. Sheshunoff v. Johnson, 124 S.W.3d 678, 687 (Tex. App.-Austin, 2003, pet. denied). The company on the losing side of that decision appealed, and the case went to the Texas Supreme Court.

• The Sheshunoff Decision

In October 2006, the Texas Supreme Court reversed the Austin Court of Appeals' decision that confidential information needed to be provided to the employee when the contract was signed in order for the non-compete agreement to be held enforceable. In its decision, the court held that a contract becomes enforceable "when the employer performs the promises it made in exchange for the covenant." Sheshunoff v. Johnson, 209 S.W.3d 644, 655 (Tex. 2006). Some members of the higher court debated whether this reasoning would allow dirty tricks by employers to prevent employees from leaving for competitors, if they provided confidential information as soon as they found out an employee was planning on leaving the firm. Id. at 662 (Jefferson, J., dissenting). The majority opinion pointed out that while such a scenario is a possibility, if the company behaves in such a manner, "the court could easily conclude that the employer's unclean hands in such circumstances render it ineligible for injunctive relief." Id. at 656.

· Consideration and Illusory Promises

The ideas in place for a non-compete covenant have been around for a while, and Texas courts have found there must be some degree of mutuality in a non-compete agreement. *Mann v. Fielding*, 289 S.W.3d 844, 850-51 (Tex. 2009) (citing *Portland*

Gasoline Co. v. Superior Mktg. Co., 150 Tex. 533, 243 S.W.2d 823, 25 (Tex.1951)).

Though a contract on its face may and by its express terms may appear to be obligatory on one party only, if it is manifest that it was the intention of the parties, and the consideration upon which one party assumed an express obligation, that there should be a corresponding and correlative obligation on the other party, such a corresponding and correlative obligation will be implied, and the contract held to be mutual, as where the act to be done by the party expressly binding himself can only be done upon a corresponding act being done or allowed by the other party.

Id. at 6.

In enforcing non-compete covenants, Texas courts dovetailed their opinions with state law and held that in a non-compete covenant, "the consideration given by the employer in the otherwise enforceable agreement must give rise to the employer's interest in restraining the employee from competing." *Mann*, 289 S.W.3d at 7 (citing *Light*, 883 S.W.2d at 644). Therefore, for non-compete agreements, there needs to be an implied promise that the employer will provide proprietary or confidential information to the employee that, if the employee were to share that information with a competitor, the employer's business would be adversely affected.

Much of the conflict between the legislature and Texas courts was based on a difference of opinion as to when this consideration must be provided. The court's decision in *Sheshunoff* showed where the line falls as to when this exchange should take place. *Sheshunoff*, 209 S.W.3d at 651. If an employer forces an employee to sign a non-compete covenant, but does not give the employee any confidential or proprietary information, and then attempts to enforce the non-compete, a court will likely hold the implied promise to share confidential information unfulfilled, and the non-compete unenforceable.

Company's Interests

The Sheshunoff court did not do away with another important requirement: the company's need to protect itself in the field in which it practices. Quoting DeSantis v. Wackenhut Corp., 793 S.W.2d 670, 682 (Tex.1990), the court pointed out that the agreement not to compete must protect a worthy interest, and that "business goodwill and proprietary interests are examples of such worthy interests." Sheshunoff, 209 S.W.3d at 648. These interests were key in Sheshunoff because the company's interest was a plan to offer a bank overdraft protection plan. Such plans were

becoming more common, but the employer treated its plan as confidential and marked it as such. *Id.* at 647.

Reasonableness

The court's opinion in *Sheshunoff* returned attention to the idea that a covenant must contain "limitations as to time, geographical area, and scope of activity to be restrained that are reasonable and do not impose a greater restraint than is necessary to protect the goodwill or other business interest of the promisee." *Id.* at 648 (citing Tex. Bus. & Com. Code 6 15.50(a)). While the court's reasoning before *Sheshunoff* had caused much debate over when the employer needed to disclose information to the employee, *Sheshunoff* allowed room to discuss the reasonableness of covenants not to compete.

For non-compete agreements, Texas courts have considered a number of examples to demonstrate what is reasonable. For example, a covenant not to compete is "overbroad and unreasonable when it extends to clients with whom the employee had no dealings during his employment." *John R. Ray & Sons, Inc. v. Stroman*, 923 S.W.2d 80, 85 (Tex.App.-Houston [14th Dist.] 1996, writ denied). However, such a covenant can be reasonable when it limits interactions with the employer's clients, contains time restraints that do not extend past industry standards for contracts, and allows employees to remain in the same industry. *See Gallagher Healthcare Ins. Serv. v. Vogelsang*, 2010 WL 966029 (Tex.App.-Waco 2010, pet. granted).

Non-Compete and Ownership-Assignment Agreements

While the covenants not to compete and ownership-assignment clauses have been presented here as analogous, it is important to remember that courts have not established a relationship between the two. Indeed, since no statute governs ownership-assignment agreements, it is hard to tell whether courts would consider them valid at all. However, courts have considered contractual agreements besides non-compete covenants. In a concurring opinion in Sheshunoff, Justice Wainwright pointed out that in several matters of law, it is not uncommon to require no consideration besides employment to create rights enforceable in a contract, and he offered arbitration as an example. Sheshunoff, 209 S.W.3d, at 665 (Wainwright, J., concurring) (referring to In Re Dallas Peterbilt, Ltd., L.L.P., 196 S.W.3d 161, 163 (Tex. 2006)). If the court uses that line of reasoning, then the real-world experience may no longer be an issue, but the consideration would come from continued employment after signing the agreement.

Overall, it seems likely the limiting factor in any court's view of the ownership-assignment clause would be the idea of reasonableness. Employers have a number of protections in place to ensure that employees do not take proprietary information to their competitors. Reaching this far into their employees' activities outside of the workplace may be a step too far for a court that has protected workers' ability to change jobs with ease.

• A Primer on Intellectual Property Law

The United States has created tools to provide legal protection for intellectual property (IP), including patents, copyrights, trademarks, and trade secrets. The two primary tools for software protection are patents and copyrights, and each will be discussed further below.

Intellectual property laws in the United States are designed to reward those who create new tools, methods, or products by offering their creators protection from free-loaders, people who would use such inventions without offering compensation to the original creators. *See generally* Janice M. Mueller, *Patent Law* 15 (2009) (explaining why people apply for patents).

Intellectual property disputes are usually handled through the United States federal court system. "The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patent, plant variety protection, copyrights, and trademarks." 28 U.S.C. 6 1338 (2009).

Patent Law as Used for Software Protection

The protection offered by patent law is meant to foster innovation, as companies that can easily make money from creations are more likely to invest in research and development. In practice, patent protection means that an inventor discloses his invention and how it works in exchange for protection during a patent term, which varies depending on the type of patent applied for. See generally Janice M. Mueller, supra, at 15 (explaining how patent protection works). Software patents are considered utility patents, and grant rights to the holder for up to twenty years from the application date. See generally id. (explaining basic types of patents). In theory, this protection spurs more investment in research and development, which provides more innovation. See generally id. (explaining some of the basics of patent law and the application process).

There is some debate whether this system truly fosters innovation. Because patents give the right to exclude others from using an invention, companies sometimes draft patents in ambiguous terms in order to maximize the number of inventions they can claim infringe on their patent. Because of this tendency, some people argue that the patent system reduces the amount of innovation due to the ambiguities as to what a particular patent may encompass. *See generally* Robert P. Merges,

Software and Patent Scope: A Report From the Middle Innings, 85 Tex. L. Rev., 1627, 1636 (2007) (discussing some of the effects of increased patent grants on the software field). That said, there is evidence that patents are not as stifling as some critics imagine. The number of start-up software firms receiving financing increased between 1995 and 2005, excluding the years from 1999-2000, during the Internet financing crash. *Id.* at 1636-39. Given that smaller start-up software firms drive a fair amount of innovation in the software industry, it would seem that the software industry is healthy despite the increasing number of patents. Id. at 1633. The fears that patent protection for software would lead to a slowdown in entry of new companies, an entrenchment of large firms, and the slow demise of the software industry have not been realized. Id. at 1632.

For employer-employee situations, there are a few facts to keep in mind when dealing with patent laws. First, patents grant a specific type of protection, and secondly, patent law in this country is based on a first-to-invent standard, which differs from other countries.

· Right to exclude

One of the key things to remember about the patent system is that it grants a negative right – "that is, a right to exclude others from making, using, selling, offering to sell, or importing the patented invention during the term of the patent." Janice M. Mueller, *supra*, at 15 (drawing on 35 U.S.C. 6154(a)(1) to explain what patent protection offers). The owner of the patent does not receive a right to use the protected product. For example, a company may patent a formula for a new medication, but the company may not sell the medication in the United States until the Food and Drug Administration approves it. The patent still exists, but the company is unable to benefit from it, aside from being able to prevent others from selling the same product.

· "First-to-invent" and the "shop-right" doctrine

The United States is unique in that it maintains a "first-to-invent" system. Most other countries use a less cumbersome, "first-to-file" system, where the first person to apply for the patent receives the patent protection if the application is approved. In the United States, inventors are not entitled to patents unless they can demonstrate they are the actual inventors of their works. 35 U.S.C. 6102 (1972). To prove that someone is the inventor, courts look at any documentation related to the invention.

It is possible for companies to benefit from patentable inventions created by their employees without owning the patent, or being considered the first to invent. United States law recognizes the "shopright" doctrine. Under this doctrine, if an employee, "during his hours of employment, working with his master's materials and appliances, conceives and perfects an invention for which he obtains a patent, he must accord his master a nonexclusive right to practice the invention." *United States v. Dubilier* Condenser Corp., 289 U.S. 178, 188 (1933). Shop-right is created through common law, though courts must determine through equity and fairness whether the circumstances demand the creation of this right. McElmurry v. Ark. Power & Light Co., 995 F.2d 1576, 1580 (Fed. Cir. 1993). However, not all courts agree on the doctrinal basis for the creation of a shopright. Id. at 1580. Some courts focus on whether the employee developed the patentable creation during the employer's time and at the employer's expense. Id. Other courts focus on whether the employee consented to this employer's use of the creation, thereby preventing him from claiming a patent right against his employer. Id. Other courts shy away from adopting either of these stances, and instead examine all the facts to determine a fair and equitable outcome. Id.

In lieu of the shop-right doctrine, employers may obtain patent rights in a creation via assignment. Applications for patents or any interest therein, are assignable in law by an instrument in writing. 35 U.S.C. 6261(1975). Some companies have been known to require employees to assign all patent rights to the company as a term of employment.

Copyright Law as Used for Software Protection

In addition to patents, parties have been able to obtain copyright protection for computer software since 1976, when the Copyright Act was amended to designate computer software as copyrightable material, treating it roughly the same as a literary work. Since then, important distinctions have arisen. The Act divides a computer program into literal and non-literal components. "The literal elements of a computer program include the source and object codes which are unquestionably covered by contract law." Butler v. Continental, 31 S.W.3d 642, 649 (Tex.App.-Houston [1st Dist.] 2000, pet. denied) (citing Cognotec Servs. Ltd. v. Morgan Guar. Trust Co. of N.Y., 862 F. Supp. 45, 49 (S.D.N.Y.1994)). However, the interesting development has been a consensus forming around what is considered a non-literal component of computer software. In Cognotec, the court declared that non-literal components include everything a programmer uses prior to actually writing the software. Non-literal components can include flowcharts, parameter lists, and other similar tools. Butler, 31 S.W.3d at 649 (explaining Cognotec).

While there are some similarities with patent law, copyright law also looks heavily at the conditions under which the work was created. The law recognizes that someone who hires a person or group to create something should be the beneficiary of copyright protection.

Specifically, copyright law considers works made for hire, and the corollary issue of job scope in determining who should benefit from copyright protection.

· Works Made for Hire

Copyright law has a concept similar to the shopright doctrine. Copyright law recognizes works "made for hire," where one person contractually hires another to create something. This concept allows businesses and organizations to maintain control over things being made at their request. The Fifth Circuit held that there are two circumstances where a work is made for hire: 1) a work is prepared by an employee within the scope of his or her employment, or 2) a work is specially ordered or commissioned if the parties expressly agree in a written instrument signed by them that the work will be considered a work made for hire. Quintanilla v. Tex. Tel. Inc., 139 F.3d 494 (5th Cir. 1998). Other federal courts have developed tests like the Ninth Circuit's "instance and expense" test. This test requires the evaluation of three factors: 1) at whose instance the work was prepared; 2) whether the hiring party had the power to accept, reject, modify or otherwise control the work; and 3) at whose expense the work was created. Siegel v. Time Warner, Inc., 496 F. Supp.2d 1111, 1136 (C.D. Cal. 2007) (citing Twentieth Century Fox Film Corp. v. Entm't Distrib., 492 F.3d 869, 879, 881(9th Cir. 2005)). This test creates a series of factual questions that can be examined to determine whether a work is truly made for hire, or if it was done outside the scope of employment.

Employment Status

A critical factor in determining who owns a piece of work is the relationship between employer and employee before the work is completed. The Fifth Circuit examines a number of criteria to determine whether a hired party is an employee or an independent contractor. The court examines:

1) the hiring party's right to control the manner and means by which the product is accomplished; 2) the skill required; 3) the sources of the instrumentalities and tools; 4) the location of the work; 5) the duration of the relationship between the parties; 6) whether the hiring party has the right to assign additional projects to the hired party; 7) the extent of the hired party's discretion over when and how long to work; 8) the method of payment; 9) the hired party's role in hiring and paying assistants; 10) whether the work is part of the regular business of the hiring party; 11) whether

the hiring party is in business; 12) the provision of employee benefits; 13) the tax treatment of the hired party.

Quintanilla, 139 F.3d at 497. None of the factors listed above is determinative in proving the status of the employee, instead the court will consider the facts of the case as they apply to these factors.

If an employee receives regular, periodic payments for his work, the payments indicated a typical employer-employee relationship, while royalty payments suggest a work-for-hire relationship.

Siegel, 496 F. Supp.2d at 1138. However, a lack of

payments for the created material suggests there was no arrangement or understanding that work done outside of the normal job scope would be property of the employer. *Id.* at 1139.

Conclusion

The facts of each particular case will determine which arguments may be useful, but this article outlines some basic considerations for dealing with ownership-assignment clause disputes, both through Texas contract law and intellectual property law.

Mr. Hartley is a paralegal with the Law Office of Scott C. Smith in Austin.

Where Do Those Legal Terms Come From?

By Heidi Beginski, Board Certified Paralegal, Personal Injury Trial Law, Texas Board of Legal Specialization

ost of the terminology used in the practice of law today, as in medicine, comes from Latin. But voir dire, however, comes from French: the Anglo-French to be exact. The precise translation is voir true, truly plus dire to day. It is usually translated to mean to speak the truth.

Voir dire is defined as 1. an oath administered to a proposed witness or juror by which he or she is sworn to speak the truth in an examination to ascertain his or her competence; 2. the examination itself. Especially, it refers the act or process of questioning prospective jurors to determine which are qualified (as by freedom from bias) and suited for service on a jury.

Latin once was the language of educated people in Europe, signaling not only education but also the social status that education betokened. After the Battle of Hastings in 1066 the Normans, a bunch of French Vikings who invaded England, displaced the local Saxons as the ruling class. For centuries, power and wealth spoke French, as did judges and lawyers. Law French survives in words like estoppel, mortgage, plaintiff, bailiff, voir dire, parol, tort, and, yes, attorney.

French as definer of social class left an indelible mark on our speech. To this day we use English names for domestic livestock, but French for their meat—mutton instead of the English sheep; pork instead of the English pig or swine; and

veal or beef instead of the English moo-cow—a reminder that Englishspeaking Saxon serfs raised the animals that their French-speaking Norman lords ate.

History has left English with lots of synonyms from many languages, often with a highbrow Latin word, a middlebrow

French word, and a lowbrow English word: Consider, for example, the Latin initiate, French commence, and English begin or start

The preference of lawyers for Latinand French-derived words stems from their historical desire not to be mistaken for Saxons or middle-class folk. This is why many American lawyers identify themselves by using the European affectation "esquire" (from a medieval French word meaning "shield-bearer"), which traditionally meant "gentleman" in the sense of a man who did not have to work for a living - or wouldn't have to if his older brother had been considerate enough to die in infancy. The legal profession was a step down the social ladder for lots of

younger sons of nobility and a step up the social ladder for sons of merchants, but both types needed to put on airs.

So we initiate legal actions and commence contract terms instead of starting them. We use preceding or prior or antecedent (all Latin) instead of the very serviceable English before, and the Latin succeeding or subsequent to instead of the

English after. We write cease and desist (both Latin verbs) instead of stop.

Although sentences in the Latin language tend to be concise because those big nouns and verbs do enough conjugating and declining to make ancillary words unnecessary, they have

the opposite effect in English. For example, when asking for one kind of relief, "or, in the alternative," another kind, the inflated and Latinate in the alternative accomplishes nothing that or can't do by itself. But we use this phrase because tradition has made that wording seem normal instead of dysfunctional.

And while the rest of you pronounce it correctly (wahr deer) be aware that in El Paso, for no reason I can find, we have traditionally called it voir (sounds like four but with a v) dire (as in dire circumstances). Maybe it was the accent of West Texas serfs.

Ms. Beginski is a paralegal at Lovett Law Firm in El Paso.

Scruples

The Ethics of Revealing Client Names to a Prospective Employer

by Ellen Lockwood, ACP, RP

e live in a mobile society where changing jobs is normal.

Whether changing jobs for a better opportunity or because of relocation, paralegals need to be aware of the ethical issues regarding potential conflicts with a prospective employer.

In July 2011, the Professional Ethics Committee for the State Bar of Texas issued Ethics Opinion 607. Although the opinion addresses the ethical issue of attorneys revealing client names to potential employers, Opinion 607 also applies to paralegals.

Opinion 607 references the Texas Disciplinary Rules of Professional Conduct which prohibit an attorney who has joined a firm from another private practice from representing a client which is adverse to a former client. That prohibition extends to the other attorneys in the firm but the firm may avoid a conflict of interest if the attorney who worked for a prior firm is screened from firm matters in which the attorney had involvement while working for the prior firm. Further, as the Opinion states, in order for a firm to avoid potential conflicts of interest, the firm must have information on the prior clients of the attorney prior to the attorney joining the firm. However, the Disciplinary Rules also generally prohibit attorneys from disclosing confidential client information unless it benefits the client.

The Opinion goes on to point out that there are exceptions to these rules in order to allow the attorney and prospective employer to identify any potential conflicts and, if necessary, set up appropriate screening of the attorney before the attorney joins the firm.

The Opinion specifies that disclosures by an attorney of the attorney's current and former clients to a prospective law firm employer is permitted if these requirements are met:

- The disclosure of client information is made when all other material issues regarding employment have been addressed and is one of the final steps in consideration of employment.
- 2. The information is provided pursuant to a legal agreement, preferably in writing, that states that the firm will keep the information confidential within the firm for as long as the information remains confidential, and only use the information for determining whether to hire the attorney and to comply with the disciplinary rules regarding conflicts of interest if the attorney is hired.
- 3. The information provided to the prospective employer is the minimum necessary for the prospective employer to determine whether to hire the attorney and to comply

- with the rules regarding conflicts of interest.
- The attorney does not disclose any client information that would produce a substantial risk.

Again, although Opinion 607 is written for attorneys, it is also applicable to paralegals. Because some firms may not be familiar with this Opinion, it is imperative that paralegals review the Opinion prior to beginning a job search, follow the requirements outlined in the Opinion, and, if necessary, educate their current and potential employer regarding the Opinion.

Paralegals who work for private law firms, whether as employees or as free-lance paralegals, should maintain a list of clients and matters on which they have worked. Depending upon the circumstances, paralegals may also need to involve their current employers in any agreement providing client information to potential employers.

By following the requirements of Opinion 607, paralegals may avoid ethical issues and potential conflicts of interest when changing jobs.



Ellen Lockwood, ACP, RP, is the Chair of the Professional Ethics Committee of the Paralegal Division and a past President of the Division. She is a frequent

speaker on paralegal ethics and intellectual property and the lead author of the Division's Paralegal Ethics Handbook published by West Legalworks. You may follow her at www.twitter.com/paralegalethics. She may be contacted at ethics@txpd.org.

TAPS 2011 Pearls of Wisdom; Celebrating 30 Years of Excellence

he 2011 Texas Advanced Paralegal Seminar (TAPS) was held at the DFW Marriott Hotel and Golf Club (North of Fort Worth) on October 5–7, 2011 and was a great SUC-CESS. There were 250 registered attendees from all over Texas. Don't miss TAPS 2012 that will be held in Dallas on October 3–5, 2012.

Kudos to the TAPS Planning Committee that did a fantastic job. The TAPS Planning Committee members are always the best of the best and willing to do whatever is needed to make this event a success; this year's committee was no exception.

Persons who served on the TAPS 2011 Planning Committee are listed below:

Debbie Oaks, Chair of the TAPS Planning Committee

Susan Wilen, PD President/Board Advisor and TAPS Volunteer Coordinator

Rhonda Brashears, On-Line CLE, Paralegal Division

Jennifer Barnes, Socials

Javan Johnson, Socials

Star Moore, Speakers

Julie Sherman, Speakers

Penny Grawunder, Registration

Sunnie Palmer, Door Prizes

Patti Giuliano, Vendors

Rhonda Brashears, Vendors

Gloria Porter, Marketing

Frank Hinnant, Innovative Legal Solutions, Public Member

Carl Seyer, HG Litigation Services, Public

Member

The Paralegal Division offers two education scholarships to the annual TAPS seminar. This year the recipients of the scholarship, which is based on membership in the Paralegal Division, professionalism, and financial need, were awarded to





Laura Rogers (Corpus Christi) and DeeDee Trotter (Lubbock).

Speaking of success, the TAPS exhibit hall was sold out. There were a total of 40 companies that exhibited during the Exhibit Hall Exposition held on Thursday, October 6. In addition the Exhibit Hall Exposition, TAPS is the place for networking. In 2011, TAPS featured a Networking Social (Everybody Have Fun Tonight) on Wednesday evening, an off-site dinner celebrating the Paralegal Division's 30th

Anniversary (Time After Time...a 30 Year Celebration) in the ballroom at the top of the Texas Motor Speedway, and an attendee luncheon, Where You are Now is Nowhere Compared to Where You Can Go!, on Friday, October 7. The keynote speaker for the attendee luncheon was Roland Johnson, TBLS Board Certified Attorney-Civil Trial Law, and Past President of the State Bar of Texas and Partner, Harris, Finley & Bogle, P. C., Fort Worth. Mr. Johnson spoke to the attendees regarding the growth of the Paralegal Division and the growth of the paralegal profession. Mr. Johnson showed a presentation of the giant steps that have been taken by the Paralegal Division over the past 30 years since its creation by the State Bar of Texas. As a past president of the State Bar of Texas, Mr. Johnson appreciates the paralegal profession has grown in the State of Texas and has made great strides in showing attorneys how paralegals can work within a team with an emphasis on enhancing both the paralegal work and the work of the attorney.

New to TAPS was a career symposium that was held on Wednesday morning, October 5 prior to the scheduled CLE presentation topics. The symposium was offered free of charge and open to current students, recent graduates, and even seasoned professionals. The symposium provided a unique opportunity for participants to interact with paralegals from across the state with various backgrounds and experience. The feedback from those who attended the symposiums was very positive. A very special thank you to each of the paralegals that participated by facilitating or speaking on the panels.

Many, many thanks go to the Grand Prize sponsors: COX SMITH (San Antonio), VICKI ISAACKS MEDIATION SERVICES (Denton), and SETTLEPOU (Dallas). The lucky recipients of the three grand prize drawings for 2011 (\$500 each) were Carolyn Ganzer of Denton, Jill Koester of Dallas, and Becky Holland of Fort Worth.

And of course, last but not least, there were 65 substantive CLE topics presented over three days. Each three-day attendee could earn up to 14 CLE hours. A few of the presentations are summarized below:











WINTER/SPRING 2012







Bruce Akerly, Cantey Hanger, LLP, Dallas—An Overview of the Hague Convention on the Service Abroad of Judicial and Extra-Judicial Documents in Civil and Commercial Matters, the Legalization and Authentication of Foreign Public Documents and the Recognition and Enforcement of Foreign Judgments in Civil and Commercial Matters-Mr. Akerly provided an overview of the Hague Convention including the process, methods of service, process and default judgments, in addition to the service of process on non-convention members. He also discussed the authentication and legalization of foreign public documents and the recognition and enforcement of foreign judgments in civil and commercial matters.

Richard T. Robinson, Manager of Technology, Gardere Wynne Sewell, LLP, Dallas—eDiscovery, Social Media and related Internet Legal Issue—Mr. Robinson discussed the new rules governing social media and e-Evidence. Covering the growth of electronic evidence due to the increase in social media, how social media is affecting the cases that lawyers get and even the selection of juries in some high profile cases, retaining and finding electronically stored information.

John G. Browning, Lewis Brisbois Bisgaard & Smith, LLP, Dallas—When the Jury Box Becomes Pandora's Box—Dangers of the Online Juror—Mr. Browning put a very funny yet informative twist on the issues lawyers are faced with in today's new kind of juror, a juror who comes to the courtroom with ideas on the case at hand due to the internet and social media. Those that can't resist the urge to share the information they have been made privy to and even asking their friends on Facebook and through blogs asking how they should vote. Jurors are also researching via the internet the legal concepts and questions being presented to them in the jury box. He provided information on these problems and what is being done to prevent jurors from surfing the web and Tweeting or using Facebook to correspond with their friends and colleagues about the case on which they are serving as a juror. He also provided some tips for attorneys and paralegals to find out more about prospective jurors through the internet and social media.







to experience. Dr. Flynn discussed four different psychological styles of people and why, because of these situations, these people react the way they do to these suits.

As with any event, its success also depends on its supporters. TAPS 2011 was very fortunate to

be supported by the following legal service companies. As a special thank you, please find a complete list of those companies that helped make TAPS 2011 a wonderful event for all of the paralegal attendees.

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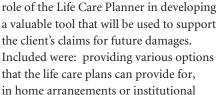
- Esquire Solutions, Dallas Thursday Social—""
- Center for Advanced Legal Studies, Houston
- HG Litigation Services, Dallas
- Hollerbach & Associates, Inc., San Antonio
- Innovative Legal Solutions, Houston
- NGP Energy Capital Management, LLC, Irving

Patron Directory Sponsor: Innovative Legal Solutions, Houston

CD Rom/Speaker Materials Sponsor: Litigation Solution, Inc., Dallas

Tote Bag Sponsor: US Legal Support Inc., Houston

Grand Prize Sponsors: Cox Smith, San Antonio; Vicki Isaacks Mediation Services (Denton); and SETTLEPOU (Dallas).



Carol Traylor, Esq., Cantey Hanger,

Plans—Ms. Traylor did a fabulous job of

covering the uses of life care plans and the

LLP, Fort Worth—Evolving Life Care

that the life care plans can provide for, in home arrangements or institutional arrangements. She also discussed several cases and how Texas courts and other jurisdictions have dealt with life care plans and Life Care Planners.

Dr. Michael Flynn, JD, Ph.D., Law Office of Michael Flynn, Fort Worth—Any Paralegal Will Tell You, It's the People—Four Personality Types and How They Fight With and Against Their Lawyers—As Dr. Flynn states in his paper "Lawsuits are stressful, whether divorces, personal injury matters, or contract disputes. Suing and being sued are difficult, contentious undertakings that bring out the worst in otherwise ordinary people." He encouraged the paralegal in dealing with clients who in many situations are dealing with one of the most stressful events they have yet



TAPS Grand Prize Winners: Becky Holland, Carolyn Ganzer and Jill Koester





EXCEPTIONAL PRO BONO SERVICE AWARD

The Paralegal Division of the State Bar of Texas is proud to sponsor an Exceptional Pro Bono Service Award. Its purpose is to promote the awareness of pro bono activities and to encourage Division members to volunteer their time and specialty skills to pro bono projects within their community by recognizing a PD member who demonstrates exceptional dedication to pro bono service. Paralegals are invited to foster the development of pro bono projects, to provide assistance to established pro bono programs, and to work closely with attorneys to provide unmet legal services to people with low incomes. This award will go to a Division member who has volunteered his or her time and special skills in providing uncompensated services in pro bono assistance to their community. The winner of the award will be announced at the Paralegal Division Annual Meeting Luncheon, his/her expenses to attend the Paralegal Division Annual Meeting Luncheon will be incurred by the Division, and a profile of the individual will be published in the *Texas Paralegal Journal*.

Please complete the following nomination form, and return it **NO LATER THAN MARCH 31, 2012** to the following:

Lyla Elk
Reginald B. Smith, Jr.
P. O. Box 1947
Sherman, TX 75091
(903) 868-8887 (o) (903) 868-8890 (fax)
probono@txpd.org

Individual's Name: _		
Firm:	Job Tit	tle:
Address:		
		Yrs. in Practice:
Work Experience:		

Give a statement (on a separate sheet using "Nominee" rather than the individual's name) using the following guidelines as to how the above-named individual qualifies as rendering Exceptional Pro Bono Service by a Paralegal Division Member.

- 1. Renders service without expectation of compensation.
- Renders service that simplifies the legal process for (or increases the availability) and quality of, legal services to those in need of such services but who are without the means to afford such service.
- 3. Renders to charitable or public interest organizations with respect to matters or projects designed predominantly to address the needs of poor or elderly person(s).
- Renders legislative, administrative, political or systems advocacy services on behalf of those in need of such services but who do not have the means to afford such service.
- Assist an attorney in his/her representation of indigents in criminal and civil matters.

PARALEGAL DIVISION

VOTE 2012

District Director Elections



District Director Elections:

The PD's ONLINE ELECTION will take place March 29 through April 12, 2012. The election of district directors to the Board of Directors will be held in even-numbered districts (Districts 2, 4, 6, 8, 10, 12, 14, and 16).

All Active members of the PD in good standing are eligible to vote. All voting must be completed on or before II:59 p.m., April 12, 2012.

Please take a few minutes to logon to the PD's website and cast your vote for your district's director (only even-numbered districts vote in 2012). The process is fast, easy, anonymous, and secure.

Between March 29th and April 12th, go to www.txpd.org
In the Member-Only section, click on "Vote"
Follow the instructions to login and vote (you will need your bar card number in order to vote).

If you do not have access to the Internet at home or the office, you can access the TXPD website at your local library. No ballots will be mailed to members as all voting will be online. An email notice will be sent to Active voting members in March giving notification of the voting period. If you need any further information, contact the Elections Chair, Gloria Porter, at Elections@txpd.org.

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