



January 2013

Health Care Law

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Recommended Citation

Mary Jean Geroulo, *Health Care Law*, 66 SMU L. REV. 929 (2013)
<https://scholar.smu.edu/smulr/vol66/iss5/5>

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HEALTH CARE LAW

Mary Jean Geroulo*

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I. INTRODUCTION

THE review period for this issue is distinguished by a decision in one of the most anticipated health care cases in recent history: *National Federation of Independent Business v. Sebelius*.¹ This case was a challenge to the 2010 Affordable Care Act,² which was frequently referred to, generally derisively, during the 2012 presidential campaign as “Obamacare.” The decision in this historical case sets the tone for most of the other cases decided during this Survey period. These cases illustrate the rapidly changing nature of the health care business environment. Some of the cases demonstrate ways in which health care providers are attempting to adapt their business practices, while others relate to high profile issues such as abortion and the relationship between health care providers and health plans.

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1. Nat’l Fed’n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2575 (2012).

2. See generally, The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

II. SCOPE OF TEXAS MEDICAL LIABILITY ACT

The Winter 2011 Health Care Law Survey Article included a discussion of the Texas Supreme Court decision in *Marks v. St. Luke's Episcopal Hospital*, which expanded the scope of claims that may be brought under the Texas Medical Liability and Insurance Improvement Act (the Medical Liability Act), codified in Chapter 74 of the Texas Civil Practice and Remedies Code.³ Cases during this current Survey period continue to illustrate the broad scope of the Medical Liability Act and the substantial limitations it places on plaintiffs seeking relief in health care related matters.

A. APPLICATION TO EMPLOYEE INJURY CLAIMS

The first case is an interesting decision by the Texas Supreme Court involving an *employee* injured on the job during an altercation with a psychiatric patient.⁴ The supreme court concluded that a "claimant" does not have to be an individual whose medical treatment is at issue for the matter to fall within the scope of the Medical Liability Act.⁵ To arrive at this conclusion, the supreme court's analysis sometimes stretched the limits of statutory interpretation.

In *Texas West Oaks Hospital v. Williams*, employee Frederick Williams (Williams) was injured while on duty at the hospital when a psychiatric patient that he was supervising attacked him.⁶ The patient died as a result of injuries sustained in the altercation, and his estate brought a health care liability claim (HCLC) against the hospital and Williams.⁷ Williams entered a cross claim against the hospital for negligence.⁸ The trial court denied the hospital's motion to dismiss the employee's negligence claim as a HCLC, and the hospital filed an interlocutory appeal.⁹

Williams's negligence claims against the hospital included the following: failure to properly train Williams, failure to adequately supervise employees, failure to provide adequate protocols to avoid or decrease the severity of altercations like the one experienced by Williams, failure to provide employees with adequate emergency notification procedures or devices, failure to warn Williams of the dangers that the hospital knew or should have known were associated with working with patients, and failure to provide a safe workplace for its employees.¹⁰ The hospital's motion to dismiss asserted that Williams's claims were HCLCs under the Texas Medical Act and should be dismissed for Williams's failure to provide an expert report as required.¹¹ The trial court denied the hospital's motion,

3. *Marks v. St. Luke's Episcopal Hosp.*, 319 S.W.3d 658, 666 (Tex. 2010).

4. *Tex. W. Oaks Hosp., LP v. Williams*, 371 S.W.3d 171, 174 (Tex. 2012).

5. *Id.*

6. *Id.* at 174–75.

7. *Id.* at 175.

8. *Id.*

9. *Id.* at 176.

10. *Id.* at 175.

11. *Id.*

as did the appeals court.¹² The appeals court addressed the similarities between the patient's and Williams's claims and concluded, at least in part in the withdrawn opinion in *Marks v. St. Luke's Episcopal Hospital*,¹³ that Williams's claims were separable from health care and were not HCLCs.¹⁴ Specifically, it concluded that Williams's safety claims "flow from the employment relationship' between Williams and West Oaks and are not 'directly related' to health care, as required by the statute."¹⁵

The supreme court's decision analyzed the Medical Liability Act's definition of the term "claimant," which means "a person, including a decedent's estate, seeking or who has sought recovery of damages in a health care liability claim."¹⁶ The supreme court concluded that the use of the term "claimant" instead of "patient" expands the breadth of HCLCs beyond the patient population, which in turn necessarily "widen[s] the reach of the expert report requirement."¹⁷

The supreme court also addressed whether Williams's "safety claims" could be characterized as HCLCs, stating that "[w]e have not decided whether safety claims *must* be 'directly related to healthcare,'"¹⁸ which seems to keep the door open to the possibility that some safety claims might appropriately be brought under negligence causes of action. However, the supreme court's conclusion in this case, while not closing that door entirely, suggests that most safety related claims brought by claimants in health care facilities will be characterized as HCLCs.

The term "safety" is not defined in the Medical Liability Act. The supreme court has thus far declined to define "the precise boundaries of the safety prong."¹⁹ The definition of a HCLC was modified by the legislature in 2003, and these modifications added the following italicized words to the definition: "a cause of action for a 'claimed departure from accepted standards of medical care, or health care, or safety *or professional or administrative services directly related to health care*, which proximately results in injury or death of a claimant."²⁰

This opinion includes a lengthy analysis of how the addition of the italicized phrase may relate to the safety prong of an HCLC, concluding that the phrase "directly related to health care" modifies only professional or administrative services and does not modify the terms medical care, health care, or safety.²¹ This appears to expand HCLCs as to safety related claims. Therefore, injuries suffered by a claimant in an altercation

12. *Id.* at 176.

13. See *Marks v. St. Luke's Episcopal Hosp.*, 52 Tex. Sup. Ct. J. 1184 (2009), *withdrawn and superseded on rehearing*, 319 S.W.3d 658 (Tex. 2010).

14. *Williams*, 371 S.W.3d at 176.

15. *Id.* (citing TEX. CIV. PRAC. CODE ANN. § 74.001(a)(13) (West 2011)).

16. *Id.* at 178 (citing TEX. CIV. PRAC. CODE ANN. § 74.001(a)(2)).

17. *Id.*

18. *Id.* at 183 (emphasis added).

19. *Id.* at 184 (citing *Diversicare Gen. Partner, Inc. v. Rubio*, 185 S.W.3d 842, 855 (Tex. 2005); *Marks v. St. Luke's Episcopal Hosp.*, 319 S.W.3d 658, 662–63 (Tex. 2010)).

20. *Id.* (emphasis in original) (quoting TEX. CIV. PRAC. CODE ANN. § 74.001(a)(13)).

21. *Id.* at 184–85.

with a patient, such as that experienced by Williams, do not have to be related to the health care provision to implicate the safety prong of HCLCs.²²

Williams also unsuccessfully argued that his claims against his employer should be classified as workers' compensation claims and not HCLCs.²³ The supreme court found no conflict between the Texas Workers' Compensation Act (TWCA) and the Medical Liability Act.²⁴ Under the TWCA, individuals working for employers that subscribe to the TWCA are generally prohibited from filing suit against their employer for injuries incurred while on the job.²⁵ However, in some cases, employees can elect to waive their right to workers' compensation coverage and instead can choose to recover damages from their employer under various common law remedies.²⁶ Likewise, employees of non-subscribing employers have the right to pursue common law rights of action for on-the-job injuries.²⁷ These two types of employees are also treated differently under the Medical Liability Act for remedies for on-the-job injuries.²⁸ Employees of health care employers that are subscribers to the workers' compensation program must bring their cases under the TWCA.²⁹ However, employees who work for non-subscriber employers must bring their injury claims as HCLCs.³⁰ Williams's employer was a workers' compensation non-subscriber, thus eliminating the basis for arguing that his claims must be classified as workers' compensation claims.³¹

In conclusion, Williams's claims that West Oaks Hospital failed to properly train, warn, and supervise his work with potentially dangerous psychiatric patients were properly characterized as HCLCs, and Williams's failure to provide an expert report as required by the Medical Liability Act was fatal to his case against the hospital.³² The supreme court reversed the appeals court and remanded the case with instructions to dismiss Williams's claims.³³

Justice Lehrmann wrote the dissent, joined by Justices Medina and Willett, arguing that

[t]he Court's strained reading of the statute runs counter to express statutory language, the Legislature's stated purposes in enacting the current version of chapter 74, and common sense. Further, the Court's decision undermines the balance struck by the Legislature to encourage employers to become subscribers under the Workers

22. *Id.* at 186.

23. *Id.*

24. *Id.*

25. *Id.*

26. *Id.* at 187.

27. *Id.*

28. *Id.*

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.* at 192-93.

33. *Id.* at 193.

Compensation Act.³⁴

The dissent strongly disagreed with the majority's position that a "claimant" under the Medical Liability Act can be an individual with no physician-patient relationship as long as a physician-patient relationship is "involved" in the matter.³⁵ A compelling discussion is provided to show that a HCLC "must be founded on a health care provider's alleged breach of a professional duty towards a patient."³⁶ Section 74.051 of the Medical Liability Act requires, as part of a claimant's notice, a form authorizing release of the medical records of "the patient" whose treatment is the subject of the claim.³⁷ The dissent points out the inconsistency of this requirement as it applies to the injured employee's claims.³⁸ The dissent further points out that the majority's decision was inconsistent with the Medical Liability Act's definition of an expert report, which is defined in relevant part as "a written report by an expert that provides a fair summary of the expert's opinions . . . regarding . . . *the manner in which the care rendered by the physician or health care provider failed to meet the standards.*"³⁹ With respect to the majority's analysis of safety, Justice Lehrmann stated that he would hold that a claim for safety must arise from the breach of a health care provider's duty to "adequately ensure a patient's safety in providing health care services."⁴⁰

Although the supreme court's decision in this case will be applauded by many health care employers, the author tends to agree with the dissent that characterizing an employee's claims of inadequate training and an unsafe workplace as HCLCs is inconsistent with the intent of the Medical Liability Act.

B. DUTY TO INFORM: EXTREMELY RARE COMPLICATIONS

Sanchez v. Martin is another interesting HCLC case, but this case arises from the use of donor organs from a person who, unknown to the health care providers, was infected with the rabies virus.⁴¹ Several individuals that received these infected organs died from the rabies infection, which is virtually fatal unless treated immediately following exposure.⁴² Dr. Sanchez, the surgeon who performed the organ transplant surgery, alleged claims against the hospital and the two transplant surgeons, including: failure to obtain informed consent, general negligence, gross

34. *Id.* (Lehrmann, J., dissenting).

35. *Id.* at 194–95 (Lehrmann, J., dissenting).

36. *Id.* at 194 (Lehrmann, J., dissenting) (citing *Diversicare Gen. Partner, Inc. v. Rubio*, 185 S.W.3d 842, 851, 854 (Tex. 2005)).

37. *Id.* at 195 (Lehrmann, J., dissenting) (citing TEX. CIV. PRAC. CODE ANN. § 74.051(d) (West 2011)).

38. *Id.* at 194–95 (Lehrmann, J., dissenting).

39. *Id.* at 195–96 (Lehrmann, J., dissenting) (emphasis in original) (citing TEX. CIV. PRAC. CODE ANN. § 74.351(r)(6)).

40. *Id.* at 198 (Lehrmann, J., dissenting).

41. *Sanchez v. Martin*, 378 S.W.3d 581, 586 (Tex. App.—Dallas 2012, no pet.).

42. *Id.*

negligence, and fraud or intentional misrepresentation.⁴³ The adequacy of the plaintiff's expert report was a primary issue analyzed by the Dallas Court of Appeals in arriving at its decision.⁴⁴ The noteworthy claims in this case included the plaintiff's allegations that (1) the defendants failed to obtain informed consent, and (2) the hospital's policies and procedures were inadequate with respect to informed consent in what were classified as "high risk donor" cases.⁴⁵ The procedural history of this case is somewhat lengthy and will not be repeated here. This case was an interlocutory appeal of a motion to dismiss by the defendants based on the inadequacy of the plaintiff's expert report.⁴⁶

A plaintiff filing a medical malpractice claim under the Medical Liability Act must file an expert report on each claim, but specific theories arising from the same group of operative facts are considered one claim with respect to this requirement.⁴⁷ The primary issue concerned informed consent and causation, i.e., did the expert report provide "proof that a reasonable person could have been influenced to decide to give or withhold consent by being informed of the risks or hazards that were not disclosed."⁴⁸ The court of appeals decided that the expert report failed to meet this standard.⁴⁹ With respect to the fraud, intentional misrepresentation, and negligence claims based on the hospital's policies and procedures, the court of appeals decided that these claims were an attempt by the plaintiff to recast the informed consent claims.⁵⁰ As such, those claims also failed because of the inadequacy of the expert report.⁵¹

The case also indirectly addressed a health care provider's disclosure obligation as part of the informed consent process. In other words, did the providers involved in this transplant have an obligation to disclose to the recipient that the donor's organs might be infected by a virus as rare as the rabies virus? The providers involved in this case did put the patient on notice that the organs came from a "high risk donor," and although the public does not have a copy of the informed consent document used in this case or detailed information about the organ recipient, it is very likely that the recipient was informed that the donor organ was more likely to have some unknown condition or infection than a donor who was not in the high risk category. It is also likely that the recipient's medical condition was so severe that death may have resulted if the transplant had not taken place. Otherwise, it is not likely that the recipient would

43. *Id.*

44. *Id.* at 587.

45. *Id.* at 586 (describing the donor as a "high-risk donor" and explaining that he had been incarcerated up until two weeks before his fatal illness and had a urine drug screen positive for cocaine and cannabinoids).

46. *Id.* at 586-87.

47. *Id.* at 588 (citing *Methodist Charlton Med. Ctr. v. Steele*, 274 S.W.3d 47, 50 (Tex. App.—Dallas 2008, pet. denied); *Nexion Health at Duncanville, Inc. v. Ross*, 374 S.W.3d 619, 624-27 (Tex. App.—Dallas 2012, pet. denied)).

48. *Id.* at 589.

49. *Id.* at 591.

50. *Id.*

51. *Id.*

have accepted a donation from a high risk donor. The expert report evidently did not demonstrate that informing the patient that the organ might contain a virus such as the rabies virus would have influenced the patient's decision. Further, the case did not offer guidance on whether this information should be included as part of the informed consent process.

C. DUTY TO INFORM: PHYSICIAN LIMITATIONS

Another case involving adequacy of informed consent is *Pelozo v. Cuevas*, a case where the plaintiff alleged that the physician's failure to inform the patient of the physician's physical condition contributed to the patient's injuries.⁵² Dr. Pelozo operated on Bright Star Cuevas (Cuevas) for back pain and then twice more in attempts to rectify the first failed procedure.⁵³ In addition to alleging a number of mistakes by Dr. Pelozo, Cuevas asserted in an amended petition that Dr. Pelozo's carpal tunnel syndrome and hip abnormality contributed to her injuries.⁵⁴ She did not file an expert report to address the allegations in her amended petition.⁵⁵ Dr. Pelozo moved to dismiss the allegations related to informed consent of his own physical limitations by asserting that the amended petition added new claims and causes of action.⁵⁶ The trial court denied Dr. Pelozo's motion to dismiss.⁵⁷

Dr. Pelozo asserted that an amended expert report was required because the claims regarding his physical conditions were "far and away different from an ordinary malpractice claim and more like a lack of informed consent claim," or alternatively that the issue of a physician's impairment "has a different causal connection from an ordinary medical negligence claim."⁵⁸ Dr. Pelozo supported his position by arguing that a physician's impairment claim is premised on the surgeon's physical ability to perform the procedure rather than the physician's thought process or judgment during the procedure as in a typical HCLC.⁵⁹ The Dallas Court of Appeals used this argument to "determine whether the new allegations regarding [Dr.] Pelozo's physical conditions constitute[d] a new cause of action for health care liability or a new theory of negligence."⁶⁰ Not surprisingly, the court of appeals concluded that Cuevas's claims that her injuries were caused in part by Dr. Pelozo's physical problems were not a new cause of action or a new theory of negligence and did not require a new expert's report.⁶¹

52. *Pelozo v. Cuevas*, 357 S.W.3d 200, 201–02 (Tex. App.—Dallas 2012, no pet.).

53. *Id.* at 201.

54. *Id.* at 202.

55. *Id.* at 202–03.

56. *Id.* at 203.

57. *Id.*

58. *Id.* at 204.

59. *Id.*

60. *Id.* at 205.

61. *Id.*

The basis for this decision is the statutory language in the Medical Practice Act defining a health care claim as “a cause of action against a health care provider or physician for treatment, lack of treatment, or other claimed departure from accepted standards of medical care . . . which proximately results in injury to or death of a claimant.”⁶² In this case, the physician’s physical limitations/conditions contributed to the patient’s injuries.

III. DISPUTES WITH HEALTH PLANS

Health care providers and the health plans that pay providers have long had an uneasy relationship. Although health care providers recognize the benefits associated with becoming a contracted or “network” provider with the major health plans, many of these providers have had longstanding dissatisfaction with the payment rates that come with these provider agreements. Health plans, in their continuing efforts to remain profitable and competitive, have used their size and market penetration to keep these rates relatively low. Most health care providers do not have the leverage to successfully negotiate higher rates, which means that they either have to accept the rates being offered or elect to perform services as an out of network (OON) provider. Payment rates for OON providers can be substantially higher than those paid to network providers, but they come with a substantial cost. Insurance subscribers who receive services from OON providers are generally subject to much higher co-payment amounts than if they used a network provider, which is a practice that is used by the health plans to incentivize subscribers to use network providers. The two cases presented in this section illustrate the interesting, and sometimes surprising, approaches used in OON disputes by both the health plans and health care providers.

A. OUT OF NETWORK DISPUTE: RICO ALLEGATION

North Cypress Medical Center (North Cypress) is a hospital that opened for business in 2007.⁶³ Prior to opening, it attempted to negotiate an in-network contract agreement with CIGNA Healthcare (CIGNA) but was unable to agree to terms.⁶⁴ As a result, North Cypress began business as an OON provider for subscribers of CIGNA.⁶⁵ To reduce the amount of money patients might have to pay when receiving services, North Cypress offered its CIGNA patients a prompt pay discount (the Policy) that could be applied to the patients’ higher OON co-payment obligations.⁶⁶ North Cypress properly put CIGNA on written notice that it was

62. *Id.* (citing TEX. CIV. PRAC. CODE ANN. § 74.001(13) (West 2011)).

63. *N. Cypress Med. Ctr. v. CIGNA Healthcare*, No. 4:09-CV-2556, 2011 WL 5325785, at *1 (S.D. Tex. Nov. 3, 2011).

64. *Id.*

65. *Id.*

66. *Id.*

offering this discount to CIGNA subscribers.⁶⁷ CIGNA responded to this notification by informing the hospital that such a discount could “constitute fraud and subject the provider to civil and criminal liability.”⁶⁸ CIGNA also put North Cypress on a special program that delayed payments to the hospital and wrote to patients to ask if North Cypress “balance billed” the patients.⁶⁹ North Cypress referred to these actions as the “Protocol” and asserted that under the Protocol CIGNA paid North Cypress an average of only \$100 per claim, regardless of the actual charges.⁷⁰ After approximately one year, North Cypress estimated that CIGNA underpaid it substantially, resulting in more than \$30 million in damages.⁷¹ North Cypress brought this suit alleging that CIGNA had paid the hospital substantially less than it should have been paid and these policies did not comply with its contractual obligations.⁷² The hospital claimed that these practices constituted illegal racketeering activities under the RICO laws.⁷³

A RICO claimant must be able to show three elements: (1) a person who engages in (2) a pattern of racketeering activity (3) connected to the acquisition, establishment, conduct or control of an enterprise.⁷⁴ In order to survive a motion to dismiss a RICO claim, a plaintiff must plead at least “two or more predicate acts,” show the predicate acts are related, and show that the acts amount to or pose a threat of continued criminal activity.⁷⁵ As predicate acts, North Cypress presented examples of how CIGNA attempted to extort North Cypress and other health care providers to contract as in-network providers by enacting “fee forgiveness” investigations and referring the facilities to its Special Investigative Units (SIU) for handling of claims.⁷⁶ The court found the pleadings sufficient to satisfy the first hurdle for demonstrating racketeering activity.⁷⁷

Although CIGNA claimed that North Cypress failed to show a threat of continued criminal activity, the court disagreed.⁷⁸ North Cypress’s claim that CIGNA investigated fee forgiving practices in the normal

67. *Id.* Although not explained in the case, the purpose for the written notice was likely an attempt on the part of North Cypress to prevent CIGNA from claiming that the hospital’s claims for services misrepresented the amount North Cypress was charging OON patients. Cases from other jurisdictions have concluded that failure to state that a discount was being offered for patient copayment obligations could be interpreted as fraud or misrepresentation in some circumstances. One way to counteract a health plan’s ability to bring such a claim is to put the health plan on notice that the hospital does not intend to collect the full amount of the patient’s copayment obligation.

68. *Id.*

69. *Id.* at *2.

70. *Id.*

71. *Id.*

72. *Id.*

73. *Id.* at *3.

74. *Id.* at *4 (citing *Real Estate Innovations, Inc. v. Houston Ass’n of Realtors*, 422 Fed. App’x 344, 350 (5th Cir. 2011)).

75. *Id.* (quoting *In re MasterCard Int’l Inc.*, 313 F.3d 257, 261 (5th Cir. 2002)).

76. *Id.* at *5.

77. *Id.*

78. *Id.*

course of business to pressure the hospital to be an in-network provider was enough to plead continuity.⁷⁹ However, North Cypress's claim of illegal racketeering activity failed with respect to showing that CIGNA used any part of its income to acquire an interest in or to operate the alleged enterprise.⁸⁰ Additionally, North Cypress failed to show how CIGNA's use of these funds injured North Cypress.⁸¹ In short, challenging a health plan's payment practices is difficult when an OON provider lacks a contractual relationship with that health plan.⁸²

B. DENIAL OF PAYMENT DISPUTE

Fisher v. Blue Cross & Blue Shield of Texas is another case involving a dispute over a provider's OON status and is notable for the defense used by Blue Cross and Blue Shield of Texas (BCBSTX).⁸³ Dr. Fisher had a number of affiliated companies that worked together to provide anesthesia services to obstetricians and gynecologists who perform surgeries in their offices (collectively referred to here as Paragon).⁸⁴ Paragon provided the physicians who performed the anesthesiology services with the equipment and supplies necessary for anesthesia.⁸⁵ Paragon entered into a Group Managed Care Agreement with BCBSTX that expressly provided for payment of the physicians's anesthesia services.⁸⁶ Paragon claimed that it had entered into agreements with BCBSTX that included an implied contract for payment of the anesthesia and equipment services to the various Paragon entities.⁸⁷ Paragon alleged that BCBSTX paid for its services beginning in 2004, but in July 2010, the health plan began to recoup amounts previously paid.⁸⁸ This change in practice gave rise to Paragon's claim that BCBSTX violated its express and implied contracts.⁸⁹

BCBSTX's position was that its policies indicated that a provider was not permitted to bill for the "services, supplies, and equipment, which are considered the 'technical component' . . . of an anesthesiologist's work."⁹⁰ BCBSTX claimed that Paragon violated this rule, and as a result,

79. *Id.*

80. *Id.* at *6.

81. *Id.*

82. *See id.*

83. *Fisher v. Blue Cross & Blue Shield of Tex.*, 879 F. Supp. 2d 581, 584 (N.D. Tex. 2012).

84. *Id.* (explaining that Paragon entities include Paragon Anesthesia Associates, P.A., Paragon Office Services, LLC, Paragon Ambulatory Health Resources, LLC, and Office Surgery Support Services).

85. *Id.*

86. *Id.*

87. *Id.* at 584–85.

88. *Id.* at 585.

89. *Id.*

90. *Id.* Under the BCBSTX policy, physicians who perform surgical procedures in their offices or "non-facility" settings furnish the equipment and supplies necessary to perform the surgical procedure in their office. *Id.* When these same procedures are performed in a facility setting, such as a surgical hospital, the hospital is reimbursed for providing the space, staff, equipment, and supplies necessary to provide the procedure; the physician's

BCBSTX inadvertently paid Paragon for services and “non-facility setting” costs it was not entitled to receive.⁹¹ BCBSTX counterclaimed, asserting that Paragon submitted its claims in violation of the Employee Retirement Income Security Act of 1974 (ERISA).⁹² Paragon moved to dismiss BCBSTX’s ERISA claims on the basis that BCBSTX lacked standing as a fiduciary to bring such a claim.⁹³

BCBSTX’s ERISA counterclaim was unsuccessful. BCBSTX argued that it overpaid Paragon because Paragon did not comply with BCBSTX’s policies, but this assertion did not involve a benefit determination, which is a requirement for an ERISA claim.⁹⁴ After dismissing BCBSTX’s ERISA counterclaim, the court ordered the parties to make certain disclosures in an attempt to end what the court characterized as a “legal merry-go-round.”⁹⁵

IV. MISCELLANEOUS DISPUTES

The next group of cases show some of the business challenges faced by health care providers, but they are otherwise unrelated. The first is a challenge to the administrative appeals process in a dispute with a Medicare law.⁹⁶ The second is a case on the duty to inform and the learned intermediary doctrine involving a pharmaceutical manufacturer and three physicians.⁹⁷ This case went to the Texas Supreme Court, despite the fact that none of the parties failed in their responsibilities or duties to the patient. The last is a fairly typical breach of contract case, but it addresses an interesting question of exclusivity and a standard health care contract provision.⁹⁸

A. CHALLENGING THE ADMINISTRATIVE APPEALS PROCESS

When health care providers have a dispute with a law, rule, or regulation involving the U.S. Department of Health and Human Services, they generally have to endure a very long administrative appeals process, and in some cases, the process is inadequate as a remedy. The following case was properly dismissed for lack of subject matter jurisdiction, but it is an example of the inadequacy of administrative remedies.⁹⁹ Additionally,

professional fee is reduced because he or she is no longer responsible for providing the equipment, supplies, space, and staff. *Id.*

91. *Id.*

92. *Id.* at 587.

93. *Id.* Paragon also claimed that BCBSTX should have included other Blue Cross home plans in the counterclaim. *Id.*

94. *Id.* at 590–91 (referring to *Lone Star OB/GYN Assoc. v. Aetna Health Inc.*, 579 F.3d 525, 531 (5th Cir. 2009) for its position that the health plan’s claims were entirely separate from coverage and arose out of Paragon’s independent duty as a contracted provider to follow the health plan’s policies).

95. *Id.* at 594.

96. *See Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649 (5th Cir. 2002).

97. *See Centocor, Inc. v. Hamilton*, 372 S.W.3d 140 (Tex. 2012).

98. *See Greater Houston Radiation Oncology, P.A. v. Sadler Clinic Assoc., P.A.*, 384 S.W.3d 875 (Tex. App.—Beaumont 2012, pet. denied).

99. *See Sebelius*, 691 F.3d at 651.

the Fifth Circuit apparently recognized the plaintiffs' difficult situation and concluded the case by saying: "[t]he ever-evolving landscape of health care in the United States may one day prompt a new structure for judicial review in a case such as this. 'If the balance is to be struck anew, the decision must come from Congress' and not from the courts."¹⁰⁰

The plaintiffs were Physician Hospitals of America, an organization that supports physician-owned hospitals, and Texas Spine & Joint Hospital (TSJH), a physician-owned hospital.¹⁰¹ Plaintiffs contested the constitutionality of a change to the federal law commonly known as the "Stark Law."¹⁰² The Stark Law was enacted in 1989 and limits the circumstances in which physicians can refer Medicare patients to entities in which the physicians have a financial relationship.¹⁰³ Until 2003, the Stark Law contained an exception that permitted physicians to refer Medicare patients to hospitals in which the physicians had an ownership interest.¹⁰⁴ This exception was essentially eliminated when limits were placed on the ability of existing physician-owned hospitals to expand their services under Section 6001 of the Patient Protection and Affordable Care Act of 2010.¹⁰⁵

Prior to passage of Section 6001, TSJH began a \$30 million expansion project that was put on hold upon passage of the law.¹⁰⁶ When TSJH stopped the project, it had spent approximately \$3 million.¹⁰⁷ TSJH claimed that in order to challenge the change to the law by filing an administrative claim, it would have to complete construction of the expansion, treat a patient in the new space, and wait for a denial of payment.¹⁰⁸ Then, TSJH would have to keep the space unoccupied for however long it would take to work through the administrative appeals process, which could possibly take years.¹⁰⁹ In an attempt to avoid such a financially disastrous outcome, TSJH and Physicians Hospitals brought this action in federal district court seeking declaratory and injunctive relief on the basis that Section 6001 is void for vagueness and violates the Equal Protection Clause of the Constitution.¹¹⁰

The district court went through a lengthy discussion citing numerous cases for its unsurprising conclusion that the plaintiffs were required to proceed with available administrative procedures before addressing the matter in federal court.¹¹¹ The plaintiffs' failure to do so meant that the

100. *Id.* at 659 (quoting *Heckler v. Ringer*, 466 U.S. 602, 627 (1984)).

101. *Id.* at 652.

102. *Id.* at 651–53 (citing 42 U.S.C. § 1395nn (2010)).

103. *See generally*, 42 U.S.C. § 1395nn.

104. Exceptions to the Referral Prohibition Related to Ownership or Investment Interests, 42 C.F.R. § 411.356 (2011).

105. *Sebelius*, 691 F.3d at 652 (citing 42 U.S.C. §§ 1395nn(i)(1)(B), (i)(3)).

106. *Id.*

107. *Id.*

108. *Id.*

109. *Id.*

110. *Id.*

111. *Id.* at 652–58.

federal district court did not have subject matter jurisdiction to hear the case.¹¹² The Fifth Circuit also declined to accept the plaintiffs' argument that forcing them to go through the administrative appeals process "would result in the practical denial of judicial review."¹¹³ The fact that the administrative appeals process could only be triggered after TSJH spent millions of dollars to complete the expansion facility did not give them the right to circumvent the administrative appeals process.¹¹⁴

B. LEARNED INTERMEDIARY DOCTRINE AND DIRECT TO CONSUMER MARKETING

Centocor, Inc. v. Hamilton is a case that addresses the duty to inform patients of the risks and benefits associated with a prescription drug.¹¹⁵ The case discusses the "learned intermediary doctrine" but makes no changes to the doctrine.¹¹⁶ However, it is notable for health care providers because it addresses this doctrine in the context of direct-to-patient marketing by pharmaceutical manufacturers, an increasingly common method by which new drugs and pharmaceuticals are marketed. The Texas Supreme Court upheld the learned intermediary doctrine with respect to the plaintiff's claims against the pharmaceutical manufacturer and reinforced that "the bedrock of our healthcare system is the physician-patient relationship, and the ultimate decision for any treatment rests with the prescribing physician and the patient," even in the context of drugs marketed directly to the consumers.¹¹⁷

The plaintiff in this case had multiple medical problems, one of which was Crohn's disease.¹¹⁸ Upon experiencing a flare up of this condition, the plaintiff agreed to treatment with a relatively new drug called Remicade, which is manufactured by Centocor, Inc. (Centocor).¹¹⁹ Dr. Hauptman prescribed the medication and alleged that he informed the patient of the risks and benefits of the drug.¹²⁰ The drug was actually administered by Dr. Bullen, a physician who ran an infusion clinic.¹²¹ Dr. Bullen provided an informational video furnished by Centocor for the patient while she was receiving the drug, but he did not provide any further information about the risks or benefits for Remicade.¹²² Following three episodes of treatment, the patient's Crohn's disease showed marked

112. *Id.* at 659.

113. *Id.* at 656 (citing *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 22 (2000)).

114. *Id.* at 657 (citing *Council for Urological Interests v. Sebelius*, 668 F.3d 704, 708 (D.C. Cir. 2011) (explaining that a "party may not circumvent the channeling requirement by showing merely that 'postponement of judicial review would mean added inconvenience or cost in an isolated, particular case'") (quoting *Shalala*, 529 U.S. at 22-23)).

115. *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 142 (Tex. 2012).

116. *Id.* at 154-59.

117. *Id.* at 166.

118. *Id.* at 143.

119. *Id.* at 144.

120. *Id.*

121. *Id.* at 146-47.

122. *Id.* at 143, 146-47.

improvement.¹²³ However, the patient started experiencing severe arthritis symptoms, for which she requested treatment from a third physician, Dr. Pop-Moody, who then prescribed additional infusions of Remicade for these symptoms; and although the patient showed short term relief, the symptoms ultimately increased.¹²⁴ Following evaluation by yet another physician, the patient was diagnosed with a rare side effect of Remicade treatment called lupus syndrome.¹²⁵ The patient filed lawsuits against Centocor, the two physicians who prescribed Remicade, and the physician who administered it.¹²⁶

At trial, the plaintiff stated the following claims against Centocor: fraud, negligent undertaking, negligent misbranding, negligent marketing, misrepresentation to a plaintiff's physician regarding the risk of lupus, and misrepresentation regarding the risk of hepatitis C.¹²⁷ Centocor objected and repeatedly raised the learned intermediary doctrine.¹²⁸ The jury found Centocor liable for, among other things, fraud, misrepresentation to the physicians, and negligent misbranding.¹²⁹ Before judgment was entered, Drs. Hauptman and Pop-Moody settled and were nonsuited.¹³⁰ On appeal, Centocor repeated its position that it had no duty to warn the plaintiff as a matter of law.¹³¹ However, the appellate court disagreed and affirmed the trial court's judgment based on the direct-to-consumer (DTC) exception to the learned intermediary doctrine.¹³²

The Texas Supreme Court presented history of the learned intermediary doctrine, including a discussion of the exceptions to the doctrine.¹³³ The DTC, or mass marketing, exception has been recognized by only a few courts.¹³⁴ Prior to the appellate court ruling, no court in Texas had adopted this exception, and the supreme court concluded that while some circumstances might require exceptions to the doctrine, the exception did not apply in this particular case.¹³⁵

Several factors entered into this conclusion. First, the plaintiff's alleged harm was not caused by Centocor's direct advertising.¹³⁶ Neither she nor her husband remembered any DTC advertising by Centocor about Remicade other than a textual banner displayed during a CNN broadcast.¹³⁷ Her claims about Centocor's advertising were based on the video she

123. *Id.* at 148.

124. *Id.* at 148-49.

125. *Id.* at 149.

126. *Id.* at 143.

127. *Id.* at 150.

128. *Id.* at 151.

129. *Id.*

130. *Id.*

131. *Id.*

132. *Id.* at 152.

133. *Id.* at 154-61.

134. *Id.* at 160 (referring to *Edwards v. Basel Pharm.*, 933 P.2d 298 (Okla. 1997) and *Perez v. Wyeth Lab. Inc.*, 734 A.2d 1245 (N.J. 1999) as examples).

135. *Id.* at 162.

136. *Id.*

137. *Id.*

viewed while receiving the infusion. After she had been prescribed the medication by her physician.¹³⁸ This video was characterized as an informational video and not the type of DTC advertising seen in other cases where the exception may have applied.¹³⁹ Appropriate safeguards for patients presently exist under federal and state laws regulating the design, marketing, and distribution of prescription drugs, as well as the requirement that patients who may be seeking a drug as a result of DTC marketing may only obtain that drug after it has been prescribed by a physician who has an obligation to provide the patient with information about the benefits and risks of the drug.¹⁴⁰ As such, the supreme court found

no reason to adopt an exception where the physician-patient relationship existed, the pharmaceutical company provided a warning to the patient's prescribing doctors that included the side effect of which the patient complains, and the patient had already visited with her prescribing physician and decided to take the drug before she saw the informational video.¹⁴¹

This conclusion is consistent with the existing obligation of physicians that requires them to obtain informed consent for the drugs they prescribe to patients.

C. EXCLUSIVE CONTRACTUAL RELATIONSHIPS

*Greater Houston Radiation Oncology, P.A. v. Sadler Clinic Association, P.A.*¹⁴² is a case involving a fairly typical breach of contract dispute, but it is noteworthy with respect to how a common non-referral obligation provision is rendered inapplicable for purposes of evaluating whether or not the agreement established an exclusive referral arrangement. It is also a reminder that contracts must accurately and *expressly* reflect the intent of the parties.

Sadler Clinic Association, P.A. (Sadler Clinic) agreed to establish a radiation oncology center (the Center) and contracted with Dr. Kanedy who owned Greater Houston Oncology, P.A. (GHRO), a physician group of radiation oncologists.¹⁴³ GHRO agreed to provide the Center with radiation oncologists, billing and collection services, and management services with related entities.¹⁴⁴ All of these entities are collectively referred to herein as GHRO. When the Center was completed, a GHRO physician began providing radiation oncology services to patients referred to the Center for treatment.¹⁴⁵ Shortly after the Center opened, the GHRO physician observed that another physician was brought to the

138. *Id.* at 162–63.

139. *Id.* at 163.

140. *Id.* at 163–64.

141. *Id.* at 164.

142. *Greater Houston Radiation Oncology, P.A. v. Sadler Clinic Assoc., P.A.*, 384 S.W.3d 875 (Tex. App.—Beaumont 2012, pet. denied).

143. *Id.* at 881.

144. *Id.*

145. *Id.*

Center for a tour.¹⁴⁶ This physician told the GHRO physician that he was interviewing for a job.¹⁴⁷ Subsequent to this interaction, Dr. Kanedy tried to amend the management agreement to a ten-year term and to increase the penalties for termination.¹⁴⁸ The Center's board declined to agree to the amendment.¹⁴⁹ Several months later, the board hired a new physician who began receiving all of the referrals from the Sadler Clinic, which resulted in the GHRO physician receiving no new referrals and his and GHRO's business sharply deteriorating.¹⁵⁰ The Center also terminated the GHRO entity management agreement by placing GHRO on notice that it was in breach of the billing services agreement.¹⁵¹ Finally, the Center filed a declaratory action seeking a judgment that the professional services agreement was not an exclusive agreement.¹⁵²

The Beaumont Court of Appeals's analysis included a breach of contract analysis that will not be reviewed in its entirety.¹⁵³ However, the discussion of exclusivity with respect to the physician services agreement (PSA) is notable. The PSA had no express provision stating that the agreement was or was not exclusive.¹⁵⁴ But it did include a "no referral obligation" provision common to many professional services and other types of agreements between health care providers.¹⁵⁵ The Center argued that the lack of any express exclusivity provisions and the "no referral obligation" provision rendered the PSA non-exclusive, and GHRO argued that the "necessary to operate" language in the introductory paragraphs of the PSA established an exclusive relationship.¹⁵⁶

The court of appeals analyzed the exclusivity issue by evaluating the PSA as a whole and explained that the PSA contemplated that GHRO would provide multiple physicians, subject to the Center's approval.¹⁵⁷ The court of appeals also noted that Texas law generally does not allow for one contract provision to be interpreted in a way that nullifies the other.¹⁵⁸ Although recognizing that the no referral obligation provision does not require the Sadler Clinic's physicians to refer patients to the

146. *Id.* at 881–82.

147. *Id.* at 882.

148. *Id.*

149. *Id.*

150. *Id.* at 883.

151. *Id.*

152. *Id.*

153. *Id.* at 884–90.

154. *Id.* at 884–86.

155. *Id.* at 886. A no referral obligation provision requires the parties to agree that nothing in the agreement requires either party to refer patients or other business to the other party and that the parties will conduct themselves in such a way that they will not violate the federal anti-kickback law as set forth in 42 U.S.C. § 1320a-7b, commonly referred to as the anti-kickback law. *See id.*

156. *Id.* at 886–87.

157. *Id.* at 888.

158. *Id.* at 886 (citing as examples *Burnett Ranches, Ltd. v. Cano Petroleum, Inc.*, 289 S.W.3d 862, 867 (Tex. App.—Amarillo 2009, pet. denied) and *Lavaca Bay Autoworld v. Marshall Pontiac Buick Oldsmobile*, 103 S.W.3d 650, 659 (Tex. App.—Corpus Christi 2003, pet. dismissed)).

GRHO physician in violation of the anti-kickback law, the court of appeals concluded that the provision does not address *which* physicians will provide the radiation oncology services.¹⁵⁹ This and other language in the agreement resulted in the court of appeals's conclusion that the parties intended that the GHRO physician or physicians would provide all of the radiation oncology services for the Center.¹⁶⁰ This would prohibit the Sadler Clinic from engaging another physician to furnish these services and would render the PSA an exclusive agreement, notwithstanding the lack of any specific exclusivity language and the no referral obligation provision.¹⁶¹

V. HIGH PROFILE CASES

The cases in this section were chosen because of the high profile of the decision or because of the subject matter of the dispute. These cases include the Supreme Court's decision in the challenge to the 2010 Affordable Care Act¹⁶² and a class action case challenging an amendment to the Texas Woman's Right to Know Act.¹⁶³

A. CHALLENGE TO THE AFFORDABLE CARE ACT

The Affordable Care Act (the Act)¹⁶⁴ was the landmark health care reform legislation passed during President Obama's first term. This law was almost immediately challenged by a number of states and parties, including the Texas Attorney General and the Attorneys Generals of twenty-five other states, private individuals, and a group of independent businesses.¹⁶⁵ This article will limit its comments to a very brief summary of two critical challenges.

The parties claimed that the Act's individual mandate and expansion of the Medicaid program were unconstitutional.¹⁶⁶ The case was initially brought in a Florida federal district court, which granted summary judgment to the plaintiffs' claim under the theories that the Medicaid expansion was unconstitutional, the individual mandate exceeded Congressional authority, and the Act was not severable.¹⁶⁷ The district court essentially declared the entire Act invalid.¹⁶⁸ The federal government appealed to the Eleventh Circuit, where the unconstitutionality of the individual mandate and the Medicaid expansion was affirmed; however, the individual mandate's non-severability was reversed.¹⁶⁹

159. *Id.* at 887.

160. *Id.* at 888.

161. *Id.*

162. *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566 (2012).

163. *See Tex. Med. Providers Performing Abortion Servs. v. Lakey*, 667 F.3d 570 (5th Cir. 2012).

164. *See generally*, 26 U.S.C. § 5000A (2010).

165. *Nat'l Fed'n of Indep. Bus.*, 132 S. Ct. at 2580 (referring to 26 U.S.C. § 5000A).

166. *Id.*

167. *Id.*

168. *Id.*

169. *Id.* at 2580–81.

The individual mandate, found at 26 U.S.C. § 5000A, requires most Americans to maintain at least a minimal level of health insurance coverage.¹⁷⁰ There are a number of exceptions to this requirement for some individuals, such as prisoners and undocumented aliens, but most Americans would be required by 2014 to secure health insurance coverage either through a private health insurance plan or through a government health care program such as Medicare or Medicaid.¹⁷¹ Individuals who fail to comply with this requirement will be subject to a “[s]hared responsibility payment” payable to the Internal Revenue Service (IRS).¹⁷² The Supreme Court held that even though the individual mandate exceeded Congressional power under the Commerce Clause, it was permissible as a tax within Congress’s taxing authority.¹⁷³

The Medicaid expansion requires states to expand coverage of the existing Medicaid program (which currently covers children, pregnant women, needy families, the elderly, and the disabled who meet certain financial hardship requirements) to cover all adults with income less than or equal to 133 percent of the federal poverty level.¹⁷⁴ This requirement increases funding to states that expand the program, but for states that do not comply with the new requirement, the Act withdraws all federal funding of those states’ Medicaid programs.¹⁷⁵ The penalty portion of the expansion was deemed improper under Congress’s spending power, but it was held to be severable from the Act.¹⁷⁶

B. CHALLENGES TO ABORTION LAW OBLIGATIONS

Texas Medical Providers Performing Abortion Services v. Lakey involves a 2011 amendment to the 2003 Texas Woman’s Right to Know Act (WRKA).¹⁷⁷ This amendment requires physicians who perform abortions to furnish women requesting the procedure with a sonogram of the fetus, make the heartbeat of the fetus audible, explain the results of the procedure, and wait twenty-four hours before performing the procedure.¹⁷⁸ Although WRKA already includes penalties for performing an abortion when not in full compliance with the statute,¹⁷⁹ the 2011 amendment also amended the Texas Occupations Code to deny or revoke a physician’s

170. *Id.* at 2580 (citing 26 U.S.C. § 5000A).

171. *Id.*

172. *Id.* (quoting 26 U.S.C. § 5000A(b)(1)).

173. *Id.* at 2585–601 (discussing the Act’s constitutionality under the Commerce Clause and as a tax).

174. *Id.* at 2581–82.

175. *Id.*

176. *Id.* at 2601–09 (discussing the constitutionality of the Medicaid expansion).

177. *Tex. Med. Providers Performing Abortion Servs. v. Lakey*, 667 F.3d 570, 572–73 (5th Cir. 2012).

178. *Id.* at 573 (citing TEX. HEALTH & SAFETY CODE ANN. § 171.012(a)(4) (West 2011)).

179. TEX. HEALTH & SAFETY CODE ANN. § 171.018 (West 2010) (providing that physicians who fail to comply with the statute are guilty of a misdemeanor and are subject to up to \$10,000 in fines).

license for violating these provisions.¹⁸⁰

Physicians and abortion providers filed a class action lawsuit against the Commissioner of the Texas Department of State Health Services and the Executive Director of the Texas Medical Board seeking injunctive relief and alleging various constitutional violations.¹⁸¹ The Fifth Circuit ruled that the plaintiffs “failed to demonstrate constitutional flaws.”¹⁸² Although the Fifth Circuit’s decision in this case may have disappointed individuals who support a woman’s right to choose, it appears to be legally sound. Another outcome would have been inconsistent with other Texas rules relating to informed consent, including those promulgated by the Texas Disclosure Panel.¹⁸³ This outcome is also consistent with previous Supreme Court cases, as discussed below.

The primary objection of the physicians was that the disclosure provisions “compel speech” in violation of the First Amendment.¹⁸⁴ They also asserted that certain portions of the provisions were vague.¹⁸⁵ The physicians asserted that the requirement to perform the sonogram, make the heartbeat of the fetus audible, and explain the results of both examinations was an assertion of the “state’s ‘ideological message’ concerning the fetal life” because it served no medical purpose except to discourage abortion.¹⁸⁶ The Fifth Circuit analyzed this assertion using the Supreme Court’s 1992 holding in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, which in addition to reaffirming a woman’s substantive due process right to terminate a pregnancy also “upheld an informed-consent statute over precisely the same ‘compelled speech’ challenges made here.”¹⁸⁷ Also, the Fifth Circuit supported its decision regarding the disclosure requirements by citing an Eighth Circuit decision from 2011 that likewise found that an abortion informed consent regulation was not compelled speech.¹⁸⁸

The Fifth Circuit’s analysis of *Casey* and the physicians’ compelled speech argument is lengthy and well worth a close reading, but its key conclusions are as follows:

- (1) Informed consent laws are part of the state’s regulation of the practice of medicine and can take into consideration the state’s compelling interest in protecting the life of the fetus as well as the mother’s health;¹⁸⁹

180. *Lakey*, 667 F.3d at 573 (referring to TEX. OCC. CODE ANN. § 164.055(a) (West 2011)).

181. *Id.* at 572.

182. *Id.* at 584.

183. See 25 TEX. ADMIN. CODE § 601 (2004) (describing the rule of the Panel with respect to informed consent for certain designated procedures).

184. *Lakey*, 667 F.3d at 573.

185. *Id.*

186. *Id.* at 574.

187. *Id.* (citing *Planned Parenthood of Se. Pa v. Casey*, 505 U.S. 833 (1992)).

188. *Id.* (citing *Planned Parenthood Minn. v. Rounds*, 653 F.3d 662 (8th Cir. 2011)).

189. *Id.* at 579.

- (2) As long as informed consent laws do not impose an undue burden on a women's right to have an abortion, the laws are permissible;¹⁹⁰ and
- (3) The disclosures and written consent required by the amendment "are sustainable under *Casey* . . . [and] are within the State's power to regulate the practice of medicine."¹⁹¹

In addition to concluding that the informed consent provisions were not a violation of the physicians's First Amendment rights, the Fifth Circuit concluded that the amendments were not impermissibly vague or in any way inconsistent with the rest of WRKA.¹⁹² While these arguments are not as compelling as the Fifth Circuit's conclusion related to the First Amendment issue, these too were probably properly decided.

VI. CONCLUSION

Anyone working in a health care field knows that the backdrop of health care laws, rules, and regulations is complex. The challenges arising from this regulatory background are not likely to decrease in the coming years. In fact, in light of new laws, such as the Affordable Care Act of 2010, the pressures on health care providers to find ways to work within the context of these laws are likely to increase. As such, we can expect to see more cases challenging interpretation of these laws brought by health care providers and those who work with them in an attempt to maintain or expand their practices.

190. *Id.*

191. *Id.* at 580.

192. *Id.* at 580-84.