

November 2015

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### Recommended Citation

DePaul College of Law, *Case Briefs*, 1 DePaul J. Health Care L. 655 (1997)  
Available at: <https://via.library.depaul.edu/jhcl/vol1/iss3/9>

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**Imposition of a Cap on Non-economic Damages  
Permissible When Plaintiff Refuses to  
Arbitrate Damages**

The District Court of Appeal of Florida, Fifth District, affirmed a lower court's decision to grant the defendant physician's motion to limit the amount of an arbitration award.<sup>1</sup> The court held the plaintiff in a medical malpractice action was subject to a non-economic damages cap when the plaintiff refused physician's offer to enter into arbitration as provided by state statute.

The plaintiff, as the personal representative of her eight-year-old daughter, brought a wrongful death action against her daughter's treating physician, his professional association, and various others.<sup>2</sup> In response, the treating physician offered to enter into binding arbitration under one of two arbitration provisions in the state medical malpractice act (Act).<sup>3</sup> The plaintiff refused, relying on a provision of the Act to argue that the physician's arbitration offer did not include an admission of liability and was, therefore, defective.<sup>4</sup> However, the physician's offer to arbitrate was made pursuant to a different section of the Act, requiring the imposition of sanctions upon a party who rejected the offer to submit to binding arbitration.<sup>5</sup> Under the section relied upon by the physician, the rejection of an arbitration offer placed a \$350,000 per incident cap on non-economic damages.<sup>6</sup>

The plaintiff argued the state statute regarding sanctions and a section requiring an admission of liability should be read *in pari materia*, thereby requiring the admission of liability set forth as a precondition to an offer to enter into arbitration. However, the court rejected this contention.<sup>7</sup> The court explained that the physician expressly made his offer to arbitrate under a section of the Act which did not require the admission of liability.

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<sup>1</sup>Platman v. Holmes Reg'l Medical Ctr., 683 So. 2d 671 (Fla. Dist. Ct. App. 1996).

<sup>2</sup>*Id.*

<sup>3</sup>*Id.* (citing FLA. STAT. ANN. § 766.207).

<sup>4</sup>*Id.* (citing FLA. STAT. ANN. § 766.106). Section 766.106 required an admission of liability when submitting to arbitration on the issue of damages.

<sup>5</sup>*Id.* at 673 (citing FLA. STAT. ANN. §§ 766.207 and 766.209).

<sup>6</sup>Platman v. Holmes Reg'l Medical Ctr., 683 So. 2d 671, 673 (Fla. Dist. Ct. App. 1996) (citing FLA. STAT. ANN. §§ 766.207 and 766.209). The Act, however, did not place a cap on potential damages upon rejection of an offer.

<sup>7</sup>*Id.*

Moreover, the court found the two sections were separate and distinct provisions of Act, and the plaintiff could not create a hybrid arbitration procedure by combining elements of both sections.<sup>8</sup> Therefore, plaintiff's rejection of defendant's offer to arbitrate required the imposition of a \$350,000 cap on non-economic damages.<sup>9</sup> *Platman v. Holmes Regional Med. Ctr.*, 683 So.2d 671 (Fla. Dist. Ct. App. 1996).

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## DISABILITY

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### Pseudonym Allowed in Civil Action for Benefits

The United States District Court for the Eastern District of Pennsylvania held parties were permitted to use a pseudonym when bringing civil actions if the privacy interests of the party outweighed the public's right of access to the identity of the litigant.<sup>10</sup> The court entered a protective order allowing the plaintiff to proceed in an action under a pseudonym pursuant to the Federal Rules of Civil Procedure which allow the court to enter a protective order upon a showing of "good cause" in order to protect a party from annoyance, embarrassment, oppression, or undue burden or expense.<sup>11</sup>

The plaintiff sought to obtain total disability benefits under a disability insurance policy issued by the defendant insurance company.<sup>12</sup> Subsequent to purchasing the policy, the plaintiff was diagnosed as suffering from a number of psychiatric disorders.<sup>13</sup> The patient underwent treatment for these illnesses and was unable to continue working.<sup>14</sup> The patient's employer subsequently paid him monthly benefits for a year and a half before terminating those benefits.<sup>15</sup> The plaintiff filed his complaint under

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<sup>8</sup>*Id.* at 674.

<sup>9</sup>*Id.*

<sup>10</sup>*Doe v. Provident Life & Accident Ins. Co.*, No. 96-5557, 1997 WL 9796, at \*1 (E.D. Pa. Jan. 8, 1997).

<sup>11</sup>*Id.* (citing FED. R. CIV. PRO. 26(c)).

<sup>12</sup>*Id.*

<sup>13</sup>*Id.*

<sup>14</sup>*Id.*

<sup>15</sup>*Doe v. Provident Life & Accident Ins. Co.*, No. 96-5557, 1997 WL 9796, at \*1 (E.D. Pa. Jan. 8, 1997).

the pseudonym "James Doe," seeking reinstatement of benefits.<sup>16</sup> The employer moved to strike the complaint under the Federal Rules of Civil Procedure which required the complaint to name all parties.<sup>17</sup>

The court cited several reasons for granting the plaintiff's motion to proceed under a pseudonym, including a desire to avoid deterring people with mental illness from litigation. The court also stated the plaintiff had used steps from the beginning of the case to assure confidentiality because he feared stigmatization in the community based on his mental disorder.<sup>18</sup> The court reasoned that the use of a pseudonym would not interfere with the public's right of access to civil proceedings, and that if the individual avoided litigation, the government may be forced to support him instead.<sup>19</sup> Because the employer had not been hampered in the discovery process, the court found the plaintiff possessed no ulterior motive in maintaining anonymity.<sup>20</sup> Thus, the court entered a protective order allowing the use of a pseudonym after finding "good cause" to do so.<sup>21</sup> *Doe v. Provident Life and Accident Ins. Co.*, No. 96-5557, 1997 WL 9790 (E.D. Pa. Jan. 8, 1997).

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### Cancer Diagnosis Does Not Establish Disability

The United States Court of Appeals for the Eleventh Circuit held that an employee who underwent chemotherapy and was subsequently fired from his job did not qualify as a disabled person; thus, the employee could not obtain relief under the Americans With Disabilities Act (ADA).<sup>22</sup> The ADA prohibits an employer from discriminating against a potential employee because of a disability.<sup>23</sup> In order to prove the existence of a disability within the meaning of the Act, an employee must prove that he or she has

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<sup>16</sup>*Id.*

<sup>17</sup>*Id.* (citing FED. R. CIV. PRO. 10(a)).

<sup>18</sup>*Id.* at \*3.

<sup>19</sup>*Doe v. Provident Life & Accident Ins. Co.*, No. 96-5557, 1997 WL 9796, at \*1 (E.D. Pa. Jan. 8, 1997).

<sup>20</sup>*Id.*

<sup>21</sup>*Id.* at \*5.

<sup>22</sup>*Gordon v. E.L. Hamm & Assocs.*, 100 F.3d 907 (11th Cir. 1996).

<sup>23</sup>*Id.* at 910 (citing 42 U.S.C. § 12112(a)).

a physical or mental impairment that substantially limits a major life activity or that people perceive him or her as having such an impairment.<sup>24</sup>

The employee in this case was hired by an employer who had contracted to do maintenance work for a military housing project.<sup>25</sup> When the employee was diagnosed with malignant lymphoma, he took an extended leave of absence from work to undergo certain tests. The employee's physician prescribed a course of treatment that included blood tests once a week and chemotherapy once every three weeks. The physician also said that this treatment would not interfere with the employee's normal activities, which included work. However, the employee's immediate supervisor did not allow the employee to return to work until he was instructed to do so by the vice president of the housing project. When the employee finally did resume working, his job description had changed significantly.<sup>26</sup> Shortly after his return to work, the employee and his supervisor had an argument which resulted in the employee's dismissal. The employee filed suit against the defendant and the jury found in his favor. The court denied the defendant's motion for judgment as a matter of law and this appeal followed.

From the facts of this case, the court found the employee was physically impaired because of the chemotherapy treatments he underwent, but this impairment did not limit any major life activities such as walking, breathing, speaking, learning, or working.<sup>27</sup> In order to show a disability "substantially limits" the activity of working, an employee must be significantly restricted in his ability to perform a job compared to an average person with comparable skills.<sup>28</sup> The court found a jury could not conclude that the employee in this case was limited in any of the specified major life activities, including his ability to work.<sup>29</sup> Specifically, the court noted the employee handled the side effects of chemotherapy well, and said himself that he was fully capable of working.<sup>30</sup>

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<sup>24</sup>*Id.*

<sup>25</sup>*Id.* at 909.

<sup>26</sup>*Id.*

<sup>27</sup>*Gordon v. E.L. Hamm & Assocs.*, 100 F.3d 907, 909 (11th Cir. 1996).

<sup>28</sup>*Id.* at 912 (citing C.F.R. § 1630.2(j)(3)(i)).

<sup>29</sup>*Id.*

<sup>30</sup>*Id.*

The court also concluded the employee was not regarded by his employer or co-employees as having an impairment.<sup>31</sup> To establish this contention, the employee had to show he had an impairment which imposed no physical limitations but was treated as such, or that he was limited in his physical capabilities only because of the attitudes of others regarding the impairment.<sup>32</sup> The court concluded that a finding could not be made that the employer viewed the employee as having an impairment.<sup>33</sup> The fact the employee did not have the exact same assignments as before his chemotherapy treatments was, in actuality, based on the nature of the project he was working on. The project required the employee to perform different activities than those he had worked on before his leave of absence because his old assignments had either been completed or taken over by other employees. Because the court found insufficient evidence to support a finding that the employee was either limited in his life activities, or that he was perceived as having a limiting impairment, the court held that the employee did not have a disability within the meaning of the ADA.<sup>34</sup> *Gordon v. E.L. Hamm & Assocs., 100 F.3d 907 (11th Cir. 1996).*

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## DISCRIMINATION

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### **Proof of Denial or Inadequate Treatment Required to Sustain Discrimination Charge Against Provider**

The United States District Court for the Eastern District of Pennsylvania granted summary judgment in favor of a hospital and various nurses in a discrimination suit brought against them by an HIV-positive patient under the Americans with Disabilities Act (ADA),<sup>35</sup> the Consolidated Omnibus

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<sup>31</sup>*Id.*

<sup>32</sup>*Gordon v. E.L. Hamm & Assocs., 100 F.3d 907, 912-913 (11th Cir. 1996).*

<sup>33</sup>*Id.*

<sup>34</sup>*Id.* at 914.

<sup>35</sup>*Doe v. Montgomery Hosp., No. CIV.A. 95-3168, 1996 WL 745524 (E.D. Pa. Dec. 23, 1996) (citing 42 U.S.C. § 12101).*

Budget Reconciliation Act (COBRA),<sup>36</sup> and the Rehabilitation Act of 1973.<sup>37</sup>

The patient sought treatment at the defendant hospital for two broken wrists sustained in an assault.<sup>38</sup> When the patient was first admitted to the hospital, he disclosed his HIV-positive status to a hospital employee.<sup>39</sup> Subsequently, the patient claimed he received inadequate and discriminatory treatment due to his HIV-positive status, and that hospital staff members impermissibly disclosed his HIV infection to numerous people, causing him to lose his job as a hairstylist and suffer extreme emotional and physical distress.<sup>40</sup> The patient brought an action against the hospital alleging that the discriminatory treatment he received as a patient violated the ADA, COBRA, and the Rehabilitation Act of 1973.<sup>41</sup>

The patient first alleged the hospital discriminated against him in violation of the ADA by denying him, *inter alia*, the opportunity to participate in the services and facilities of the hospital.<sup>42</sup> Although the patient was able to allege sufficient facts to demonstrate that he was disabled within the meaning of the ADA<sup>43</sup>, the court found the patient demonstrated no instance in which he was denied treatment on the basis of his HIV-positive status.<sup>44</sup> Because the patient offered no evidence that the hospital denied him care or gave him unequal care as a result of his HIV-positive status, the court concluded the patient failed to meet his burden of proving the hospital discriminated against him on the basis of his

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<sup>36</sup>*Id.* (citing 42 U.S.C. § 1395dd).

<sup>37</sup>*Id.* (citing 42 U.S.C. § 701).

<sup>38</sup>*Id.* at \*1.

<sup>39</sup>*Id.*

<sup>40</sup>*Doe v. Montgomery Hosp.*, No. Civ. A. 95-3168, 1996 WL 745524, at \*3 (E.D. Pa. Dec. 23, 1996).

<sup>41</sup>*Id.* The patient also asserted state law claims against the hospital for disclosure of his HIV-positive status, including claims for breach of the Pennsylvania Confidentiality of HIV-Related Information Act, 35 PA. CONS. STAT. ANN. § 7601 (1993), breach of physician-patient confidentiality, invasion of privacy through the public disclosure of private facts, negligent supervision and training, intentional infliction of emotional distress, slander, corporate liability, and punitive damages. The court, however, declined to exercise supplemental jurisdiction over these claims and dismissed them without prejudice for lack of subject matter jurisdiction pursuant to FED. R. CIV. P. 12(b)(1).

<sup>42</sup>*Id.* at \*4.

<sup>43</sup>*Id.*

<sup>44</sup>*Id.* at \*7.

disability.<sup>45</sup> Thus, the court granted summary judgment in favor of the hospital and its employees on each of the patient's claims under the ADA.<sup>46</sup>

The patient next alleged the hospital violated the Emergency Medical Treatment and Active Labor Act (EMTALA) provision of COBRA by failing to employ appropriate screening mechanisms and by failing to stabilize his emergency conditions.<sup>47</sup> To establish a violation of EMTALA, a claimant must demonstrate the following:

- (1) the patient had an emergency medical condition;
- (2) the hospital actually knew of this condition;
- (3) the patient was not stabilized before being transferred; and
- (4) prior to the transfer of an unstable patient, the transferring hospital did not obtain the proper consent or follow the appropriate certification and transfer procedures.<sup>48</sup>

In determining whether the patient alleged a sufficient cause of action under EMTALA, the court noted that recovery under EMTALA is limited to those circumstances in which a hospital fails to provide a patient suffering an emergency medical condition<sup>49</sup> with appropriate screening and stabilization prior to transfer or discharge.<sup>50</sup> Because the patient failed to produce any evidence that he suffered from an emergency medical condition or that he received inadequate or inappropriate screening of his condition, the court concluded the patient failed to state a claim against the hospital under EMTALA.<sup>51</sup> Therefore, the court granted summary judgment in favor of the hospital.<sup>52</sup>

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<sup>45</sup>*Doe v. Montgomery Hosp.*, No. Civ. A. 95-3168, 1996 WL 745524, at \*7 (E.D. Pa. Dec. 23, 1996).

<sup>46</sup>*Id.*

<sup>47</sup>*Id.*

<sup>48</sup>*Id.* at \*8 (citing *Holcomb v. Humana Medical Corp.*, 831 F. Supp. 829 (M.D. Ala. 1993), *aff'd sub nom.*, *Holcomb v. Monahan*, 30 F.3d 116 (11th Cir. 1994) (citing *Baber v. Hospital Corp. of Am.*, 977 F.2d 872, 883 (4th Cir. 1992)).

<sup>49</sup>*Id.* (citing *Tolton v. American Biodyne*, 854 F. Supp. 505 (N.D. Ohio 1993), *aff'd*, 48 F.3d 937 (6th Cir. 1995)). An emergency medical condition exists only if a patient is in imminent danger of death or serious injury.

<sup>50</sup>*Doe v. Montgomery Hosp.*, No. Civ. A. 95-3168, 1996 WL 745524, at \*8 (E.D. Pa. Dec. 23, 1996) (citing *Griffith v. Mount Carmel Medical Ctr.*, 831 F. Supp. 1532 (D. Kan. 1993)).

<sup>51</sup>*Id.*

<sup>52</sup>*Id.*



Finally, the patient claimed the alleged substandard treatment he received and the alleged disclosure of his HIV-positive status by the hospital constituted a violation of the Rehabilitation Act of 1973.<sup>53</sup> In evaluating the validity of the patient's claim under the Rehabilitation Act, the court noted the well-established principal that, "whether a suit is filed under the Rehabilitation Act or under the ADA, the substantive standards for determining liability are the same."<sup>54</sup> The court found that, due to the similar nature of statutes, Congress made it clear that identical standards should be applied to claims raised under either act.<sup>55</sup> Therefore, in compliance with the clear congressional intent of the ADA, the court concluded summary judgment on the plaintiff's claim under the Rehabilitation Act must also be granted in favor of the hospital.<sup>56</sup> *Doe v. Montgomery Hosp.*, No. Civ. A. 95-3168, 1996 WL 745524 (E.D. Pa. Dec. 23, 1996).

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### **Patient Claim of Disability Discrimination Based Upon Personal Relationship with Therapist That Interfered with Therapy**

The United States Court of Appeals for the Seventh Circuit upheld the dismissal of a claim alleging a violation of the Rehabilitation Act due to discrimination in a patient's treatment for a mental disorder.<sup>57</sup> The court reached its decision after reviewing the legislative history of the Rehabilitation Act, the statute itself, and case law relating to the Act.<sup>58</sup>

The patient was admitted to the hospital as a psychiatric patient<sup>59</sup> for a condition which was considered a handicap under the Rehabilitation

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<sup>53</sup>*Id.*

<sup>54</sup>*Id.* at \*9 (citing *Myers v. Hose*, 50 F.3d 278, 281 (4th Cir. 1995)).

<sup>55</sup>*Doe v. Montgomery Hosp.*, No. Civ. A. 95-3168, 1996 WL 745524, at \*9 (E.D. Pa. Dec. 23, 1996).

<sup>56</sup>*Id.*

<sup>57</sup>*Grzan v. Charter Hosp. of Northwestern Ind.*, 104 F.3d 116 (7th Cir. 1997).

<sup>58</sup>*Id.* at 123.

<sup>59</sup>*Id.* at 118. Ms. Grzan was admitted for "major depressive episode," "borderline personality disorder," and "post-traumatic stress disorder," all of which constitute a handicap under the Rehabilitation Act.

Act.<sup>60</sup> The patient was treated by a therapist employed by the hospital.<sup>61</sup> During her hospitalization, the patient became intimately involved with the therapist, and continued this intimate relationship even after discharge from the hospital.<sup>62</sup> Two years after the relationship ended, the patient filed a suit against the hospital and the therapist alleging disability discrimination that prohibited her from receiving adequate treatment for her handicap.<sup>63</sup> The patient's claim was dismissed based on the Congressional intent that the statute apply only to people denied employment opportunities and program accessibility based on disability discrimination.<sup>64</sup>

The issue presented to this court was whether the patient's claim fell under the Rehabilitation Act.<sup>65</sup> The court reviewed the statute as applied, the legislative history, and the case law to determine whether the patient had a claim.<sup>66</sup> First, the Rehabilitation Act covers only those programs or entities that receive federal funds and although the hospital received federal funds, the therapist, as an employee of the hospital, did not.<sup>67</sup> However, the patient's "denial" of proper treatment was due to the therapist's actions, and not discrimination by the hospital.<sup>68</sup> Further, the patient's claim was based on a comparison between her treatment and the treatment of other handicapped patients, yet the Rehabilitation Act was meant to apply only when handicapped and non-handicapped people were treated differently.<sup>69</sup>

Finally, the therapist's relationship with the patient was not part of the hospital's treatment plan, and further, if the Rehabilitation Act had been

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<sup>60</sup>*Id.*

<sup>61</sup>*Id.*

<sup>62</sup>*Grzan v. Charter Hosp. of Northwestern Ind.*, 104 F.3d 116, 118 (7th Cir. 1997).

<sup>63</sup>*Id.*

<sup>64</sup>*Id.*

<sup>65</sup>*Id.*

<sup>66</sup>*Id.* Ms. Grzan had to prove four elements to survive the motion to dismiss: (1) she was handicapped under the definition in the act; (2) she was qualified for the benefit she sought; (3) she was discriminated against only because of her handicap; and (4) the program in question received federal funds.

<sup>67</sup>*Id.*

<sup>68</sup>*Id.* at 122.

<sup>69</sup>*Id.* The legislative history of §504 of the Rehabilitation Act of 1973, 39 U.S.C. § 794, indicated to the court Congress intended the act to provide equal employment and program accessibility to people with disabilities, not to complaints regarding a handicapped person's "receipt of benefits."

applicable, it would only cover the treatment plan of an institution, and not the individual behavior of a particular employee.<sup>70</sup> Thus, the court concluded the patient's claim was improper under the Rehabilitation Act, and should have been brought under a tort theory instead.<sup>71</sup> *Grzan v. Charter Hosp. of Northwestern Ind.*, 104 F.3d 116 (7th Cir. 1997).

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## Employment Contracts

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### Discharge of Medical Student for Educational Reasons Does Not Breach Hospital-Residency Agreement

The Supreme Court of Connecticut held that a hospital did not breach a residency agreement when it discharged a resident because he failed to meet educational standards. The Court reasoned the context in which the resident was discharged was based not on an employment relationship, but on an educational decision.<sup>72</sup>

A resident physician was dismissed during the final year of his surgical residency training program.<sup>73</sup> The resident and the hospital had entered into a residency agreement which was subject to yearly renewal, dependent upon a favorable evaluation by faculty members at the hospital.<sup>74</sup> In his fourth year, the hospital determined that the resident did "not show any potential for being a safe and independent" surgeon and dismissed him.<sup>75</sup> The resident sought damages from the hospital for an alleged breach of an employment contract.<sup>76</sup> The trial court granted the hospital's motion for summary and the state supreme court affirmed on appeal.

First, the court held that the resident failed to identify any disputed issues of material fact which would characterize his relationship with the hospital as coming under an "employment contract."<sup>77</sup> The court assessed

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<sup>70</sup>*Id.* at 123.

<sup>71</sup>*Grzan v. Charter Hosp. of Northwestern Ind.*, 104 F.3d 116, 123 (7th Cir. 1997).

<sup>72</sup>*Gupta v. New Britain Gen. Hosp.*, 687 A.2d 111 (Conn. 1996).

<sup>73</sup>*Id.* at 113-114.

<sup>74</sup>*Id.*

<sup>75</sup>*Id.* at 114.

<sup>76</sup>*Id.*

<sup>77</sup>*Gupta v. New Britain Gen. Hosp.*, 687 A.2d 111, 115 (Conn. 1996).

the nature of the resident's employment status through the language of the residency agreement.<sup>78</sup> The court concluded that despite the hybrid nature of the residency agreement which contained both employment and educational features,<sup>79</sup> the fact that the resident was dismissed due to poor clinical performance implicated the educational component of the residency agreement and was, therefore, an academic decision.<sup>80</sup>

Next, the resident alleged that even if his dismissal was properly grounded on academic reasons, the hospital (1) failed to provide him with appropriate training, and (2) discharged him arbitrarily, capriciously, or in bad faith.<sup>81</sup> With regard to the former claim, the court followed the common law rule that "educational malpractice" claims were not cognizable; because they put the judiciary in the awkward position of defining what was a reasonable educational program and of deciding whether that standard has been breached.<sup>82</sup> With regard to the second claim, the court's approach was one of academic deference, particularly in the area of medical education.<sup>83</sup> The resident did not satisfy the heavy burden of showing the hospital's decision had "no discernible rational basis," the test required to implicate substantive due process in this type of case.<sup>84</sup> Because the hospital's decision to dismiss the resident was both educational and rational, the court affirmed summary judgment in favor of the hospital. *Gupta v. New Britain Gen. Hosp.*, 687 A.2d 111 (Conn. 1996).

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<sup>78</sup>*Id.*

<sup>79</sup>*Id.* at 116. On the one hand, the agreement provided that the "objective" of the program was to provide a "proper educational experience" and the "program covered by this agreement is part of an overall program of education." Conversely, the agreement contained provisions indicative of an employment contract such as salary, insurance coverage, and vacation time.

<sup>80</sup>*Id.* at 117.

<sup>81</sup>*Id.*

<sup>82</sup>*Gupta v. New Britain Gen. Hosp.*, 687 A.2d 111, 119 (Conn. 1996) (citing *Peter W. v. San Francisco Unified School District*, 60 Cal. App. 3d . 814 (1976)).

<sup>83</sup>*Id.* at 119.

<sup>84</sup>*Id.*

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**EVIDENCE**

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**DNA Population Frequency Statistics Admissible  
Only After Satisfying *Frye* Test**

The Supreme Court of Florida held that DNA evidence was not admissible unless both distinct steps of the DNA testing process satisfied the requirements delineated for new or novel scientific evidence announced in *Frye v. United States*.<sup>85</sup> The *Frye* test requires a judicial determination, based upon a preponderance of the proponent's evidence, that the underlying principles have been sufficiently tested and accepted among the relevant scientific community.<sup>86</sup>

The court began its analysis by clarifying the two distinct steps in the DNA testing process. The first step results in an indication that two DNA samples look the same and according to the court, this step will always satisfy the *Frye* test if conducted properly.<sup>87</sup> The second step involves a quantitative, scientifically valid estimate showing how closely the two patterns match.<sup>88</sup> The court explained the second step is necessary to give significance to the first step, and assists a court or jury to understand the importance of a match.<sup>89</sup> The court stated the second step in the DNA testing process was based on principles of statistics and population genetics, and therefore, the *Frye* test was an appropriate validation method.<sup>90</sup> The court also refuted arguments that the calculation of population frequency statistics was not new or novel.

After determining that both steps in the DNA testing process required satisfaction of *Frye*, the court addressed the issue of whether two or more different frequency calculations could simultaneously satisfy *Frye*. The court explained that while two conflicting calculations could not both typically satisfy *Frye*, an alternative modification of the DNA testing

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<sup>85</sup>*Brim v. State*, 695 So. 2d 268 (Fla. 1997) (citing *Frye v. United States*, 293 F.2d 1013 (D.C. Cir. 1923)).

<sup>86</sup>*Id.* at 272 (citing *Ramirez v. State*, 651 So. 2d 1164 (Fla. 1995)).

<sup>87</sup>*Id.* at 269.

<sup>88</sup>*Id.* at 270.

<sup>89</sup>*Id.*

<sup>90</sup>*Brim v. State*, 695 So. 2d 268, 270 (Fla. 1997).

procedure would be admissible if it satisfied *Frye*.<sup>91</sup> As an example, the court explained the differences between a "ceiling principle" and a "modified ceiling principle," both of which are methods of determining how closely two DNA patterns match.<sup>92</sup> The modified version was created after the original version was found to give extremely conservative results. Although the original version is no longer used, it is still considered a reliable method; thus, both the original and modified principles are capable of simultaneously satisfying *Frye*.

The court remanded this case for further evidentiary determinations because of significant changes in the science of DNA testing since the beginning of the trial.<sup>93</sup> The court found it was unable to make a decision in this case without knowledge of the state's exact methods of calculating population frequency statistics at the time of the trial.<sup>94</sup> *Brim v. State*, 645 So. 2d 268 (Fla. 1997).

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### Evidence Excluded in Products Liability Action

The United States Court of Appeals for the Fifth Circuit held that evidence which merely suggested a link between Ethylene Oxide exposure and increased risk of brain cancer, and was only clearly linked to causation of brain tumors in animal studies, did not rise to the level of evidentiary sufficiency under the federal rules of evidence to allow the admission of such evidence in a products liability action.<sup>95</sup>

An employee who worked at a hospital for over twenty years died of brain cancer.<sup>96</sup> His family brought a products liability action against the manufacturers of Ethylene Oxide (EtO) cylinders, alleging the employee had been exposed to EtO while employed at the hospital, and that such

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<sup>91</sup>*Id.* at 271.

<sup>92</sup>*Id.*

<sup>93</sup>*Id.* at 274.

<sup>94</sup>*Id.*

<sup>95</sup>*Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194 (5th Cir. 1996) (citing FED. R. EVID. 702, FED. R. EVID. 703).

<sup>96</sup>*Id.*

exposure was the cause of his death.<sup>97</sup> The trial court granted the manufacturer's motion for judgment as a matter of law on the grounds that the opinions of all three of the plaintiff's experts were inadmissible in federal court for lack of scientific grounding. The appellate court affirmed. The court excluded evidence produced by the plaintiff's expert witnesses including:

- (1) human epidemiological studies that merely "suggested" an association between EtO exposure and brain cancer;
- (2) studies that showed EtO was capable of causing tumors in certain rats; and
- (3) the fact the EtO was a known carcinogen.<sup>98</sup> The court held that "suggestive" evidence<sup>99</sup> and "inconclusive" animal studies<sup>100</sup> were not sufficient to scientifically support a causal connection between EtO exposure and human brain cancer.<sup>101</sup>

Next, the court determined the "weight of the evidence" standard<sup>102</sup> used by regulatory and advisory bodies, such as the Environmental Protection Agency (EPA), was not scientifically acceptable in demonstrating a medical link between EtO exposure and brain cancer.<sup>103</sup> The court stated the "weight of the evidence" standard was lower<sup>104</sup> than the standard appropriate in tort law which required a more particularized showing of cause and effect and required a plaintiff to prove "that it is more likely than not that another individual has caused him or her harm."<sup>105</sup> *Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194 (5th Cir. 1996).

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<sup>97</sup>*Id.*

<sup>98</sup>*Id.* at 196.

<sup>99</sup>*Id.* at 197.

<sup>100</sup>*Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194, 196 (5th Cir. 1996).

<sup>101</sup>*Id.* at 197.

<sup>102</sup>*Id.* at 198. This "weight of the evidence" standard is one used by regulatory and advisory bodies such as the EPA to assess the carcinogenicity of various substances in human beings and to suggest or make rules governing human exposure.

<sup>103</sup>*Id.*

<sup>104</sup>*Id.* The agencies' lower burden of proof is based on the preventative perspective that the agencies adopt in order to reduce public exposure to harmful substances.

<sup>105</sup>*Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194, 198 (5th Cir. 1996) (citing *Wright v. Willamette Industries*, 91 F.3d 1105, 1107 (8th Cir. 1996)).

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**EXPERT WITNESS**

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**Witness' Testimony Inadmissible When Theory on Use of Bone Marrow Transplants Not Widely Accepted**

The Court of Appeals of Minnesota upheld a trial court's grant of a judgment notwithstanding the verdict (JNOV) in a medical malpractice suit, because the trustees of the deceased patient based their entire proof of causation on a medical expert's testimony which was later determined inadmissible.<sup>106</sup> The court reached its decision after analyzing the witness' testimony under both the *Daubert* and *Frye* standard, and found the testimony did not satisfy either test.<sup>107</sup>

At age nine, the decedent was diagnosed with attention deficit disorder by the physicians in this case.<sup>108</sup> Two years later, a specialist discovered that the decedent suffered from a degenerative brain disease called metachromatic leukodystrophy (MLD) which, without treatment, would eventually result in death.<sup>109</sup> A specialist recommended a bone marrow transplant (BMT)<sup>110</sup> and the trustees consented to a transplant with an unrelated donor.<sup>111</sup> Six months after the BMT, the decedent died from a fungal infection which was systemic, but largely attacked his brain.<sup>112</sup> The trustees brought a malpractice claim against the physicians who had first diagnosed the decedent with attention deficit disorder, claiming their misdiagnosis delayed treatment of the decedent and led to his death.<sup>113</sup>

The issue presented to the court was whether a medical expert's testimony to prove causal link between the original physician's misdiagnosis and the decedent's death was impermissible, making the grant of the JNOV proper.<sup>114</sup> The trial court reserved its ruling on a motion in

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<sup>106</sup>Wesely v. Alexander, No. CO-96-613, 1996 WL 722084 (Minn. Dec. 19, 1996).

<sup>107</sup>*Id.* at \*3-4. See *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) and *Daubert v. Merrell-Dow Pharmaceutical*, 509 U.S. 579 (1996).

<sup>108</sup>*Id.* at \*4-6.

<sup>109</sup>*Id.* at \*1.

<sup>110</sup>*Id.* at \*2.

<sup>111</sup>Wesely v. Alexander, No. CO-96-613, 1996 WL 722084, at \*2 (Minn. Dec. 19, 1996).

<sup>112</sup>*Id.*

<sup>113</sup>*Id.*

<sup>114</sup>*Id.*



limine to exclude the testimony of the expert for the trustees.<sup>115</sup> Instead, the admissibility of the testimony was reviewed during the trial at the same time the jury heard the testimony.<sup>116</sup> After the jury returned a verdict for the trustees, the court granted the motion for JNOV, stating the expert's testimony did not pass the *Frye* test for admissibility and was the only evidence the trustees had to prove causation.<sup>117</sup> The *Frye* standard, typically used by courts in the state, requires the witness to be an expert and his principle of BMT with MLD to be a well-recognized scientific principle.<sup>118</sup> In this case, the expert's testimony did not pass the *Frye* test because BMT treatment was not a generally accepted treatment for MLD in the medical field. Moreover, the specifics of the procedure performed here were rare, therefore, it could not be proven that the decedent would have lived if the treatment had been given two years earlier, at the time of the misdiagnosis.<sup>119</sup>

The court also analyzed the case under *Daubert* and found the procedure satisfied the requirement that the procedure be a medically tested and published treatment.<sup>120</sup> However, because the treatment was so rare and the potential rate of error was uncertain, the procedure had not yet been "generally accepted by the scientific community."<sup>121</sup> Therefore, the court concluded the expert's testimony stating that BMT would have saved the decedent's life if it had been performed earlier did not pass either the *Frye* or *Daubert* tests. Because the trustees' entire showing of causation rested upon this expert's testimony, the grant of JNOV was

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<sup>115</sup>*Id.*

<sup>116</sup>*Wesely v. Alexander*, No. CO-96-613, 1996 WL 722084, at \*2 (Minn. Dec. 19, 1996). The court's reason for permitting the trial to proceed before determining the admissibility of the evidence was to promote judicial economy, a faster trial. *Id.*

<sup>117</sup>*Id.*; *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). The *Frye* court stated the principle that the expert witness' testimony is based on must be "sufficiently established to have gained general acceptance in the particular field in which it belongs."

<sup>118</sup>*Wesely*, 1996 WL 722084 at \*5.

<sup>119</sup>*Id.* The plaintiff's expert witness was considered an expert witness in his field, just his procedure was in question. *Id.*

<sup>120</sup>*Id.* (citing *Daubert v. Merrell-Dow Pharmaceutical, Inc.*, 509 U.S. 579 (1993)). The *Daubert* court stated that the testimony the expert witness is giving must "assist the trier of fact to understand a fact in issue." For this to be accomplished, a preliminary assessment to guarantee the testimony is scientifically valid and the methodology can be applied to the specific facts of the case must be done.

<sup>121</sup>*Wesely v. Alexander*, No. CO-96-613, 1996 WL 722084, at \*6 (Minn. Dec. 19, 1996).

proper. *Wesely v. Alexander*, No. CO-96-613, 1996 WL 722084 (Minn. Dec. 19, 1996).

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**Expert Witnesses Against Pharmaceutical  
Manufacturer and Prescribing Physician Must Meet  
*Daubert* Standard for Scientific Testimony**

The United States Court of Appeals for the District of Columbia reversed a lower court's grant of summary judgment in favor of a drug manufacturer, and remanded the case for further proceedings consistent with the court's determination that the testimony of the plaintiff's expert witnesses satisfied the *Daubert* standard.<sup>122</sup>

The plaintiff and her parents filed suit against the manufacturer of the drug Depo-Provera and the physician who prescribed it, alleging the drug caused birth defects with which plaintiff was born.<sup>123</sup> The manufacturer moved for summary judgment, claiming the plaintiff failed to provide scientific evidence linking the drug to the birth defects.<sup>124</sup> In response, the plaintiff submitted the affidavits of two physicians -- an epidemiologist and a teratologist.<sup>125</sup> Because both physicians failed to identify publications, studies, or methodologies upon which they based their testimony, the district court granted summary judgment for the manufacturer noting the experts' opinions were "conclusory and unsupported."<sup>126</sup> Plaintiff appealed, and the district court reversed and remanded for further inquiry into whether the expert testimony was admissible.<sup>127</sup> On remand, the district court ruled the expert testimony was inadmissible and insufficient to create an issue of material fact, and therefore, summary judgment for the manufacturer was appropriate. Plaintiff appealed again.

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<sup>122</sup>*Ambrosini v. Labarraque*, 101 F.3d 129 (D.C. Cir. 1996) (citing *Daubert v. Merrell Dow Pharmaceutical Inc.*, 509 U.S. 579, 597 (1993)).

<sup>123</sup>*Id.* at 131.

<sup>124</sup>*Id.*

<sup>125</sup>*Id.* at 132.

<sup>126</sup>*Id.*

<sup>127</sup>*Ambrosini v. Labarraque*, 101 F.3d 129, 132 (D.C. Cir. 1996).

Relying on *Daubert*, the appellate court explained that the district court performed a "gate keeping" role in assessing the admissibility of scientific testimony.<sup>128</sup> When determining the admissibility of such evidence, the court must satisfy a two-prong test. First, the testimony must be based upon scientific knowledge which requires the testimony be derived through the use of the "scientific method."<sup>129</sup> Second, the testimony must assist the trier of fact to understand a fact at issue.<sup>130</sup>

The plaintiff's first expert, an epidemiologist, asserted a general causal link between Depo-Provera and the brain defect from which plaintiff suffered. The epidemiologist testified his conclusion was premised upon standard epidemiological methods. After setting forth the method employed, the court held the testimony of the epidemiologist satisfied the first prong of the *Daubert* standard.<sup>131</sup> Further, because the testimony could assist the jury in deciding the case, the court found the epidemiologist's testimony satisfied the second prong and was, therefore, admissible.<sup>132</sup>

Next, the court addressed the testimony of the second expert, the teratologist, and found that this expert's findings were based upon an accepted methodology which was confirmed by journal publications.<sup>133</sup> Furthermore, the court found the testimony was not controverted by any epidemiological evidence, and therefore, satisfied the *Daubert* standard.<sup>134</sup> Because the testimony of both physicians satisfied the *Daubert* standard, the court held the testimony was admissible and summary judgment was reversed. *Ambrosini v. Labarraque*, 101 F.3d 129 (D.C. Cir. 1996).

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<sup>128</sup>*Id.* (citing *Daubert v. Merrell Dow Pharmaceutical*, 509 U.S. 579, 592-93 (1993)).

<sup>129</sup>*Id.* at 133.

<sup>130</sup>*Id.*

<sup>131</sup>*Id.* at 136.

<sup>132</sup>*Ambrosini v. Labarraque*, 101 F.3d 129, 136 (D.C. Cir. 1996).

<sup>133</sup>*Id.* at 137.

<sup>134</sup>*Id.*

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**INFORMED CONSENT**

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**Surgical Incision and Scarring Necessary Part  
of Vasectomy Procedure, Not Material Risk**

The Court of Appeal of Louisiana, Third Circuit, affirmed the trial court's grant of summary judgment in favor of defendant physician in a medical malpractice action.<sup>135</sup> The court held that an informed consent issue did not exist where the patient had consented to the vasectomy procedure.<sup>136</sup>

The patient was examined by the defendant physician in order to obtain a "no scalpel" vasectomy.<sup>137</sup> Since this type of vasectomy procedure entailed a smaller incision than a conventional vasectomy, minimal bleeding occurred and no stitches were necessary.<sup>138</sup> Prior to surgery, the patient was informed of possible risks and complications of the procedure and subsequently, the patient and his wife signed a consent form.<sup>139</sup> The physician successfully performed the "no scalpel" vasectomy on the patient's left side, however, difficulties arose while trying to perform the procedure on the patient's right side, and the physician was unable to complete the procedure.<sup>140</sup> The physician explained to the patient the difficulties which had arisen and the various treatment options at that point.<sup>141</sup> The patient disliked the idea of having the procedure completed at a later time and authorized the physician to make an incision in order to complete the vasectomy.<sup>142</sup>

After the operation, the patient was dissatisfied with the length of the incision, which required several stitches and resulted in a scar.<sup>143</sup> Instead of returning to the defendant physician for post-operative care, the patient was examined by two other urologists.<sup>144</sup> The first physician assured the

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<sup>135</sup>Hayes v. Autin, 685 So. 2d 691 (La. Ct. App. 1996).

<sup>136</sup>*Id.* at 696.

<sup>137</sup>*Id.* at 692.

<sup>138</sup>*Id.*

<sup>139</sup>*Id.*

<sup>140</sup>Hayes v. Autin, 685 So. 2d 691 (La. Ct. App. 1996).

<sup>141</sup>*Id.*

<sup>142</sup>*Id.*

<sup>143</sup>*Id.*

<sup>144</sup>*Id.* at 693.

patient the tenderness was normal following the procedure.<sup>145</sup> About a month later, the second physician prescribed an antibiotic and painkillers since the patient still complained of tenderness.<sup>146</sup> Despite a medical review panel's determination that the defendant physician did not breach the appropriate standard of care, the patient filed suit against the physician and his insurance carrier.<sup>147</sup> The trial court granted the defendant physician's motion for summary judgment to which plaintiff appealed.<sup>148</sup> First, the court assessed the applicable standard for summary judgment.<sup>149</sup> The court adopted the more liberal federal standard for summary judgment, maintaining that a recent amendment to the state code of civil procedure supported such an interpretation.<sup>150</sup> Second, the court determined the applicable state law regarding informed consent.<sup>151</sup> The court explained that a patient must be informed of the material risks of a procedure.<sup>152</sup> Thus, if a reasonable person would have foregone the procedure if he or she had known of the undisclosed risk, the physician's failure to inform would be the cause of the patient's injury.<sup>153</sup> The court concluded that the patient's injury, namely the larger incision and subsequent scar, was a necessary part of the procedure rather than a material risk.<sup>154</sup> Further, the court found that the patient had consented to the larger incision in order to ensure sterilization, thereby supporting the trial court's granting of summary judgment since no material issue of fact existed.<sup>155</sup> *Hayes v. Autin*, 685 So. 2d 691 (La. Ct. App. 1996).

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<sup>145</sup>*Hayes v. Autin*, 685 So. 2d 691 (La. Ct. App. 1996).

<sup>146</sup>*Id.*

<sup>147</sup>*Id.*

<sup>148</sup>*Id.* at 693-94.

<sup>149</sup>*Id.*

<sup>150</sup>*Hayes v. Autin*, 685 So. 2d 691, 694-95 (citing LA. CODE CIV. P. Art. 966, No. 89, § 1 (1984) (amended by Act of May 1, 1996, No. 9, § 1)).

<sup>151</sup>*Id.* at 695.

<sup>152</sup>*Id.*

<sup>153</sup>*Id.*

<sup>154</sup>*Id.* at 695.

<sup>155</sup>*Hayes v. Autin*, 685 So. 2d 696 (La. Ct. App. 1996).

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**Insurance**

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**Fiduciary of Health Care Plan Lacked Standing to  
Bring Suit Under ERISA to Recover  
Benefits for Employee**

The United States Court of Appeals for the Fourth Circuit reversed the judgment of the district court by granting summary judgment to an employer in an Employee Retirement Income Security Act of 1974 (ERISA) action.<sup>156</sup> The court held that the employer, as the fiduciary of a health care plan, could not recover benefits for employees under ERISA because the employer lacked standing to bring suit.<sup>157</sup>

In an attempt to reduce its premiums, the employer canceled a group insurance plan, replacing it with a reinsurance policy and a self-insured plan.<sup>158</sup> An employee who was not working at the time the old plan was replaced, and did not return to work prior to his readmittance to the hospital for a heart condition, died.<sup>159</sup> Prior to death, the employee incurred substantial medical expenses amounting to \$160,000 that were paid by his employer.<sup>160</sup> Since the employee did not work on the effective date of the new plan and did not return to work before his death, the employee was not covered by the new reinsurance policy or self-funded plan.<sup>161</sup> The employer attempted to obtain reimbursement from the former insurance company and subsequently filed suit when the former insurance company declined payment.<sup>162</sup> The employer alleged the insurance company breached its fiduciary duties by refusing to pay the employee's medical expenses.<sup>163</sup> Specifically, the employer sought \$160,000 in damages and requested specific performance of the former plan.<sup>164</sup>

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<sup>156</sup>Coyne & Delany Co. v. Blue Cross & Blue Shield, 102 F.3d 712 (4th Cir. 1996).

<sup>157</sup>*Id.* at 713.

<sup>158</sup>*Id.*

<sup>159</sup>*Id.*

<sup>160</sup>*Id.*

<sup>161</sup>Coyne & Delany Co. v. Blue Cross & Blue Shield, 102 F.3d 712, 713 (4th Cir. 1996).

<sup>162</sup>*Id.*

<sup>163</sup>*Id.*

<sup>164</sup>*Id.*

Although the employer was denied monetary recovery, the lower court held the employee was indeed covered under the former insurance plan.<sup>165</sup> Accordingly, the court ordered the former insurance company to pay the employee's medical expenses incurred between the date the new plan became effective and the employee's death.<sup>166</sup> The insurance company appealed, arguing that a fiduciary, such as the employer, was not entitled to recover benefits for a participant under ERISA.<sup>167</sup>

On appeal, the court reversed the judgment of the district court, holding the employer lacked standing to recover benefits for the employee under ERISA.<sup>168</sup> First, the court found that fiduciaries did not have a cause of action under ERISA since the relevant provision stated that only "participants" or "beneficiaries" may sue for benefits.<sup>169</sup> Second, the court relied on *Massachusetts Mutual Life Ins. Co. v. Russell* for the proposition that ERISA permitted recovery only for the plan as a whole, rather than for individual beneficiaries.<sup>170</sup> Third, the court stated that the language of ERISA suggested that Congress intended ERISA to apply to more general violations of the plan as opposed to relief for individual beneficiaries.<sup>171</sup> The court reasoned that Congress did not intend to provide fiduciaries with a cause of action for benefits under ERISA, particularly since Congress addressed fiduciary actions under separate provisions of the Act, and did not include fiduciaries in the provisions relating to causes of actions for benefits.<sup>172</sup>

The court acknowledged the United States Supreme Court's statement in *Varity Corp. v. Howe* that ERISA could be construed to provide relief for breach of a fiduciary duty in cases where adequate relief was not provided.<sup>173</sup> However, the court distinguished *Varity* on the basis the plaintiffs in *Varity* were former plan participants, not fiduciaries as was the case in this action.<sup>174</sup> The court concluded the remedy under ERISA for

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<sup>165</sup>*Id.*

<sup>166</sup>*Coyne & Delany Co. v. Blue Cross & Blue Shield*, 102 F.3d 712, 713-14 (4th Cir. 1996).

<sup>167</sup>*Id.* at 714.

<sup>168</sup>*Id.* at 717. The employer's suit was brought under § 502(a)(1) of ERISA.

<sup>169</sup>*Id.* at 714.

<sup>170</sup>*Id.* at 714-15 (citing *Mass. Mutual Life Ins. Co. v. Russell*, 473 U.S. 134 (1985)).

<sup>171</sup>*Coyne & Delany Co. v. Blue Cross & Blue Shield*, 102 F.3d 712, 715 (4th Cir. 1996).

<sup>172</sup>*Id.*

<sup>173</sup>*Id.* at 716 (citing *Varity Corp. v. Howe*, 116 S.Ct. 1065 (1996)).

<sup>174</sup>*Id.* at 716.

payment of benefits was adequate without permitting fiduciaries to sue, as was evidenced by the absence of other fiduciaries filing suit for benefits.<sup>175</sup> The court further reasoned that denying fiduciaries recovery was consistent with the ERISA exhaustion requirement mandating claimants use internal claim procedures since fiduciaries do not have the requisite medical information to file such claims.<sup>176</sup> *Coyne & Delany Co. v. Blue Cross & Blue Shield, Inc.*, 102 F.3d 712 (4th Cir. 1996).

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### **Hospital Lacks Standing to File Suit for Payment of Medical Expenses Against Insurance Company as Fiduciary for ERISA Plan**

The United States Court of Appeals for the Fourth Circuit affirmed the district court's decision to grant summary judgment in favor of the defendant employer in a suit brought by a hospital under the Employee Retirement Income Securities Act of 1974 (ERISA).<sup>177</sup> The court held the hospital lacked standing to file a suit against the employer because the insurance company that provided the ERISA plan was not a fiduciary, and therefore, lacked the authority necessary to alter the plan.<sup>178</sup>

The employer maintained a self-insured ERISA welfare plan for its employees.<sup>179</sup> Pursuant to a contract, an insurance company provided administrative services for the employer, although the insurance company did not have the authority to alter the ERISA plan.<sup>180</sup> An employee of the defendant enrolled himself as a participant in the ERISA plan, choosing not to enroll any dependent children as beneficiaries.<sup>181</sup> When the employee's son was taken to the plaintiff hospital for rehabilitation therapy, the child's

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<sup>175</sup>*Id.*

<sup>176</sup>*Coyne & Delany Co. v. Blue Cross & Blue Shield*, 102 F.3d 712, 716-17 (4th Cir. 1996).

<sup>177</sup>*Healthsouth Rehabilitation Hosp. v. American Nat'l Red Cross*, 101 F.3d 1005 (4th Cir. 1996).

<sup>178</sup>*Id.* at 1009.

<sup>179</sup>*Id.* at 1006.

<sup>180</sup>*Id.* at 1006-07.

<sup>181</sup>*Id.* at 1007.



mother stated the child was covered under his father's insurance plan.<sup>182</sup> Before providing any treatment, the hospital's admissions coordinator telephoned the insurance company to verify the child's coverage under the ERISA plan.<sup>183</sup> The insurance company's representative incorrectly informed the hospital coordinator that the child was covered.<sup>184</sup> Over a month later, an employee of the hospital was notified that the child was not a beneficiary of his father's plan.<sup>185</sup> Shortly thereafter, the child was discharged from the hospital having incurred medical expenses totaling \$82,967.<sup>186</sup> Because the employer refused to pay the child's medical bills, the hospital filed suit.<sup>187</sup> The district court granted summary judgment for the employer, and the hospital appealed.<sup>188</sup>

The court of appeals affirmed the district court's conclusion that the hospital lacked standing to file suit under ERISA.<sup>189</sup> The insurance company was found not to be a fiduciary under the ERISA plan, the court reasoned, since the insurance company's duties were limited to processing claims and determining which individuals were covered by looking at a computer screen.<sup>190</sup> Since the insurance company was not a fiduciary, the insurance company lacked the authority to extend the ERISA plan's coverage to a non-beneficiary.<sup>191</sup> The court further stated that even if the insurance company was a fiduciary, the oral representations made by the employer that a child was covered would not be sufficient to extend coverage since modifications to the plan must be in writing and must comply with formal amendment procedures.<sup>192</sup>

Additionally, the court affirmed the district court's discovery ruling rejecting the hospital's argument that it did not have sufficient time to

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<sup>182</sup> *Healthsouth Rehabilitation Hosp. v. American Nat'l Red Cross*, 101 F.3d 1005, 1007 (4th Cir. 1996).

<sup>183</sup> *Id.*

<sup>184</sup> *Id.*

<sup>185</sup> *Id.*

<sup>186</sup> *Id.*

<sup>187</sup> *Healthsouth Rehabilitation Hosp. v. American Nat'l Red Cross*, 101 F.3d 1005, 1007 (4th Cir. 1996).

<sup>188</sup> *Id.* at 1008.

<sup>189</sup> *Id.*

<sup>190</sup> *Id.* at 1009.

<sup>191</sup> *Id.*

<sup>192</sup> *Healthsouth Rehabilitation Hosp. v. American Nat'l Red Cross*, 101 F.3d 1005, 1009 (4th Cir. 1996).

complete discovery.<sup>193</sup> The court explained that additional time for discovery would not change the fact that the child was not entitled to coverage under the plan.<sup>194</sup> Finally, the court upheld the district court's refusal to allow the hospital to amend its complaint to include an estoppel cause of action.<sup>195</sup> The court found that written plans have never been changed based on estoppel arguments.<sup>196</sup> *Healthsouth Rehabilitation Hosp. v. American Nat'l Red Cross*, 101 F.3d 1005 (4th Cir. 1996).

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### IMMUNITY

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#### **Qualified Immunity Granted to Public Health Department Publishing Manual Identifying Certain HIV-Infected Participants in State Program**

The United States Court of Appeals for the Second Circuit upheld a district court order granting the state department of education's (Department) motion for summary judgment on the basis of qualified immunity after the department published and distributed an AIDS prevention manual identifying the plaintiffs as HIV- positive.<sup>197</sup>

The plaintiffs were HIV-positive individuals who participated in educational seminars for social workers and educators focusing on HIV prevention.<sup>198</sup> The defendants were employed by the Department's HIV/AIDS program where they developed and implemented seminars for people teaching HIV prevention.<sup>199</sup> The Department published and distributed a manual entitled "Setting up HIV Prevention Education Programs Including People Living with HIV/AIDS."<sup>200</sup> Included in the manual were the full names of the plaintiffs and mention of their HIV-

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<sup>193</sup>*Id.* at 1009-10.

<sup>194</sup>*Id.*

<sup>195</sup>*Id.* at 1010.

<sup>196</sup>*Id.*

<sup>197</sup>*Doe v. Marsh*, 105 F.3d 106 (2nd Cir. 1997).

<sup>198</sup>*Id.* at 108.

<sup>199</sup>*Id.*

<sup>200</sup>*Id.*

positive status.<sup>201</sup> Outraged by the public exposure received from the manual, the plaintiffs brought a civil rights claim, alleging the department violated their right to privacy under the First Amendment to the United States Constitution.<sup>202</sup>

At the time the manual was released, the law was unclear regarding what constituted a waiver of one's right to privacy.<sup>203</sup> Therefore, the main issue before the court was whether it was objectively reasonable for the department to have included the plaintiffs' name in the manual.<sup>204</sup> In reaching its decision, the court analyzed the doctrine of governmental qualified immunity, noting that "[g]overnment actors performing discretionary functions are shielded from liability for civil damages insofar as their conduct does not violate clearly established statutory or constitutional rights of which a reasonable person would have known."<sup>205</sup>

Because both plaintiffs previously identified themselves at educational seminars and conferences as HIV-positive, and one plaintiff disclosed her HIV-positive status in an educational videotape that she acknowledged would be used in a variety of educational settings, the court determined that reasonable government officials could disagree on whether the plaintiffs knowingly and voluntarily waived their right not to have their HIV-positive status disclosed to educators involved in HIV prevention.<sup>206</sup> From this, the court concluded the department was entitled to qualified governmental immunity for publishing the plaintiff's names and their HIV-positive status in the educational manual.<sup>207</sup> *Doe v. Marsh*, 105 F.3d 106 (2nd Cir. 1997).

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<sup>201</sup>*Id.*

<sup>202</sup>*Doe v. Marsh*, 105 F.3d 106, 109 (2nd Cir. 1997) (citing 42 U.S.C. § 1983)). The plaintiffs also included a pendent state law claim under New York Public Health Law § 2782, which generally prohibits the disclosure of an individual's HIV-related information except upon written consent of the individual.

<sup>203</sup>*Id.*

<sup>204</sup>*Id.*

<sup>205</sup>*Id.* (citing *Lennon v. Miller*, 66 F.3d 416, 420 (2d Cir. 1995)) (quoting *Harlow v. Fitzgerald*, 457 U.S. 800, 818 (1982)).

<sup>206</sup>*Id.* at 110-11.

<sup>207</sup>*Doe v. Marsh*, 105 F.3d 106 (2nd Cir. 1997).

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### University Professor Not Entitled to Absolute Immunity When Treating Private Patient

The Court of Appeals of Tennessee affirmed the decision of the state claims commission. The court determined that a physician acted beyond the scope of his employment, as an associate professor at the state university school of medicine, because the physician practiced medicine on behalf of a private employer when treating a patient.<sup>203</sup>

As a board certified emergency physician, the defendant physician was employed by both the state university school of medicine and a private medical group comprised of university faculty.<sup>209</sup> The physician treated a patient for an acute exacerbation of asthma.<sup>210</sup> After the patient died from this condition, her husband filed two simultaneous medical malpractice suits, alleging first that the physician was an employee of the private medical group, and second that he was acting as a state employee.<sup>211</sup> The state claims commission determined the physician was working within the scope of his employment with the private practice group and not as a state employee.<sup>212</sup> Therefore, the physician was not entitled to absolute immunity from liability.<sup>213</sup> The physician appealed.<sup>214</sup>

The court of appeals reasoned that the physician was engaged in dual employment in which the university paid the physician for administrative, teaching, and research responsibilities while the private medical group paid the physician for direct patient care.<sup>215</sup> The court noted that since the private medical group paid the physician to treat the patient, the physician was acting beyond his scope of employment at the university and was not

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<sup>203</sup>Hayden v. Waller, No. 02A01-9511-BC-00241, 1996 WL 740820 (Tenn. Ct. App. Dec. 30, 1996).

<sup>209</sup>*Id.* at \*1-2.

<sup>210</sup>*Id.* at \*3.

<sup>211</sup>*Id.*

<sup>212</sup>*Id.*

<sup>213</sup>Hayden v. Waller, No. 02A01-9511-BC-00241, 1996 WL 740820, at \*3 (Tenn. Ct. App. Dec. 30, 1996).

<sup>214</sup>*Id.*

<sup>215</sup>*Id.* at \*5.

entitled to immunity.<sup>216</sup> *Hayden v. Waller*, No. 02A01-9511-BC-00241, 1996 WL 740820 (Tenn. Ct. App. Dec. 30, 1996).

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### LONG-TERM CARE

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#### **Home for Developmentally Disabled has Duty to Protect from Reasonable Dangers, Including Sexual Assault by Staff**

The Supreme Court of Washington ruled a group home for developmentally disabled persons had a duty to protect its residents from foreseeable consequences of their impairments including sexual assault by an employee.<sup>217</sup> Although there was no duty to prevent a third party from intentionally injuring another, the court ruled the nature of the residential care created a "special relationship," thereby making the home responsible for the protection of its residents from foreseeable third party conduct.<sup>218</sup>

The plaintiff was afflicted with cerebral palsy and had been a resident of the defendant group home, a licensed provider of residential care for persons suffering from developmental disabilities, since 1986.<sup>219</sup> On several occasions, the resident was sexually assaulted by an employee of the home.<sup>220</sup> At the time of the assaults, the employee was the only staff member on duty violating a rule which prohibited male employees to be alone with female residents.<sup>221</sup> Following the assaults, the resident brought an action against the home and employee on several tort theories including:

- (1) breach of duty to protect from reasonable harms;
- (2) negligent supervision of the employee; and
- (3) the home's vicarious liability for the actions of its employee.<sup>222</sup>

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<sup>216</sup>*Id.* at \*8.

<sup>217</sup>*Niece v. Elmview Group Home*, 929 P.2d 420 (Wash. 1997).

<sup>218</sup>*Id.* at 427.

<sup>219</sup>*Id.* at 423.

<sup>220</sup>*Id.*

<sup>221</sup>*Id.* at 423.

<sup>222</sup>*Niece v. Elmview Group Home*, 929 P.2d 420, 423 (Wash. 1997).

The trial court dismissed all of the resident's claims.<sup>223</sup> On appeal, the court held the home had a duty to protect its residents from foreseeable harms including sexual assaults by staff members.<sup>224</sup>

The Supreme Court noted although there was no duty to prevent a third party from intentionally injuring another person, such a duty was created when a "special relationship" existed between the defendant and third party.<sup>225</sup> The court stated that here, as with a hospital-patient relationship, the home had a special relationship with its residents, especially since those residents were totally unable to protect themselves and were therefore, completely dependent on the home and its care givers for personal safety.<sup>226</sup> Although the home argued this duty extended only to foreseeable harm, *i.e.* abuse by third parties or visitors, the court explained that patients in group homes were, in fact, most susceptible to injury by staff members.<sup>227</sup> Since staff members have less restricted access to the patients, the potential for abuse is even greater than from a third party or visitor.<sup>228</sup> The court reasoned that because residents were least able to protect themselves from abuse at the hands of group home staff, even the most narrow reading of foreseeability would include protection from such internal abuse.<sup>229</sup>

The court defined "foreseeable" to include all injuries within the general field of danger which should have been anticipated.<sup>230</sup> Further, intentional or criminal behavior may be foreseeable unless it is so extraordinary or improbable as to be beyond the range of expectability.<sup>231</sup> Since the employee had no prior offenses and came to the home with positive references from a previous employer, the court stated although there was a duty to protect against foreseeable danger, a jury must decide whether the sexual assault by the employee himself was a foreseeable risk.<sup>232</sup> Although the court ruled sexual assault was not totally

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<sup>223</sup>*Id.*

<sup>224</sup>*Id.*

<sup>225</sup>*Id.*

<sup>226</sup>*Id.* at 425.

<sup>227</sup>*Niece v. Elmview Group Home*, 929 P.2d 420, 425 (Wash. 1997).

<sup>228</sup>*Id.*

<sup>229</sup>*Id.*

<sup>230</sup>*Id.* at 426.

<sup>231</sup>*Id.* at 426.

<sup>232</sup>*Niece v. Elmview Group Home*, 929 P.2d 420, 426 (Wash. 1997).

unforeseeable, the issue was remanded for a jury to decide whether such an assault was foreseeable in this particular case.<sup>233</sup>

Nevertheless, the court refused to rule in favor of the resident based on a theory of vicarious liability. Vicarious liability imposes liability on a employer for the torts of its employees while acting on the employer's behalf. However, the court stated that vicarious liability does not extend to instances, such as the present case, in which the employee stepped aside from the his/her responsibilities at work and pursued a personal objective. Here, the staff member was clearly not acting in accordance with any authorized policy, and was in fact acting in furtherance of his own personal desires. Admittedly, even when an employee has strayed from the bounds of employment, there is still a limited level of liability to which the group home is indeed subjected to through vicarious liability. The court was unwilling to extend such a liability to the group home, and ruled such a matter would be better decided through legislation in accordance with public policy. *Niece v. Elmview Group Home*, 929 P.2d 420 (Wash. 1997).

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### MEDICAL MALPRACTICE

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#### **Lack of Clarity Not Fatal in Jury Instructions Failing to State that a Nationwide Standard of Care Could be Applied to Establish a Local Standard of Care**

The Supreme Court of Delaware upheld a jury verdict in favor of a cardiologist charged with negligence by a patient who received a cardiac catheterization which resulted in the patient having to undergo heart surgery.<sup>234</sup> The court reached its decision even though jury instructions lacked clarity in telling the jury they could apply a national standard of care when the national standard was also found to be the local standard.<sup>235</sup>

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<sup>233</sup>*Id.*

<sup>234</sup>*McKenzie v. Blasetto*, 686 A.2d 160 (Del. 1996).

<sup>235</sup>*Id.* at 163. See Health Care Malpractice Insurance and Litigation Act, 13 Del. C. § 6804, which states: "The standard of skill and care required of every health care provider in rendering professional services or health care to a patient shall be that degree of skill and care ordinarily employed ... by members of the profession in good standing in the same community or locality..."

A family physician referred the patient to the cardiologist after the patient began experiencing chest pain.<sup>236</sup> Tests indicated there may have been coronary disease present, so the cardiologist recommended cardiac catheterization.<sup>237</sup> During the catheterization, the cardiologist tore the patient's right artery and the patient underwent emergency surgery to save her life.<sup>238</sup> The patient and her husband filed a suit alleging malpractice on the part of the cardiologist in the decision to catheterize and in the performance of the catheterization.<sup>239</sup> The first trial resulted in a hung jury and in the second trial, the jury found in favor of the physician.<sup>240</sup>

The issue presented to this court was whether the trial court's failure to give a national standard of care jury instruction violated the parties' agreement to "dispense with any trial testimony [on the] local standards issue" to save time in bridging the national standard of care with the local standard of care. Although the agreement was never put on the record, the court reviewed the jury instructions and the agreement between the parties to determine whether the instructions violated the agreement.<sup>241</sup> The court found the agreement applied only to testimony given, not to the standard of care actually applied and given in the instructions.<sup>242</sup> The jury was informed in the instructions they could apply a national standard of care if that standard was also the local standard.<sup>243</sup> The court held that although the instructions were not perfect, as long as they were not misleading and stated the applicable law, they were permissible.<sup>244</sup> *McKenzie v. Blasetto*, 686 A.2d 160 (Del. Supr. 1996).

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<sup>236</sup>*Id.* at 161.

<sup>237</sup>*Id.*

<sup>238</sup>*Id.*

<sup>239</sup>*McKenzie v. Blasetto*, 686 A.2d 160, 161 (Del. 1996). The plaintiffs included Delaware Heart Group, P.A., the professional organization Dr. Blasetto belonged to in the suit. *Id.*

<sup>240</sup>*Id.* at 162.

<sup>241</sup>*Id.* at 163.

<sup>242</sup>*Id.*

<sup>243</sup>*Id.*

<sup>244</sup>*McKenzie v. Blasetto*, 686 A.2d 160 (Del. 1996). See also *Haas v. United Technologies Corp.*, 450 A.2d 1173, 1179 (Del. Sup. 1982).



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**MEDICARE/MEDICAID**

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**Showing of Irreparable Harm to Residents Justifies  
Continued Medicare Funding of Nursing Home  
Pending Outcome of Administrative Hearing**

The United States District Court for the District of Columbia granted in part and denied in part a motion brought by a long term skilled nursing facility (nursing home) to prevent the Health Care Financing Administration of the Department of Health and Human Services (HHS) from terminating its Medicare funding.<sup>245</sup> The court ordered the continuation of Medicare funds pending the outcome of an administrative hearing to determine whether the nursing home committed Medicare violations. The court denied both the nursing home's motion for a temporary restraining order and the Administration's motion to dismiss.<sup>246</sup>

The state department of health services (Department) inspected the nursing home and found substantial deficiencies in its compliance with Medicare regulations. Consequently, the Department informed the nursing home its Medicare funding would be terminated. Two days before termination of funding, the nursing home filed a "plan for correction," and filed a motion for a temporary restraining order to prevent the funding termination on the following day.<sup>247</sup> The Department made a second inspection, and although some progress had been made since the first visit, the Department still found a lack of compliance. Thereafter, HHS informed the nursing home its Medicare funding would be terminated, the previously imposed civil penalties would continue, and payment for new admissions would be denied.<sup>248</sup> The home responded by filing a motion for emergency injunctive relief, alleging it was now in full compliance and therefore should not have its Medicare funding terminated. An administrative hearing was scheduled.<sup>249</sup>

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<sup>245</sup>*International Long Term Care v. Shalala*, 947 F. Supp. 15 (D.D.C. 1996).

<sup>246</sup>*Id.* at 21.

<sup>247</sup>*Id.* at 16.

<sup>248</sup>*Id.*

<sup>249</sup>*Id.*

In order to succeed in its injunctive relief motion, the nursing home was required to show a substantial "likelihood" of success on the merits, and that "irreparable harm" would result if injunctive relief was not granted. The court also had to consider any harm to the HHS or other interested parties, and whether the injunction would be adverse to public interest.<sup>250</sup> The court measured these elements on a "continuum."<sup>251</sup> Because the nursing home presented a sufficiently substantial case to prevail on the merits and a "clear showing" of irreparable harm existed to the nursing home's residents if Medicare funding ceased, the court ordered the continuation Medicare funding.<sup>252</sup> The court believed the irreparable harm to residents alone was enough to grant preliminary injunctive relief. However, the court was careful to note the continuation of funds would only continue until the administrative hearing's determination, scheduled only a few weeks following this opinion.<sup>253</sup> The court concluded by rejecting all the arguments raised against preliminary injunctive relief, stating the extremely limited nature of this relief best served the administrative process "given the unusual circumstances presented by this case."<sup>254</sup> *International Long-Term Care, Inc. v. Shalala*, 947 F. Supp. 15 (D.D.C. 1996).

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**Physician-Patient Privilege Does Not Provide Basis  
for *in Camera* Review of Patient Files Seized in  
Medical Fraud Prosecution**

The Court of Appeal of California, Second District, Division Three, denied a physician's motion for an *in camera* review of patients' records arising out of state charges against the physician for state Medicaid insurance fraud.<sup>255</sup> The physician allegedly engaged in criminal activity by preparing false patient histories and creating "ghost patients" in violation of various

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<sup>250</sup>*International Long Term Care v. Shalala*, 947 F. Supp. 15, 17 (D.D.C. 1996).

<sup>251</sup>*Id.*

<sup>252</sup>*Id.* at 19.

<sup>253</sup>*Id.* at 19-20.

<sup>254</sup>*Id.* at 21.

<sup>255</sup>*Brillantes v. Superior Court*, 58 Cal. Rptr. 2d 770 (Cal. Ct. App. 1996).

state statutes.<sup>256</sup> Investigators from the state bureau for medical insurance fraud (Bureau) executed a valid search warrant on the physician's residence and medical office, and seized patient records and billing information which revealed sufficient information to charge the physician.<sup>257</sup> The physician filed an objection to the search and seizure and filed a motion to seal the records, stating he had a right to an *in camera* review of the patient files in determining the "applicability of the patient-physician privilege."<sup>258</sup> The lower court denied the physician's objection, yet sealed the files for thirty days allowing time for the physician to appeal.

The appellate court first examined the physician's complaint and cited authority for the claim that the physician was entitled to *in camera* review. The court held the cited opinion did not require the trial court to provide an *in camera* review to the physician.<sup>259</sup> The cited opinion involved a breach of the attorney-client privilege, and did not provide a sweeping right to a statutory hearing in all cases. The opinion merely held a court has "the inherent power to protect a privilege-holder from improper disclosure of confidential information."<sup>260</sup> Moreover, the court stated, unlike the attorney-client privilege, the physician in this case asserted privilege for his *own* protection, not the protection of his patients. Further, the court found that state Medicaid patients were aware certain information would be communicated to the state for the purpose of payment and would remain available to the state for audits conducted during the course of Medicaid fraud investigations.<sup>261</sup> Additionally, the court agreed with the state's assertion that the state had an interest in the welfare of its citizens and concern for the public at large. The court found this interest further justified a requirement of record inspection by a "responsible state agency" to prevent insurance fraud.<sup>262</sup> Finally, the court rejected the physician's constitutional objections because the search warrant delineated specific files to be taken and therefore protected patients' privacy interests, and no

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<sup>256</sup>*Id.* at 773. The statutory violations were as follows: Welfare & Institutions Code §14107 (Submission of False Claims); Welfare and Institutions Code § 14107.2 (Kickbacks) and Penal Code § 487.1 (Grand Theft).

<sup>257</sup>*Id.*

<sup>258</sup>*Id.*

<sup>259</sup>*People v. Superior Court (Bauman & Rose)*, 44 Cal. Rptr. 2d 734 (Cal. Ct. App. 1995).

<sup>260</sup>*Id.* at 777.

<sup>261</sup>*Id.* at 779.

<sup>262</sup>*Id.*

less intrusive alternative could be used to minimize the invasion on the patients' privacy rights. Thus, the court concluded the trial court did not abuse its discretion when it rejected the physician's motion for an *in camera* review.<sup>263</sup> *Brillantes v. Superior Court*, 51 Cal. App. 4th 323, 58 Cal. Rptr. 2d 770 (Cal. Ct. App. 1996).

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## MENTAL HEALTH

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### State Regulations Permitting Human Subject Research of Mental Health Patients Held Unconstitutional

The Supreme Court of New York, Appellate Division, First Department, affirmed the lower court's decision to hold the state office of mental health (Office) did not have proper authority to establish regulations pertaining to human subject research, and the challenged research regulations were unconstitutional.<sup>264</sup>

The Office established regulations pertaining to the use of human subjects in "more than minimal risk" experiments on adults and minors who were incapable of consenting to the procedures and resided at or were treated in the Office's mental health facilities.<sup>265</sup> The regulations governing the research procedures provided for the administration of approved and experimental antipsychotic and psychotropic drugs.<sup>266</sup> Further, the regulations set forth the procedures for screening potential subjects and ensuring the experiments would not conflict with the patient's treatment.<sup>267</sup> A challenge to the Office's human subject research regulations was brought by patients who were involuntarily hospitalized in the Office's psychiatric facilities.

The patients first contended the Office lacked the authority to promulgate the regulations because such authority was exclusively given to the state commissioner of the department of health (Commissioner).

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<sup>263</sup>*Id.* at 783-84.

<sup>264</sup>*T.D. v. New York State Office of Mental Health*, 650 N.Y.S.2d 173 (N.Y. App. Div. 1996).

<sup>265</sup>*Id.* at 175.

<sup>266</sup>*Id.* at 176.

<sup>267</sup>*Id.*

The court examined the text and legislative history of the relevant state public health law, and concluded the state legislature intended to divide the authority over medical research between the Office and Commissioner.<sup>268</sup> The Office had the authority to encourage and promote research in furtherance of the its goal of preventing, diagnosing, and treating mental illness.<sup>269</sup> By contrast, the Commissioner had the duty to oversee all human subject research and to protect the rights of those who may be subject to such research.<sup>270</sup> As a result, any regulations governing human subject research enacted solely by the Office were invalid.<sup>271</sup>

In response, the Office argued because its regulations were in compliance with federal regulations, the state public health law did not apply.<sup>272</sup> However, the court found that because the Office failed to comply with all applicable federal regulations, the state public health law did indeed apply. Thus, the Office was required to get consent from the Commissioner regarding human subject research regulations using minors, incompetents, or the the mentally disabled. The Office's failure to do so was a violation of state law.<sup>273</sup>

Finally, even though the Office's regulations were invalid, the court examined the patients' constitutional claims in anticipation of future controversy. Because the Office's experiments involved highly invasive and painful procedures, and because the procedural guidelines set forth, particularly those regarding patient consent, were inadequate, the court held the regulations violated the patients' due process rights.<sup>274</sup> *T.D. v. New York State Office of Mental Health*, 650 N.Y.S.2d 173 (N.Y. App. Div. 1996).

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<sup>268</sup>*Id.* at 180.

<sup>269</sup>*T.D. v. New York State Office of Mental Health*, 650 N.Y.S.2d 173, 180 (N.Y. App. Div. 1996).

<sup>270</sup>*Id.*

<sup>271</sup>*Id.* at 182.

<sup>272</sup>*Id.* at 183.

<sup>273</sup>*Id.*

<sup>274</sup>*T.D. v. New York State Office of Mental Health*, 650 N.Y.S.2d 173, 183 (N.Y. App. Div. 1996).

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**NEGLIGENCE**

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**Exposure to HIV is Necessary to Maintain Claim for  
Negligent Infliction of Emotional Distress**

The Supreme Court of Tennessee affirmed a lower court's denial of summary judgment, holding actual exposure to human immune deficiency virus (HIV) was necessary to maintain a claim for negligent infliction of emotional distress.<sup>275</sup> The court further found that a hospital's policy of non-segregated room assignments did not constitute outrageous conduct because it was in accordance with current health standards.<sup>276</sup>

The plaintiff entered an alcohol and drug rehabilitation center and, without his knowledge or consent, was assigned to a room with a patient carrying the HIV virus.<sup>277</sup> As roommates for eight days, the two men shared a bathroom and toilet.<sup>278</sup> After accidentally using his roommate's razor, the roommate told the plaintiff he was infected with HIV.<sup>279</sup> The plaintiff left the hospital before completion of the program and complained that the hospital's policy of placing HIV-infected and non-infected patients in the same room constituted outrageous conduct.<sup>280</sup> He claimed that he had suffered emotional distress in fearing contraction of the AIDS virus.<sup>281</sup>

The court held the hospital's housing policy was not outrageous conduct because the hospital had complied with all applicable health care standards. Nor did the hospital's actions fall into one of the limited circumstances where patient segregation was recommended by the American Hospital Association.<sup>282</sup> Further, the court found the plaintiff's claim of emotional distress was without merit because he neglected to establish a reasonable connection between the act of the hospital and the injury alleged.<sup>283</sup> The court stated public policy imposed no legal duty to

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<sup>275</sup>Bain v. Wells, 936 S.W.2d 618, 620 (Tenn. 1997).

<sup>276</sup>*Id.*

<sup>277</sup>*Id.*

<sup>278</sup>*Id.*

<sup>279</sup>*Id.*

<sup>280</sup>Bain v. Wells, 936 S.W.2d 618, 620 (Tenn. 1997).

<sup>281</sup>*Id.*

<sup>282</sup>*Id.*

<sup>283</sup>*Id.* at 625-26.

protect against the fear of contracting AIDS in the absence of actual exposure to HIV.<sup>284</sup> To hold otherwise, the court reasoned, would encourage public misconceptions about AIDS and the transfer of the HIV virus.<sup>285</sup> *Bain v. Wells*, 936 S.W.2d 618, 620 (Tenn. 1997).

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### **Physician Barred From Bringing Negligence Claim Against Silicon Breast Manufacturer**

The Supreme Court of New York, Appellate Division, Second Department, reversed a lower court's decision to deny a motion to dismiss submitted by the manufacturer of silicone breast implants and silicone gel in a case brought by a physician against the manufacturer for allegedly causing injury to the physician. The court held the physician could not maintain a negligence cause of action against the manufacturer for damages the physician suffered as a result of negative publicity concerning the implants; because the manufacturer failed to disclose risks to the physician, and because the Uniform Commercial Code (UCC) applied and barred such a claim.<sup>286</sup>

The physician was a reconstructive and plastic surgeon who devoted a large portion of his practice to cosmetic breast surgery.<sup>287</sup> Prior to 1992, the physician regularly used silicone implants purchased from the defendant manufacturer. However, in 1992 the Food and Drug Administration (FDA) announced silicone breast implants were unsafe and called for a moratorium on their use.<sup>288</sup> Following the announcement, many of the physician's patients filed lawsuits against him.<sup>289</sup> In turn, the physician filed a suit against the manufacturer alleging the negative publicity and failure to disclose risks associated with the implants resulted in economic harm

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<sup>284</sup>*Bain v. Wells*, 936 S.W.2d 618, 626 (Tenn. 1997).

<sup>285</sup>*Id.* at 625.

<sup>286</sup>*Vitolo v. Dow Corning Corp.*, 651 N.Y.S.2d 104 (1996).

<sup>287</sup>*Id.*

<sup>288</sup>*Id.*

<sup>289</sup>*Id.*

and a loss of income to the physician.<sup>290</sup> The manufacturer moved to dismiss the claim.<sup>291</sup>

The court determined the claim depended upon the classification of the underlying transaction because physician sought to recover economic damages rather than damages suffered due to an injury to person or property.<sup>292</sup> If the transaction was classified as a sale of goods, Article 2 of the UCC would be invoked.<sup>293</sup> Such a classification would limit the physician's recovery to contractual remedies and preclude a cause of action for negligence and strict products liability.<sup>294</sup> By contrast, a classification of the transaction as predominately service oriented would exempt the claim from UCC coverage and prevent the physician from recovering under theories of breach of implied or express warranty.<sup>295</sup>

Upon examining the transaction, the court held the transaction was properly defined as a sale of goods under the UCC.<sup>296</sup> The court acknowledged that the manufacturer serviced the physician's account by inspecting defective implants and by supplying medical and product information to the plaintiff.<sup>297</sup> However, because such actions were incidental to the sale of the implants, the transaction constituted a sale of goods and the UCC applied.<sup>298</sup> Therefore, the physician could not maintain a cause of action against the manufacturer for negligence and his claim was properly dismissed.<sup>299</sup> *Vitolo v. Dow Corning Corp.*, 651 N.Y.S.2d 104 (1996).

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<sup>290</sup>*Id.*

<sup>291</sup>*Vitolo v. Dow Corning Corp.*, 651 N.Y.S.2d 104, 105 (1996).

<sup>292</sup>*Id.*

<sup>293</sup>*Id.*

<sup>294</sup>*Id.*

<sup>295</sup>*Id.*

<sup>296</sup>*Vitolo v. Dow Corning Corp.*, 651 N.Y.S.2d 104, 105 (1996).

<sup>297</sup>*Id.*

<sup>298</sup>*Id.*

<sup>299</sup>*Id.*



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### Surgeon Need Not Be Present During the Administration of Anesthesia

The Supreme Court of Mississippi affirmed the circuit court's holding that a surgeon need not be present during the administration of anesthesia provided the surgeon was present in the operating suite. The court ruled that under the circumstances the surgeon could not be held liable under the theories of "borrowed servant" or "captain of the ship."<sup>300</sup>

The plaintiff patient underwent hernia surgery under anesthesia administered by a certified registered nurse anesthesiologist (CRNA) when the regular anesthesiologist was not present.<sup>301</sup> Under state law, the surgeon was not required to take part in the process.<sup>302</sup> In this case, the surgeon was paged and took the call in the operating suite as the anesthesia process was being completed.<sup>303</sup> When the surgeon returned, he noticed that the patient had experienced an adverse reaction to the anesthesia and had suffered brain damage as a result.<sup>304</sup>

The court held the surgeon was not negligent in being absent from the operating room during the administration of anesthesia.<sup>305</sup> It found that the CRNA could administer anesthesia without a surgeon or anesthesiologist present, and it was fairly common practice in hospitals to do so.<sup>306</sup> The court also refused to hold the surgeon liable under the borrowed servant rule, which provides that a servant who is temporarily loaned to another person to do his employer's work becomes a servant of the person who borrowed that individual's services.<sup>307</sup> The court found the surgeon had no right of control over the actions of CRNA, and the CRNA was, therefore, not his borrowed servant.<sup>308</sup> Similarly, the court found the surgeon was not liable under the "captain of the ship" doctrine which states

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<sup>300</sup>*Starcher v. Byrne*, 687 So. 2d 737 (Miss. 1997).

<sup>301</sup>*Id.* at 738-39.

<sup>302</sup>*Id.* at 740.

<sup>303</sup>*Id.* at 739.

<sup>304</sup>*Id.*

<sup>305</sup>*Starcher v. Byrne*, 687 So. 2d 737, 740 (Miss. 1997).

<sup>306</sup>*Id.*

<sup>307</sup>*Id.* at 741.

<sup>308</sup>*Starcher v. Byrne*, 687 So. 2d 737, 741 (Miss. 1997).

a surgeon has the ultimate responsibility for the care of the patient.<sup>309</sup> The court held the CRNA had ultimate responsibility under the circumstances of this case.<sup>310</sup> *Starcher v. Byrne*, 687 So. 2d 737 (Miss. 1997).

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## PHYSICIAN-ASSISTED SUICIDE

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### No Constitutional Right to Physician-Assisted Suicide

The United States District Court for the Eastern District of Michigan held no constitutional right exists for physician assisted suicide and a state statute prohibiting physician assisted suicide did not violate the due process clause or the equal protection clause of the United States Constitution.<sup>311</sup>

In this action, a physician and his patient sought a court order to prohibit the county attorney from prosecuting them under the state statute prohibiting physician-assisted suicide.<sup>312</sup> A lower court granted a permanent injunction against the county attorney.<sup>313</sup> However, while this order was on appeal, the state enacted a statute which created a new crime of "criminal assistance of suicide."<sup>314</sup> Two circuit court judges declared the criminal provisions of the new statute unconstitutional, and appeals were subsequently filed. The state supreme court held assisted suicide was a crime at common law.<sup>315</sup> In response to this decision, the judge which had originally entered an injunction prohibiting prosecution of the physician and patient entered a new order of permanent injunction against the physician, enjoining him from participating in the act of assisted suicide.<sup>316</sup> The appellate court affirmed the lower court's permanent injunction, and the case was taken up on a petition for certiorari by the federal district court.<sup>317</sup>

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<sup>309</sup>*Id.* at 742.

<sup>310</sup>*Id.*

<sup>311</sup>*Kervorkian v. Thompson*, 947 F. Supp. 1152 (E.D. Mich. 1997).

<sup>312</sup>*Id.* at 1154.

<sup>313</sup>*Id.*

<sup>314</sup>*Id.* (citing MICH. COMP. LAWS § 750.505 (1993)).

<sup>315</sup>*Id.* at 1167.

<sup>316</sup>*Kervorkian v. Thompson*, 947 F. Supp. 1152, 1167 (E.D. Mich. 1997).

<sup>317</sup>*Id.*

First, the federal district court found the physician had standing to contest the permanent injunction on two grounds: (1) the physician satisfied the "injury" requirement because he faced enjoinder of activities (assisted suicide) which would create a "real and immediate" injury or threat of injury;<sup>318</sup> and (2) a physician may derivatively assert the constitutional rights of his terminally ill patients.<sup>319</sup>

Next, the court addressed whether it should abstain from adjudicating this case due to the *Younger* doctrine.<sup>320</sup> In *Younger*, the Supreme Court held that federal courts should not enjoin pending state criminal proceedings except in the very unusual circumstance where an injunction is necessary to prevent great, immediate, and irreparable injury.<sup>321</sup> The court applied a three prong test and determined:

- (1) there was a pending state proceeding;
- (2) the plaintiff had adequate opportunity to raise his constitutional claims in the state proceeding; and
- (3) there were not sufficient extraordinary circumstances which warranted federal intervention.<sup>322</sup>

Thus, the court abstained from adjudicating the physician's requested injunction against the county prosecutor. However, the court also analyzed the patient's request for declaratory judgment. The court reasoned since there was no pending state proceeding against the patient, the *Younger* doctrine did not apply.<sup>323</sup>

Next, the court held the *Rooker-Feldman* doctrine, which prohibits a federal court from hearing a case already litigated in state court, did not apply to the patient's case.<sup>324</sup> The court indicated the patient was never a party in any of the state court actions involving her physician and his

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<sup>318</sup>*Id.* at 1159 (citing *O'Shea v. Littleton*, 414 U.S. 488, 493 (1974)).

<sup>319</sup>*Id.* at 1160 (citing *Quill v. Vacco*, 117 S. Ct. 36 (1996)).

<sup>320</sup>*Younger v. Harris*, 401 U.S. 37 (1971).

<sup>321</sup>*Kervorkian v. Thompson*, 947 F. Supp. 1152, 1161 (E.D. Mich. 1997) (citing *Younger* at 44-46).

<sup>322</sup>*Id.*

<sup>323</sup>*Id.*

<sup>324</sup>*Rooker v. Fidelity Trust Co.*, 263 U.S. 412 (1923). This doctrine stands for the proposition that a federal district court may not hear what is effectively an appeal of a case already litigated in state court.

challenges of the state assisted suicide laws, thus the *Rooker-Feldman* doctrine could not be used to defeat her claim in federal court.<sup>325</sup>

Finally, the court addressed the merits of the patient's constitutional claims. First, the court held no cognizable right to assisted suicide exists.<sup>326</sup> The court reasoned the right to assisted suicide was not "deeply rooted in the Nation's history or traditions," or without support in the text of the Constitution.<sup>327</sup> The court also found that suicide was traditionally a criminal offense<sup>328</sup> and thirty-two jurisdictions had statutes which criminalized assisted suicide.<sup>329</sup> The court rejected the patient's claim that assisted suicide was a fundamental right protected by the Due Process Clause of the Fourteenth Amendment.<sup>330</sup> Given the historical treatment of assisted suicide, the court did not want to create or find a new constitutional right "where none existed before."<sup>331</sup> Rather, the court determined assisted suicide was an issue of policy which should be decided by the policy branches of government, and not the courts.<sup>332</sup>

The court also held the plaintiff's equal protection claim was without merit.<sup>333</sup> The patient contended that persons seeking physician assistance with suicide are denied equal protection under the laws when the law protects the right to reject medical treatment for those on life support, but prohibits assisted suicide for those not on life.<sup>334</sup> The court stated that the two situations were distinguishable in that suicide involved an affirmative act to end life, whereas the refusal or cessation of life support simply allowed life to run its course.<sup>335</sup> The court held there was no equal protection violation since "the Constitution does not require things which

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<sup>325</sup>*Kervorkian*, 947 F. Supp. at 1166.

<sup>326</sup>*Kervorkian v. Thompson*, 947 F. Supp. 1152, 1166 (E.D. Mich. 1997).

<sup>327</sup>*Id.* at 1167 (citing *Palko v. Connecticut*, 302 U.S. 319, 325-326 (1937)).

<sup>328</sup>*Id.*

<sup>329</sup>*Id.*

<sup>330</sup>*Id.* at 1168-1170.

<sup>331</sup>*Kervorkian v. Thompson*, 947 F. Supp. 1152, 1169 (E.D. Mich. 1997).

<sup>332</sup>*Id.* at 1171.

<sup>333</sup>*Id.* at 1172-1173.

<sup>334</sup>*Id.* at 1172. *See generally*, *Cruzan v. Director, Mo. Dep't of Health*, 497 U.S. 261, 296 (1990). Plaintiffs rely on Justice Scalia's concurrence in *Cruzan* for the proposition that there is no meaningful difference between the withdrawal of life support and an overt act to terminate life. However, the *Cruzan* majority rejected Justice Scalia's position.

<sup>335</sup>*Id.*

are different in fact or opinion to be treated in law as though they were the same."<sup>336</sup> *Kervorkian v. Thompson*, 947 F. Supp. 1152 (E.D. Mich. 1997).

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## PHYSICIAN-PATIENT PRIVILEGE

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### Waiver of Physician-Patient Privilege Leads to Estoppel of Privilege Claim in Subsequent Action

The Supreme Court of Michigan held a motorist who had disclosed his medical records in a previous action for negligence was estopped from asserting the physician-patient privilege in a related case between the same plaintiff and the motorist's physicians.<sup>337</sup> Because the motorist had waived his physician-patient privilege in the prior case, he has was estopped from "picking and choosing" among similarly situated parties where the information sought was identical and requested for the same purpose in both cases.<sup>338</sup>

Years earlier, the motorist suffered a seizure and thereby lost control of his vehicle, striking the plaintiff and injuring the plaintiff severely and permanently.<sup>339</sup> Plaintiff settled out of court with the motorist's insurance company; however, he commenced a second suit with the motorist's hospital and physician.<sup>340</sup> Plaintiff claimed the hospital and physician were liable for his injuries due to their failure to diagnose and properly treat the motorist's epilepsy.<sup>341</sup> During the original suit, the motorist waived his physician-patient privilege, giving the plaintiff access to all of his medical records concerning the case and his epilepsy.<sup>342</sup> However, in the failure to diagnose suit, the defendant hospital and physician refused to disclose the motorist's medical records to plaintiff and asserted the physician-patient

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<sup>336</sup>*Kervorkian v. Thompson*, 947 F. Supp. 1152, 1173 (E.D. Mich. 1997) (citing *Plyler v. Doe*, 457 U.S. 202, 216 (1982)).

<sup>337</sup>*Landelius v. Sackellares*, 556 N.W.2d 472 (Mich. 1996).

<sup>338</sup>*Id.* at 477.

<sup>339</sup>*Id.* at 473.

<sup>340</sup>*Id.*

<sup>341</sup>*Id.*

<sup>342</sup>*Landelius v. Sackellares*, 556 N.W.2d 472, 473 (S.C. Mich. 1996).

privilege on their own behalf.<sup>343</sup> Because plaintiff was unable to present a *prima facie* case against the second set of defendants without the medical records as evidence, he subsequently sued the motorist a second time, alleging breach of the original settlement agreement.<sup>344</sup> Both the trial court and the appellate court found nothing in the original release agreement which required the motorist to disclose the medical records in the separate action against the hospital and physician.<sup>345</sup>

On review, the supreme court stated the physician-patient privilege was not designed to shield information from plaintiffs who previously had access to the very same information.<sup>346</sup> Rather, the privilege was intended to prevent embarrassment and to encourage the free disclosure and confidential communication between physicians and their patients.<sup>347</sup> The court cited *Hamilton v. Verdow*, where a defendant was estopped from asserting the physician-patient privilege in a case against him for murder where he had previously waived that same privilege in an unrelated case for a different murder.<sup>348</sup> In the present case, the court determined the plaintiff was entitled to the information because the records pertained to one underlying event and the very same plaintiff in both the original motorist action and the action against the hospital and physician.<sup>349</sup> Therefore, the court refused to allow the motorist to choose one cause of action over another and reassert his physician-patient privilege against the same plaintiff in a suit arising from the same circumstances.<sup>350</sup> In closing, the court examined the original waiver form, which authorized the release of information to be used "in a pending lawsuit."<sup>351</sup> Since specific parties were not mentioned in the waiver, the court read the document to be a general waiver applicable to all suits arising from the same underlying event.<sup>352</sup> *Landelius v. Sackellares*, 556 N.W.2d 472 (Mich. 1996).

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<sup>343</sup>*Id.* at 473-474.

<sup>344</sup>*Id.* at 474.

<sup>345</sup>*Id.*

<sup>346</sup>*Id.* at 475.

<sup>347</sup>*Landelius v. Sackellares*, 556 N.W.2d 472, 475 (Mich. 1996).

<sup>348</sup>*Id.* at 475-76 (citing *Hamilton v. Verdow*, 287 Md. 544, 414 A.2d 914 (1980)).

<sup>349</sup>*Id.* at 476 (Mich. 1996).

<sup>350</sup>*Id.*

<sup>351</sup>*Id.* at 477.

<sup>352</sup>*Landelius v. Sackellares*, 556 N.W.2d 472, 477 (Mich. 1996).

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**PHYSICIAN-PATIENT RELATIONSHIP**

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**Relationship Not Created by Mailing X-ray Report to Insured**

The Superior Court of Pennsylvania ruled a physician did not initiate a physician-patient relationship by sending an x-ray report to an insured individual in accordance with the insurance carrier's policy. Therefore, the physician did not subject herself to medical malpractice liability with the insured individual.<sup>353</sup> The court ruled no relationship between the physician and plaintiff was created because the report merely notified the insured individual as to the existence of the report, as opposed to advising the individual about the content of the report.<sup>354</sup> Thus, no physician function was performed for the individual and the insured individual could not recover for medical malpractice.<sup>355</sup>

The plaintiff underwent chest x-rays after complaining of a persistent cough and fear of suffering from pneumonia.<sup>356</sup> The x-rays and subsequent CAT scan revealed the existence of a malignant granuloma tumor and therefore, the patient underwent surgery for its removal.<sup>357</sup> Previously, and prior to the tumor discovering x-ray, the plaintiff received numerous x-rays in order to fulfill the requirements of her life insurance carrier.<sup>358</sup> One set of x-rays was ordered and performed by one of the insurance carrier's contracted physicians, but interpreted by the defendant physician, who had contracted individually with the insurance physician.<sup>359</sup> The report submitted to the insurance company and plaintiff contained defendant's observations of a small lesion, which she believed to be a benign granuloma, but did not contain any advice or recommendations for follow up visits.<sup>360</sup> Although the plaintiff stipulated a physician-patient

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<sup>353</sup>Promubol v. Hackett, 686 A.2d 417 (Pa. Super. Ct. 1996).

<sup>354</sup>*Id.* at 419.

<sup>355</sup>*Id.*

<sup>356</sup>*Id.* at 417-18.

<sup>357</sup>*Id.* at 418.

<sup>358</sup>Promubol v. Hackett, 686 A.2d 417, 418 (Pa. Super. Ct. 1996).

<sup>359</sup>*Id.* The x-ray performing physician was under a contract for such services directly with the insurance company. Although defendant was not under a contract from the insurance company herself, she did have a contract with the insurance contracted physician to interpret the x-rays and issue reports on her own observations.

<sup>360</sup>*Id.* at 418.

relationship was not created where a physician examines a patient at the behest of an insurance company, she claimed the relationship was created when defendant directly sent her a copy of the x-ray report.<sup>361</sup> The plaintiff claimed the mailing of the report constituted the rendering of negligent advice because the defendant physician failed to diagnose the apparent lesion as malignant and therefore, defendant was open to negligence liability.<sup>362</sup>

The court recognized a long line of precedent which clearly stated a patient may not succeed on a negligence action against a physician where a third party has sponsored or ordered the examination of that patient.<sup>363</sup> Because there was no relationship created in those cases, there was no duty owed to the patient by the physician in question. Therefore, no breach regardless of negligence.<sup>364</sup> In the present case, the court stated the plaintiff did not employ the defendant, nor did she seek defendant's advice or receive defendant's treatment.<sup>365</sup> Therefore, based on this lack of contact, no physician-patient relationship had been created and defendant owed no duty of care to the plaintiff whatsoever.<sup>366</sup>

The court next addressed and clarified the difference between advice and notification, stating the x-ray report was clearly not advice because it did not contain any, "opinion expressed as to wisdom of future conduct."<sup>367</sup> The x-ray report was simply mailed in accordance with the insurance carrier's policy that the insured be notified of the information being submitted to the insurance company itself.<sup>368</sup> Therefore, because the report was a simple notification and did not constitute advice or recommendations in any sense, no physician-patient relationship was created and, thus, the defendant physician was not liable for the failure to diagnose the plaintiff's malignant tumor.<sup>369</sup> *Promubol v. Hackett*, 686 A.2d 417 (Pa. Super. Ct. 1996).

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<sup>361</sup>*Id.* at 419.

<sup>362</sup>*Id.*

<sup>363</sup>*Promubol v. Hackett*, 686 A.2d 417, 420 (Pa. Super. Ct. 1996).

<sup>364</sup>*Id.*

<sup>365</sup>*Id.* at 421.

<sup>366</sup>*Id.*

<sup>367</sup>*Id.* at 420 (citing BLACKS LAW DICTIONARY 74 (4th Ed. 1968)).

<sup>368</sup>*Promubol v. Hackett*, 686 A.2d 417, 421 (Pa. Super. Ct. 1996).

<sup>369</sup>*Id.*



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**PRODUCTS LIABILITY**

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**Medical Device Found "Unreasonably Dangerous  
*Per Se*" Not Preempted by Medical Device  
Amendments of 1976**

The United States Court of Appeals for the Fifth Circuit held a metal bone implant which aggravated and compounded a plaintiff's back injuries was "unreasonably dangerous *per se*" and not preempted by the Medical Device Amendments (MDA) of 1976.<sup>370</sup> The court further ruled the damage award from the trial was reasonable; however, the inventor of the device could not be held liable under a theory of products liability, because he was considered neither a manufacturer nor a supplier.<sup>371</sup>

The plaintiff seriously injured her back, was diagnosed with spinal stenosis, and subsequently underwent surgery to alleviate this condition.<sup>372</sup> The procedure used to correct the condition involved bone grafting from plaintiff's hip and fusing the grafts with metal bone plates and screws manufactured by the defendant.<sup>373</sup> Six months after the surgery, plaintiff began to complain about back pains not present prior to the surgery and alleged the pains were caused by defective plate and screw devices.<sup>374</sup> The trial court determined the 1976 Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act preempted the failure to warn cause of action.<sup>375</sup> Although this preemption also prevented plaintiff from asserting her claims for defective design and manufacturing, the jury concluded that defendant's devices did cause plaintiff's pains and were "unreasonably dangerous *per se*."<sup>376</sup> Therefore, the jury awarded a judgment to plaintiff for \$318,000 in damages.<sup>377</sup>

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<sup>370</sup>Reeves v. Acromed, 103 F.3d 442 (5th Cir. 1997).

<sup>371</sup>*Id.* at 444.

<sup>372</sup>*Id.*

<sup>373</sup>*Id.*

<sup>374</sup>*Id.*

<sup>375</sup>Reeves v. Acromed, 103 F.3d 442, 444 (5th Cir. 1997) (citing Medical Device Amendments to the Food Drug, and Cosmetic Act, 21 U.S.C. § 301).

<sup>376</sup>*Id.*

<sup>377</sup>*Id.*

On appeal, the defendant manufacturer claimed MDA also preempted the “unreasonably dangerous *per se*” cause of action and therefore, the \$318,000 judgment was inappropriate.<sup>378</sup> The metal bone plate device had been FDA approved through the 510(k) “substantial equivalency” process, an exception to the rigorous Pre-Market Approval (PMA) process required for all new post-1976 devices.<sup>379</sup> Although the device qualified for 510(k) approval, the court stated the 510(k) process merely assured “substantial equivalence” and did not concern itself with safety.<sup>380</sup> Therefore, even though defendant’s metal bone plate had been approved by FDA, this approval did not preempt liability based on safety; because a “substantially equivalent” device was never formally reviewed under the MDA for safety and efficacy.<sup>381</sup> The defendant was allowed to bypass the rigorous requirements of formal PMA approval; consequently, the defendant subjected itself to liability based on negligent manufacture and design.<sup>382</sup> The defendant’s device could not escape claims for negligent manufacturing and design simply by being “substantially similar” to a pre-1976 device.<sup>383</sup> Further, because a 510(k) approval did not require the defendant to produce the device in any particular form, defendant remained liable for “unreasonably dangerous *per se*” claims and strict liability defective design claims.<sup>384</sup>

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<sup>378</sup>*Id.* at 444-445.

<sup>379</sup>*Id.* at 445. Before a new medical device can be marketed to the public, it must receive approval from the FDA through the Pre-Market approval process. This process is expensive and very time consuming, requiring multiple research and safety studies before approval will be given. However, there are two exceptions to this rigorous process. First, all pre-1976 devices come under a “grandfather clause.” Those pre-1976 devices did not require PMA approval and were therefore allowed to remain on the market until FDA initiated and required a PMA to be performed. (21 U.S.C. § 360e(b)(1)(A)). Second, a post-1976 device may avoid the PMA process by submitting a 510(k) application to FDA demonstrating the proposed device is “substantially similar” to a pre-1976 “grandfather clause” device. (21 U.S.C. § 360e(b)(1)(B)).

<sup>380</sup>*Reeves v. Acromed*, 103 F.3d 442, 446 (5th Cir. 1997).

<sup>381</sup>*Id.*

<sup>382</sup>*Id.*

<sup>383</sup>*Id.*

<sup>384</sup>*Id.* A 510(k) application simply states the manufacturer’s device (predicate device) is substantially equivalent to the pre-1976 device (parent device). Substantial equivalence merely requires the predicate device to have the same intended use and same technological characteristics of the parent device. Therefore, once “substantial equivalence” has been shown, a 510(k) device manufacturer is not bound to the parent device’s manufactured form or process. Since manufacturing process may vary among 510(k) devices, the manufacturer is still liable for negligent design and negligent manufacturing claims which are not preempted by the MDA.

The court reversed the trial court's determination that plaintiff's defective design and defective manufacturing claims were preempted by MDA and upheld the judgment of \$318,000 against the defendant on the "unreasonably dangerous *per se*" charge.<sup>385</sup>

The court ruled plaintiff's claim against the inventor of the metal bone plate could not be upheld.<sup>386</sup> Under basic theories of recovery for product liability, the plaintiff must establish the defendant was the manufacturer or supplier of the product in question.<sup>387</sup> Because the inventor did not place the device on the market or introduce it into the stream of commerce, he could not be considered a manufacturer or supplier in an individual capacity.<sup>388</sup> *Reeves v. Acromed Corp.*, 103 F.3d 442 (5th Cir. 1997).

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## Public Health

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### **Municipal Health Board Cannot Promulgate Smoking Regulations Encompassing Policies Specifically Reserved for Other Municipality Bodies**

The Court of Appeals of North Carolina reversed summary judgment for the County Board of Health (Board) in a declaratory judgment action filed by county residents and taxpayers who challenged the enactment of county smoking control rules promulgated by the Board.<sup>389</sup> Residents and taxpayers alleged:

- (1) the Board failed to follow the proper notice procedures for enacting health regulations;
- (2) the Board exceeded its statutory authority when it enacted the smoking control rules;

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<sup>385</sup>*Reeves v. Acromed*, 103 F.3d 442, 447 (5th Cir. 1997).

<sup>386</sup>*Id.*

<sup>387</sup>*Id.*

<sup>388</sup>*Id.*

<sup>389</sup>*City of Roanoke Rapids v. Peedin*, 478 S.E.2d 528 (N.C. Ct. App. 1996).

- (3) if the Board was granted statutory authority to enact Smoking Control Rules, this was an unconstitutional delegation of legislative powers;
- (4) residents and taxpayers in the plaintiff class lost business and profits without due process of law as a result of the Board's actions; and
- (5) the terms and provisions of the smoking control rules discriminated between similarly situated businesses.<sup>390</sup>

Both parties filed motions for summary judgment. The lower court granted the Board's motion, and the plaintiffs appealed.<sup>391</sup>

The appellate court held the Board's actions would fall within the scope of its authority only if the health rules enacted:

- (1) related to the promotion or protection of health;
- (2) were reasonable in light of the health risk;
- (3) did not violate any law or constitutional provision;
- (4) did not discriminate; and
- (5) did "not make distinctions based upon policy concerns traditionally reserved for legislative bodies."<sup>392</sup>

Because the smoking control rules contained distinctions in its application which should have been reserved for "legislative policy-making," the court held the rules were invalid, and found it unnecessary to discuss any of the remaining factors.<sup>393</sup>

Assuming the Board was able to promulgate smoking regulations, the court found the plaintiffs had demonstrated the Smoking Control Rules in this case were invalid because they exempted some business establishments based on non-health related factors. The burden of proof, therefore,

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<sup>390</sup>*Id.* at 531-32.

<sup>391</sup>*Id.* at 532.

<sup>392</sup>*Id.* at 533 (citing *State v. Curtis*, 52 S.E.2d 364, 365 (N.C. 1949); *Clark's Charolette v. Hunter*, 134 S.E.2d 364, 369 (N.C. 1964); *Cookie's Diner, Inc. v. Columbus Bd. of Health*, 640 N.E.2d 1231, 1236 (Ohio 1994); *Weber v. Board of Health*, 74 N.E.2d 331, 336 (Ohio 1947); *Borealis v. Axelrod*, 517 N.E.2d 1350, 1353 (N.Y. 1987); *Matter of Council for Owner Occupied Housing v. Abrams*, 511 N.Y.S.2d 966, 969 (N.Y. App. Div. 1987)).

<sup>393</sup>*City of Roanoke Rapids v. Peedin*, 478 S.E.2d 528, 534 (N.C. Ct. App. 1996) (citing *Cookie's Diner*, 640 N.E.2d at 1240-41).

shifted to the Board to rebut this assertion.<sup>394</sup> The court found the Board had failed to provide a health-related explanation for why some establishments fell under the Smoking Control Rules while others did not. Therefore, the court reversed the lower court's grant of summary judgment for the Board, and granted summary judgment for the plaintiffs.<sup>395</sup> *City of Roanoke Rapids v. Peedin*, 478 S.E.2d 528 (N.C. Ct. App. 1996).

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## Reproductive Issues

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### State Statute Regulating Abortions After Twenty Weeks Gestation Places an Undue Burden on a Woman's Right to Choose

On remand from the United States Supreme Court, the United States Court of Appeals for the Tenth Circuit held that a state statute<sup>396</sup> restricting abortions after twenty weeks gestational age placed an undue burden on a woman's right to choose whether to abort a nonviable fetus and therefore, violated the Due Process Clause of the United States Constitution.<sup>397</sup>

The issue presented to the court on remand was whether the state's attempt to regulate abortions after twenty weeks gestational age was constitutional.<sup>398</sup> The court adopted the "undue burden" test, first articulated by the United States Supreme Court in *Planned Parenthood v. Casey*<sup>399</sup> to reach its decision.<sup>400</sup> In *Casey*, the Supreme Court held that "[a]n undue burden exists, and therefore, a provision of law is invalid, if its purpose or effect is to place a substantial obstacle in the path of a woman

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<sup>394</sup>*Id.* at 535.

<sup>395</sup>*Id.*

<sup>396</sup> UTAH CODE ANNOTATED § 76-7-302(3) (1995).

<sup>397</sup> *Jane L. v. Bangerter*, 102 F.3d 1112 (10th Cir. 1996).

<sup>398</sup> *Id.* at 1113. The United States Supreme Court limited its review to determine whether two provisions of the Utah statute § 76-7-302(2) and § 76-7-302(3) were severable. The Court ultimately held that the provisions were in fact severable. See *Leavitt v. Jane L.*, 116 U.S. 2068 *aff'd per curiam*. (1996).

<sup>399</sup> *Planned Parenthood v. Casey*, 505 U.S. 833 (1992).

<sup>400</sup> *Jane L.*, 102 F.3d at 1114.

seeking an abortion before the fetus attains viability.”<sup>401</sup> Of consequence, the *Casey* Court expressly rejected the strict scrutiny standard of review applied in similar abortion cases decided since *Roe v. Wade*.<sup>402</sup>

Looking to the legislature’s express purpose for passing the abortion provisions, the court determined that the state made a deliberate decision to disregard controlling Supreme Court precedent and to ignore the Court’s directive that viability is a matter for an attending physician to decide.<sup>403</sup> The court, therefore, declared the state abortion statute was enacted with the specific purpose of placing an “insurmountable obstacle in the path of a woman seeking the nontherapeutic abortion of a nonviable fetus after twenty weeks.”<sup>404</sup> Based on those facts, the court concluded the state statute imposed both an unconstitutional burden on a woman’s right to choose to have an abortion and an impermissible impact upon those women whose conduct the statute sought to effect.<sup>405</sup> For those women seeking an abortion, the court believed the statute “[i]mposed more than a substantial obstacle; it constituted an outright ban.”<sup>406</sup> As such, the court declared the statute unconstitutional.<sup>407</sup> *Jane L. v. Bangerter* 102 F.3d 1112 (10th Cir. 1996).

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### Settlement

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#### **A Tortfeasor Who Settles Cannot Recover in a Separate Lawsuit From a Hospital Center Alleged to be a Joint Tortfeasor When the Hospital Not Part of Original Suit**

The District of Columbia Court of Appeals held a tortfeasor who settles a claim may not recover a contribution of the settlement from a hospital

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<sup>401</sup>*Id.* (citing *Planned Parenthood v. Casey*, 505 U.S. 833, 878 (1992)).

<sup>402</sup>*Roe v. Wade*, 410 U.S. 113 (1973).

<sup>403</sup>*Jane L. v. Bangerter*, 102 F.3d 1112, 1115 (10th Cir. 1996).

<sup>404</sup>*Id.*

<sup>405</sup>*Id.* at 1116.

<sup>406</sup>*Id.* at 1117.

<sup>407</sup>*Id.*

center alleged to be a joint tortfeasor when the plaintiff had never sued the center.<sup>408</sup>

The plaintiff, on behalf of herself and her child, filed an action against the District of Columbia (District) for injuries sustained when they were struck by a motor vehicle which was involved in a high speed car chase with a District police officer.<sup>409</sup> The plaintiff was treated at the hospital center for these injuries.<sup>410</sup> Without regard to causation, the plaintiff suffered severe and permanent injuries.<sup>411</sup> The District settled with the plaintiff for \$300,000.<sup>412</sup> Subsequently, the District brought an action against the hospital center to recover a contribution for the sum it paid to settle the lawsuit. The District alleged the hospital center's negligence exacerbated and proximately caused the injuries to the plaintiff.<sup>413</sup> The trial court granted the hospital center's motion for judgment on the pleadings and the appellate court affirmed.<sup>414</sup>

The appellate court held that a settling tortfeasor is not entitled to contribution from non-settling defendants, even when the latter are found to be negligent.<sup>415</sup> The court stated the policy behind settlements is to allow the settling tortfeasor to "buy his peace"<sup>416</sup> for a specified sum. The settling tortfeasor assumes the risk that it may pay a greater portion of the plaintiff's damages than it would have paid after trial and verdict.<sup>417</sup> The court reasoned it would be unfair to disadvantage a defendant tortfeasor with a settlement to which he was not a party and to which he did not consent.<sup>418</sup> *District of Columbia v. Washington Hospital Center, No. 94-CV-319, 1996 WL 752952 (D.C. Dec. 31, 1996).*

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<sup>408</sup>*District of Columbia v. Washington Hosp. Center*, 686 A.2d 1053 (D.C. App. 1996), 1996 WL 752952 (D.C. Dec. 31, 1996).

<sup>409</sup>*Id.* at \*1.

<sup>410</sup>*Id.*

<sup>411</sup>*Id.*

<sup>412</sup>*Id.*

<sup>413</sup>*District of Columbia v. Washington Hosp. Ctr.*, 686 A.2d 1053 (D.C. App. 1996).

<sup>414</sup>*Id.*

<sup>415</sup>*Id.* at \*3.

<sup>416</sup>*Id.*

<sup>417</sup>*Id.*

<sup>418</sup>*District of Columbia v. Washington Hosp. Ctr.*, 686 A.2d 1053, 1055 (D.C. App. 1996) (citing *Martello v. Hawley*, 112 U.S. App. D.C. 129, 131 (1962)).

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**Statutes of Limitations**

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**Occurrence-Based Medical Malpractice Statute of Limitations Held Unconstitutional**

The Court of Appeals of Indiana reversed the trial court's decision, holding the statute of limitations contained in the state medical malpractice act was unconstitutional.<sup>419</sup> The court further held even if the statute of limitations was constitutional, the limitations period should have tolled by the doctrine of fraudulent concealment when a physician withheld important information from the patient.<sup>420</sup>

The patient went to her physician after noticing a lump in her breast.<sup>421</sup> The physician was out of town so a nurse completed a mammography which revealed a benign cyst.<sup>422</sup> The patient scheduled a biopsy with another physician, but her regular physician convinced her to cancel the appointment and performed a needle aspiration instead.<sup>423</sup> Although the physician assured the patient she had no basis for concern; nearly three years later, an adenocarcinoma of the breast forced the plaintiff to undergo chemotherapy.<sup>424</sup> The plaintiff subsequently filed a complaint against her former physician for negligence.<sup>425</sup> The trial court ruled plaintiff's claim was time-barred under the statute of limitations, and that her physician's actions did not amount to fraudulent concealment.<sup>426</sup>

The court of appeals first stated the state statute of limitations for medical malpractice actions was unconstitutional because it was an occurrence-based statute while other tort actions were covered by a discovery-based statute.<sup>427</sup> The statute for medical malpractice actions began to run at the time of the occurrence of the alleged negligence, rather than at the time the alleged negligence was discovered.<sup>428</sup> Although the

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<sup>419</sup>Martin v. Richey, 674 N.E.2d 1015 (Ind. Ct. App. 1997).

<sup>420</sup>*Id.*

<sup>421</sup>*Id.* at 1017.

<sup>422</sup>*Id.*

<sup>423</sup>*Id.*

<sup>424</sup>Martin v. Richey, 674 N.E.2d 1015, 1018 (Ind. Ct. App. 1997).

<sup>425</sup>*Id.*

<sup>426</sup>*Id.*

<sup>427</sup>*Id.* at 1019.

<sup>428</sup>*Id.*



court recognized this difference was reasonably related to the goal of decreasing medical malpractice litigation, the court reasoned those who discover their medical negligence after the statute has run were treated unequally, therefore, the statute was ruled unconstitutional.<sup>429</sup>

The court further held that even if the statute of limitations was constitutional, the statute of limitations in this case should have tolled by the doctrine of fraudulent concealment.<sup>430</sup> The court found the physician's conduct prevented the patient from discovering the truth about her condition, thereby preventing the discovery of his wrong.<sup>431</sup> The court remanded the case to the trial court. *Martin v. Richey*, 674 N.E.2d 1015 (Ind. Ct. App. 1997).

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<sup>429</sup>*Martin v. Richey*, 674 N.E.2d 1015, 1019 (Ind. Ct. App. 1997).

<sup>430</sup>*Id.* at 1019.

<sup>431</sup>*Id.* at 1018.