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INFORMED CONSENT AND THE SCOPE OF A PHYSICIAN'S DUTY OF DISCLOSURE

I. INTRODUCTION

When Justice Benjamin Cardozo stated that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body," he described the basic concept behind the doctrine of informed consent and a physician's duty of disclosure.[1] However, the fundamental notion of a person's right to medical autonomy that Justice Cardozo described has become clouded with issues that he most likely never contemplated.[2]

The purpose of this note is to explore the nature of the doctrine of informed consent as it has evolved in relation to the scope of what a physician must tell a patient in order to achieve full disclosure. Emerging from this exploration are the questions: how much information do patients require before they are truly informed, and what limits will be placed on the kinds of information a physician is required to provide?

This note will examine informed consent beyond the traditional notion of a physician's failure to fully inform a patient of all medical risks and cover the scope of what, if any, personal or financial information a physician must provide to patients in order to achieve a truly "informed" consent. Section II will provide a general background of the doctrine of informed consent, including the status of informed consent in North Dakota. Section III will explore the issues emerging in informed consent, including the physician's duty to disclose personal information, such as drug or alcohol use, health condition, or medical experience, and the physician's duty to disclose financial interests in a patient's care. Section IV will examine legislative responses to these issues. Finally, section V will discuss the potential implications of these issues.

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1. Schloendorff v. Soc'y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914). When Justice Cardozo wrote this opinion, he was a New York appellate court judge.

2. Judith F. Daar, *Informed Consent: Defining Limits Through Therapeutic Parameters*, 16 WHITTIER L. REV. 187, 208 (1995). The author notes:

> [T]he goals of informed consent appear to be shifting away from providing adequate medical information for patients to gain control of their health care and toward revealing an assortment of medical and nonmedical details which allow patients to contemplate the risks associated with treatment as well as those risks posed by their physicians.

Id.

II. INFORMED CONSENT: THE BASICS

In *Salgo v. Leland Stanford Jr. University Board of Trustees*,[3] a California appellate court first used the term "informed consent" to describe a physician's obligation to disclose facts that are necessary for a patient to consent to treatment.[4] The general rule for informed consent is that a physician must, except in certain situations, obtain the consent of a patient before treatment.[5] However, *mere consent* to treatment does not suffice: the patient must receive a clear and honest explanation of the proposed treatment so that he or she can give an *informed consent*.[6]

A. THE CAUSE OF ACTION

An informed consent action is most often framed either as an action for battery or as an action for negligence.[7] Early cases utilized the tort of battery based on the fact that the physician had committed an intentional and unauthorized touching of the patient.[8] In a battery action, a patient does not have to establish the causation element necessary to a negligence action, nor do damages need to be proven.[9] Therefore, the patient does not have to demonstrate that he or she would not have consented to a procedure if properly informed.[10]

Informed consent cases today generally ground their complaint on a negligence action.[11] If a physician obtains consent to perform a

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3. 317 P.2d 170 (Cal. Ct. App. 1957).

4. *Id.* at 181. The court stated that a physician should recognize that every "patient presents a separate problem, that the patient's mental and emotional condition is important and in certain cases may be crucial, and that in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent." *Id.* (citations omitted).

5. *See* 61 AM. JUR. 2D *Physicians, Surgeons, and Other Healers* § 187 (1999) (noting that the theory of informed consent arises from a patient's right of self-determination and the fiduciary relationship between the patient and the physician).

6. *Id.*; *see also* Rizzo v. Schiller, 445 S.E.2d 153, 155-65 (Va. 1994) (noting that consent that is not informed amounts to no consent at all).

7. *Risk Analysis: Informed Consent,* HOSP. RISK CONTROL (ECRI, Plymouth Meeting, Pa.), Nov. 1993, at 5-6.

8. S. SANDY SANBAR ET AL., LEGAL MEDICINE 268 (4th ed. 1998). Cases for battery usually involve those in which "(1) the patient consented to one procedure and another was actually performed, (2) the physician failed to disclose a disability that was certain to result from a proposed nonemergency procedure, or (3) the physician performed an experimental procedure without advising the patient of its experimental nature." *Id.*; *see also Risk Analysis: Informed Consent*, *supra* note 7, at 6 (noting that another ground for an informed consent battery action exists when a surgeon, other than the one the patient approved, performs a consented-to operation).

9. *Risk Analysis: Informed Consent, supra* note 7, at 5-6.

10. *See* Gouse v. Cassel, 615 A.2d 331, 333-34 (Pa. 1992) (holding that the patient need only establish that he was deprived of information a reasonable patient would have considered significant to a decision for treatment).

11. *See Risk Analysis: Informed Consent, supra* note 7, at 5-6 (noting that Pennsylvania still characterizes a physician's failure to obtain a patient's informed consent as battery).

procedure, but the patient is not adequately informed, the patient has not given informed consent.[12] In a negligence action against a physician for failure to obtain informed consent, a patient must establish the following elements: duty to inform, breach of that duty, causation, and resulting injury.[13] Alternatively, some patients frame their complaint as one for fraud or negligent misrepresentation, if the physician failed to disclose information about himself or herself that the patient believed would have been relevant to treatment decisions.[14]

1. *Exceptions to the Duty to Disclose*

Generally, a duty exists on the part of a physician to disclose a patient's choices and the risks associated with those choices.[15] The doctrine of informed consent has its foundation in the tort of battery, which recognizes that people should be free from a violation of their bodily integrity.[16] *Schloendorff v. Society of New York Hospital*[17] first most clearly invoked the idea that a patient has a fundamental right to make his or her medical decisions.[18] The past thirty years have seen a change in the notion of informed consent because people's readiness to allow physicians to be in control of all medical decisions has declined.[19] Correspondingly, the requirement that a patient give consent to treatment has broadened to the requirement that the consent be "informed." [20]

The law, however, recognizes some general exceptions to a physician's duty to obtain informed consent.[21] For example, a physician may treat an unconscious patient or a patient otherwise unable to consent when the potential harm from a failure to treat outweighs the potential danger of the treatment.[22] A physician does not have to inform a patient

12. 61 AM. JUR. 2D *Physicians, Surgeons, and Other Healers* § 187 (1999).

13. Scott v. Bradford, 606 P.2d 554, 558 (Okla. 1979). Because a plaintiff must prove duty, breach of duty, causation, and injury in a negligence action of any type, these elements are not unique to informed consent cases. *See generally* 57A AM. JUR. 2D *Negligence* § 82 (1989 & Supp. 2000).

14. Faya v. Almaraz, 620 A.2d 327, 330 (Md. 1993).

15. Cobb v. Grant, 502 P.2d 1, 10 (Cal. 1972).

16. ARNOLD J. ROSOFF, TREATISE ON HEALTH CARE LAW § 17.01(1)(a) (2000). In battery, a person is held liable for the harmful offensive touching of another. RESTATEMENT (SECOND) OF TORTS § 18 (1965). In an informed consent action based on this principle, the physician is held liable because his or her failure to disclose the necessary information prevented the patient from truly giving consent to the procedure or treatment. Joan H. Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 IOWA L. REV. 261, Part IV.A.1 (1999). When the physician then has physical contact with the patient, that contact is an impermissible touching. *Id.*

17. 105 N.E. 92 (N.Y. 1914).

18. *Id.* at 93; *see also* ROSOFF, *supra* note 16, § 17.01(1)(c).

19. ROSOFF, *supra* note 16, § 17.01(2)(a).

20. *Id.* § 17.02.

21. Canterbury v. Spence, 464 F.2d 772, 788 (D.C. Cir. 1972).

22. *See id.* (noting that a physician should attempt to seek consent from a relative if time and circumstances allow).

of risks considered common knowledge or those of which the patient already has knowledge.[23] Patients may waive their rights to a full disclosure by requesting that the physician not inform them of the attendant risks of a treatment.[24]

A physician also can withhold information if he or she feels that disclosing the risks of a treatment would cause a "threat of detriment" and hinder the patient's treatment.[25] If a physician feels that presenting treatment information to the patient would cause stress, illness, or otherwise damage his or her well-being, the physician has the right to withhold that information.[26] For example, in *Nishi v. Hartwell,*[27] physicians did not tell their patient about the risks of a thoracic aortography, a diagnostic procedure used to detect an aneurysm.[28] A reaction to the dye used in the procedure left the patient paralyzed below his waist.[29] The physicians claimed that telling a frightened patient, who suffered from heart disease and high blood pressure, about the risks of the procedure would have frightened him, and perhaps caused more problems than those suffered.[30]

The Hawaii Supreme Court held that the physician's failure to disclose the risks of the procedure fell within a therapeutic privilege, and therefore, the lower court was correct in granting the physicians' motion to dismiss.[31] The patient's wife also claimed that if her husband was not in a condition for the physicians to tell him about the risks of his procedure, they should have told her.[32] However, the court noted that the physicians owed no duty of disclosure to the spouse of a patient because

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23. SANBAR ET AL., *supra* note 8, at 267.

24. *Id.*

25. *Canterbury*, 464 F.2d at 786-87. The United States Court of Appeals for the District of Columbia Circuit cautions, however, that this privilege, if not restrained, has the potential to "devour the disclosure rule itself." *Id.*; *see also* SANBAR ET AL., *supra* note 8, at 267 (stating that for a physician to utilize what some courts call "the therapeutic privilege" or "professional discretion," he or she must have established knowledge that the patient would be excessively alarmed if completely informed of the risks).

26. *Canterbury*, 464 F.2d at 789.

27. 473 P.2d 116 (Haw. 1970), *overruled in part by* Carr v. Strode, 904 P.2d 489 (Haw. 1995).

28. *Id.* at 118. The dismissal of the complaint in *Nishi* was also affirmed on the grounds that the patient did not meet his burden under a physician-orientated disclosure standard of introducing evidence of what a physician in the community normally disclosed to a patient regarding a procedure. *Carr*, 904 P.2d at 494. This portion of the opinion was overruled when the Hawaii Supreme Court adopted the patient-oriented disclosure standard. *Id.* at 499. However, under the therapeutic privilege doctrine, in cases like *Nishi*, the physician-based standard would still apply because the physician must use his or her professional judgment to determine the patient's best interest. *Carr*, 904 P.2d at 498.

29. *Nishi*, 473 P.2d at 118.

30. *Id.* at 120.

31. *Id.* at 121.

32. *Id.* at 122.

the duty emerges from the relationship between the physician and the patient and is owed to the patient alone.[33]

2. Disclosure Standards

Jurisdictions use either a physician-based, patient-based, or hybrid standard of disclosure to determine what information a physician needs to disclose to his or her patients.[34] Under the physician-based standard, the court looks to what risks the reasonable physician would disclose to the patient.[35] The court will judge whether a disclosure was adequate by examining whether common practice in the community required the disclosure of a particular risk.[36] Under this standard, a patient usually must present expert testimony to demonstrate that a physician, following acceptable medical practice, would have disclosed the injury-causing risk.[37]

Under the patient-based standard, a physician must disclose those risks to patient that a reasonable patient would consider material to decisions about medical treatment.[38] A patient should find it easier to recover for a physician's failure to disclose personal information under this standard because the patient can argue that a reasonable patient would find this information material.[39] Because this standard does not focus on expert testimony,[40] it also avoids the difficulty that some patients face in trying to obtain physicians to testify against other physicians.[41]

The hybrid standard of disclosure encompasses those jurisdictions who have not clearly articulated a standard or who use a combination of

33. *Id.*

34. *See* TREATISE ON HEALTH CARE LAW: STATE BY STATE ANALYSIS OF APPROACHES TO INFORMED CONSENT 17A app. (2000) (classifying the states according to one of three disclosure standards: physician-based, patient-based, or a hybrid standard.)

35. Natanson v. Kline, 350 P.2d 1093, 1106, *decision clarified on denial of reh'g by* 354 P.2d 670 (Kan. 1960).

36. Canterbury v. Spence, 464 F.2d 772, 783 (D.C. Cir. 1972).

37. Cornfeldt v. Tongen, 262 N.W.2d 684, 699 (Minn. 1977), *rev'd*, 295 N.W.2d 638 (Minn. 1980). The court modified its prior opinion by stating that the disclosure duty extends beyond disclosing significant risks to include professional competence and patient self-determination. *Cornfeldt*, 295 N.W.2d at 640 n.2.

38. *Canterbury*, 464 F.2d at 786-87.

39. Mary Anne Bobinski, *Autonomy and Privacy: Protecting Patients from their Physicians*, 55 U. PITT. L. REV. 291, 344 (1994).

40. Ketchup v. Howard, 247 Ga. App. 54, 62 (2000). However, under this standard, expert testimony may be needed to demonstrate that the risk that produced the injury is one that the physician knew or should have known about. *Id.* Under this patient-based standard, expert testimony is generally not used to establish a physician's duty to disclose. *Id.* Rather, the jury decides "whether a reasonable person in the patient's position would have considered the risk significant in making the decision to have or reject the proposed treatment." *Id.*

41. ROSOFF, *supra* note 16, § 17.03(3)(a); *see also* Winkjer v. Herr, 277 N.W.2d 579, 589 (N.D. 1979) ("We are well aware of the contention that the reluctance of the members of the medical profession to testify against a fellow physician makes the search for a medical expert very difficult and nearly impossible in some cases.").

physician and patient disclosure standards and, therefore, cannot be categorized as one or the other.[42]

3. *The Connection Between the Injury and Failure to Disclose*

For the causation element, courts use either an objective test or a subjective test to determine whether a patient would have refused treatment if the physician had made an adequate disclosure.[43] The majority of jurisdictions follow an objective test under which a plaintiff must prove that a reasonable person would not have undergone the procedure/ treatment if he or she was properly informed.[44] A minority of jurisdictions use a subjective test, which examines whether or not the individual patient would have chosen the procedure/treatment if he or she had been fully informed.[45]

4. *Injury*

Finally, the patient must suffer an injury from the risk that the physician failed to disclose.[46] If the undisclosed risk fails to materialize, the patient has not established the final element of the negligence cause of action.[47] Most informed consent cases involve physical injuries,[48] but claims for wrongful death,[49] emotional injuries,[50] and loss of consortium[51] have also been asserted.

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42. ROSOFF, *supra* note 16, § 17.03(4).

43. *See* SANBAR ET AL., *supra* note 8, at 268.

44. ROSOFF, *supra* note 16, § 17.03(2)(b)(ii); *e.g.*, Canterbury v. Spence, 464 F.2d 772, 791 (D.C. Cir. 1972).

45. Scott v. Bradford, 606 P.2d 554, 559 (Okla. 1979). The court criticizes the *Canterbury* Court's "reasonable man" standard because it denies protection to a patient who would have chosen not to have a treatment if a reasonable person would have chosen the treatment after receiving proper disclosure. *Id.* at 558-59. To the *Scott* Court, this reasoning unacceptably hampers a patient's right to self-determination. *Id.* at 559.

46. *Id.*

47. *Id.*

48. Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees, 317 P.2d 170, 172 (Cal. 1957) (malpractice action for paralysis).

49. Kaskie v. Wright, 589 A.2d 213, 214 (Pa. Super. Ct. 1991) (wrongful death of claimants' son).

50. Faya v. Almaraz, 620 A.2d 327, 330 (Md. 1993) (emotional distress due to exposure to the AIDS virus).

51. Albany Urology Clinic, P.C. v. Cleveland, 528 S.E.2d 777, 778 (Ga. 2000) (the patient's spouse claimed loss of consortium).

B. INFORMED CONSENT LAW IN NORTH DAKOTA

In 1977, North Dakota passed a statute[52] in reaction to medical malpractice claims in an attempt to limit the liability of health care providers.[53] Informed consent was defined as "consent to a procedure based on information which would ordinarily be provided to the patient under like circumstances by health care providers."[54] By this definition the statute created a physician-based disclosure standard.[55] Because the statute changed the test for failure to consent to treatment from a subjective to an objective standard, the information that should be disclosed to a patient would be determined by the custom of health care providers.[56] The North Dakota Supreme Court ultimately held the chapter as a whole unconstitutional.[57]

The North Dakota Supreme Court has not ruled whether the disclosure standard should be judged based on "the custom of the physician practicing in the community" or based on what is "reasonable under the circumstances."[58] In *Winkjer v. Herr*,[59] the court considered the extent of a physician's duty to disclose a patient's treatment choices, the associated risks, and the standard by which that duty should be measured.[60] As a treatment for glaucoma, the physician prescribed a

52. N.D. CENT. CODE ch. 26-40.1 (1977) (held unconstitutional in *Arneson v. Olson*, 270 N.W.2d 125, 126 (N.D. 1978)).

53. *Arneson*, 270 N.W.2d at 127, 130.

54. N.D. CENT. CODE § 26-40.1-02(5) (held unconstitutional).

55. *Id.* § 26-40.1-05 (held unconstitutional). Before a patient may recover damages in an action based on failure to obtain informed consent, the patient must establish "that a reasonably prudent person in the claimant's position would not have undergone the treatment had he been properly informed and that the performance of the treatment was the proximate cause of the injury and damages claimed." *Id.* Through this language, the statute also created an objective standard by which to judge the causation element of an informed consent action. *See supra* Part II.A.3.

56. *See Arneson*, 270 N.W.2d at 126, 133. The legislature attempted to contain the applicability of this chapter to those patients who consented to its provisions by signing a form. *Id.* However, if a patient did not consent, the physician did not have to provide treatment. *Id.* at 133-34. Therefore, if a physician denied treatment, the patient could choose "to suffer or die of his ailment or to travel outside the State to obtain medical attention." *Id.* at 134. The court considered the harshness of these choices in its decision to find the statute unconstitutional. *Id.*

57. *Id.* at 138. The North Dakota Supreme Court held that the entire Act violated due process on several grounds: it was applied to only one category of health care providers (physicians), consent was imposed under duress and in emergencies, the doctrine of res ipsa loquitur was limited, and the collateral source doctrine was nearly abolished. *Id.* at 137. Under the collateral source doctrine, payments made to an injured party by a third party, or a collateral source, will not reduce a tort defendant's liability to the injured party. RESTATEMENT (SECOND) OF TORTS § 920-A (1965). Thus, if an injured person recovers under his or her own insurance policy, the tort defendant's liability will not be reduced correspondingly. *Id.*

58. Lemke v. United States, 557 F. Supp. 1205, 1212 (D.N.D. 1983) (quoting Winkjer v. Herr, 277 N.W.2d 579, 587-88 (N.D. 1979)).

59. 277 N.W.2d 579 (N.D. 1979).

60. *Id.* at 587.

phospholine iodine eye solution for the patient.[61] The patient later developed cataracts in both eyes, a condition he blamed on the eye solution.[62] The court examined the duty of disclosure both on the basis of what a reasonable medical practitioner would disclose and on the basis of what risks a patient would consider material.[63]

However, the court declined to decide which standard to adopt and instead decided the case on the basis of lack of expert testimony.[64] The court noted that a physician has no duty to inform a patient of extremely rare risks or of risks that the physician does not know exist.[65] In this case, the patient failed to provide expert testimony to refute the physician's expert witnesses who testified that developing cataracts from using that strength phospholine iodine for less than a year was highly unlikely and actually unheard of.[66] Thus, the court affirmed the lower court's granting of summary judgment.[67]

In *Wasem v. Laskowski*,[68] decided after the Medical Malpractice Act was found unconstitutional, the North Dakota Supreme Court affirmed a lower court's jury instructions on informed consent that suggested a patient-based disclosure standard.[69] Another portion of the instructions indicated that what physicians in similar circumstances would disclose is "relevant and material" to whether proper disclosure was made.[70] However, the court specifically stated that jury instructions must be examined as a whole.[71] Thus, an emphasis on one specific portion of the instructions may not be wise, especially given the court's later failure to decide, in *Winkjer*, which standard to adopt.[72]

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61. *Id.* at 582.
62. *Id.*
63. *Id.* at 588-89. The North Dakota Supreme Court acknowledged the "persuasive reasoning" in *Canterbury* that "the test for determining whether a particular peril must be divulged is its materiality to the patient's decision: all risks potentially affecting the decision must be unmasked." *Id.* at 588 (quoting Canterbury v. Spence, 464 F.2d 772, 786-87 (D.C. Cir. 1972)).
64. *Id.* at 588-89. The court noted that generally expert testimony plays a more important role in determining the disclosure standard for the reasonable physician. *Id.* at 587-88. However, when the medical questions fall beyond the understanding of laymen, expert testimony is needed. *Id.* at 588.
65. *Id.* at 588. The court stated that "there is no need to disclose risks of little consequence, those that are extremely remote, or those that are common knowledge as inherent in the treatment." *Id.* (citing Cobb v. Grant, 502 P.2d 1, 11 (Cal. 1972)).
66. *Id.* at 588-89.
67. *Id.* at 589.
68. 274 N.W.2d 219 (N.D. 1979).
69. *Id.* at 226. The jury instructions stated in part:

> The duty of a doctor to inform the patient is measured by a standard of reasonableness. The doctor must make such disclosures as appear necessary to enable a reasonable person, under the same or similar circumstances confronting the patient at the time of the disclosure to intelligently exercise his right to consent or to refuse the procedure proposed.

Id.

70. *Id.*
71. *Id.* at 222-23.
72. Winkjer v. Herr, 277 N.W.2d 579, 588-89 (N.D. 1979).

The North Dakota Supreme Court has also declined to decide whether the objective or subjective test should be used in determining causation for informed consent actions.[73] In *Buzzell v. Libi*,[74] a patient consented to have her right ear operated on, but the consent form mistakenly listed her left ear.[75] When the surgeon operated, he found no sign of the suspected problem in her right ear, but after examining her left ear, he operated on a problem he subsequently discovered.[76] Although the court found that the physician had breached his duty of disclosure, the patient's action failed to establish the causation element.[77] Causation was lacking because the patient admitted that had the physician recommended the left-ear surgery she would have agreed to it.[78] The court noted that a patient "has no complaint if he would have submitted to the treatment if the physician had complied with his duty and informed him of the risks."[79] The court, therefore, never reached a conclusion as to whether the objective or subjective test would apply in determining whether a patient would have consented to the procedure.[80]

Currently, North Dakota statutory law concerning informed consent involves very specific situations, such as consent for abortion,[81] consent for Human Immunodeficiency Virus (HIV) testing,[82] and consent issues involving those individuals, such as minors and the incapacitated, who are unable to give consent.[83]

Thus, the North Dakota Supreme Court has not explicitly stated whether it will follow a physician or patient-based standard of disclosure.[84] However, based on the affirmation of jury instructions using a patient-based standard[85] and the fact that expert testimony is not re-

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73. Buzzell v. Libi, 340 N.W.2d 36, 41 n.3 (N.D. 1983).

74. 340 N.W.2d 36 (N.D. 1983).

75. *Id.* at 38. The court noted that even though the patient had signed a consent form for surgery listing her left ear, that consent was void because the physician had never discussed surgery on that ear or told the patient of the risks. *Id.* at 40. The physician was aware at the time of the surgery that the consent form mistakenly listed the left ear instead of the right. *Id.* at 38.

76. *Id.* at 38.

77. *Id.* at 40-41.

78. *Id.* at 41.

79. *Id.* (citing Scott v. Bradford, 606 P.2d 554, 558 (Okla. 1979)).

80. *Id.* at 41 n.3.

81. *See* N.D. CENT. CODE § 14-02.1-02 (1997) (listing definitions under the abortion control act, including a definition for "informed consent"); *see also* N.D. CENT. CODE § 14-02.1-03 (1997) (consent to abortion).

82. *See* N.D. CENT. CODE § 23-07.5-02 (Supp. 1999) (informed consent for HIV testing or disclosure).

83. *See id.* § 23-12-13 (Supp. 1999) (persons authorized to provide informed consent to health care for incapacitated persons).

84. Lemke v. United States, 557 F. Supp. 1205, 1212 (D.N.D. 1983) (citing Winkjer v. Herr, 277 N.W.2d 579, 587-88 (N.D. 1979)).

85. Wasem v. Laskowski, 274 N.W.2d 219, 226 (N.D. 1979).

quired for informed consent cases,[86] North Dakota courts would likely follow a patient-based standard.[87]

III. INFORMED CONSENT: ISSUES FOR TODAY

Today, the doctrine of informed consent and the duty of disclosure have broadened beyond the traditional elements to include information about the provider of the medical care.[88] This expansion poses some dilemmas for caregivers as they determine the relevant facts to disclose to a patient.[89] Ultimately, the changing requirements of the duty of disclosure have the potential to change the way society thinks about informed consent.[90]

A. DUTY TO DISCLOSE PERSONAL INFORMATION

An issue that has recently arisen in the area of informed consent involves whether physicians have a duty to disclose personal information that arguably might affect a patient's consent to treatment.[91] Examples of the areas of personal information that patients have claimed a right to know include a physician's substance abuse,[92] Human Immunodeficiency Virus (HIV) or Acquired Immune Deficiency Syndrome (AIDS) status,[93] and a physician's qualifications.[94]

1. *Drug and Alcohol Use*

The question of whether a physician's use or abuse of drugs or alcohol can void a patient's consent to an otherwise informed course of treatment poses interesting and wide-reaching possibilities, if expanded to other professions.[95] If a court finds that drug or alcohol use by a

86. *See* N.D. CENT. CODE § 28-01-46 (Supp. 1999) (expert opinion is required to maintain an action based upon medical negligence except in obvious cases and in cases based on a lack of informed consent).

87. *See generally* TREATISE ON HEALTH CARE LAW: STATE BY STATE ANALYSIS OF APPROACHES TO INFORMED CONSENT 17A app. (2000).

88. *See* Bobinski, *supra* note 39, at 312.

89. *Risk Analysis: Informed Consent*, *supra* note 7, at 2-3.

90. *See* ROSOFF, *supra* note 16, § 17.01(2)(d) (noting that developments, such as the changing ways health care is financed and the changes in the type and amount of information available regarding treatments and health care providers, "have the potential to unleash a new round of doctrinal growth in the law governing informed consent").

91. *See, e.g.*, Kaskie v. Wright, 589 A.2d 213, 216-17 (Pa. Super. Ct. 1991) (holding that the informed consent doctrine does not encompass the duty of a physician to disclose his alcoholism).

92. Albany Urology Clinic, P.C. v. Cleveland, 528 S.E.2d 777 (Ga. 2000).

93. Faya v. Almaraz, 620 A.2d 327 (Md. 1993).

94. Johnson by Adler v. Kokemoor, 545 N.W.2d 495 (Wis. 1996).

95. *Albany*, 528 S.E.2d at 782 & n.19. The Georgia Supreme Court examines a hypothetical in which an attorney, whose physician diagnoses him as a binge drinker, might be required to disclose this fact to his clients even though his drinking does not affect his work. *Id.* at n.19. Going further, the court contemplates whether the attorney would have to disclose his habits to a client who opposed

physician does not void consent, an injured patient has other recovery opportunities.[96] Physicians can still be held accountable through traditional malpractice claims if it can be demonstrated that because of alcohol or drug use a patient was harmed during treatment.[97]

In examining whether certain undisclosed physician characteristics, like substance abuse, should provide a patient with grounds for an informed consent action, a slippery slope argument easily takes shape: what would be the limits of the personal characteristics an individual would have to disclose in a professional relationship?[98] The Georgia Supreme Court noted, in reversing a lower court's decision to allow a claim for a physician's failure to disclose his drug use, that the disclosure standard including life factors would ultimately depend on the subjective beliefs and standards of the individual involved.[99] If physicians are held to heightened disclosure requirements, perhaps accountants, lawyers, architects, and other professionals could also be required to disclose personal information.[100]

In *Albany Urology Clinic, P.C. v. Cleveland*,[101] a physician recommended that a patient have a lump on his penis removed, expressing concerns about penile cancer.[102] After the operation, the patient was unable to have intercourse.[103] He claimed that the physician performed the surgery negligently and that the surgery was unnecessary.[104] One of the grounds of the patient's suit was that the physician had fraudulently concealed his cocaine use during the time he treated the patient.[105] The court in *Albany* posed some interesting hypotheticals about the potential consequences of requiring a physician to disclose drug or alcohol use: would a physician who one night learns of a parent's illness or who

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drinking for religious reasons. *Id.*

96. *Id.* at 780.

97. *See id.* (noting that the patient could use evidence that the physician's drug use caused the doctor to provide "deficient professional services" to support a medical malpractice claim).

98. *Id.* at 781-82.

99. *Id.* At the time this case was decided, Georgia was the only state that did not recognize the doctrine of informed consent. Ketchup v. Howard, 247 Ga. App. 54, 54 (2000). Georgia provided a statutory duty for medical providers to disclose the risks of certain procedures, including surgery performed under general, regional, or spinal anesthesia and procedures that involve the injection of a contrast material. GA. CODE ANN. § 31-9-6.1 (Harrison 1998), *amended by* 2001 Georgia Laws Act 2 (H.B. 107). However, in *Ketchup*, a Georgia appeals court overruled previous case law and recognized the common law doctrine of informed consent. 247 Ga. App. at 65-66. *Albany* dealt with the statutory duty to disclose risks, so it is unclear what effect the recognition of a common law duty of disclosure would have had on that case. *Ketchup*, 247 Ga. App. at 65.

100. Lawrence Viele, *Disclosure Suit Against Doctor Could Affect Other Professions*, FULTON COUNTY DAILY REP. (Fulton County, Ga.), Aug. 19, 1999.

101. 528 S.E.2d 777 (Ga. 2000).

102. *Id.* at 778.

103. *Id.* The patient suffered a painful curvature of his penis during erections, which made him unable to have intercourse. *Id.*

104. *Id.*

105. *Id.*

receives divorce papers have a duty to tell her patients?[106] The court also noted the "impossibility of defining which of a professional's life factors would be subject to such a disclosure requirement."[107]

The dissenting justice, however, observed that the physician in the case intended that his patients remain unaware of his drug use.[108] He reasoned that informed consent to a procedure includes more than just consent to the procedure and encompasses the qualifications of the physician performing it.[109] He was critical of the majority's public policy argument that defining which of a professional's personal characteristics would be subject to disclosure would become impossible to limit.[110] The dissenting justice would have decided the case by focusing only on the characteristics related to the medical profession and the requirement that a patient must give consent to the treatment in question.[111] If the physician has not provided proper disclosure, then he or she will have committed a battery.[112] He countered the majority's argument that what information a physician would have a duty to disclose would be too subjective to determine, noting that in Georgia, a physician's license may be revoked for crimes of moral turpitude or the use of an illegal drug.[113] Therefore, this case did not turn on the subjective beliefs and standards of a patient because the physician had demonstrably violated both professional and societal mores.[114]

In *Kaskie v. Wright*,[115] parents sued a physician after their son died in his surgical care, when they that learned the doctor had alcohol problems and did not possess a state medical license.[116] A Pennsylvania appeals court considered the parents' claim of a lack of informed consent by examining the traditional informed consent principles: whether the patient was aware of the material risks of an operation, including its nature and seriousness, the problem trying to be cured, and the potential

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106. *Id.* at 782 n.19.
107. *Id.* at 781-82.
108. *Id.* at 783 (Carley, J., concurring in part and dissenting in part).
109. *Id.*
110. *Id.* at 784.
111. *Id.*
112. *Id.*
113. *Id.*
114. *Id.* The dissenting justice noted:

> Regardless of where the line ultimately is drawn with regard to a doctor's duty to disclose in order to avoid civil liability for an unauthorized touching, Dr. Trulock crossed the line when he obtained Mr. Cleveland's consent without disclosing a factor which could result in the doctor's criminal prosecution and put his professional license in jeopardy.

Id.

115. 589 A.2d 213 (Pa. 1991).
116. *Id.* at 214.

results.[117] However, the court was reluctant to go beyond the traditional analysis to examine not only the procedure but also the physician performing it.[118]

The court noted that matters such as "personal weaknesses and professional credentials" should be left to the management of the hospitals and corporations who employ the physicians.[119] Thus, the court concluded that any liability for negligence due to the personal qualities or qualifications should fall on those who hire the physicians.[120] The court was simply unwilling to extend the doctrine of informed consent that far beyond its "original boundaries" to the point where the limits defied definition.[121]

In *Hidding v. Williams,*[122] a Louisiana appeals court reached a contrary conclusion regarding a physician's duty to disclose personal life factors that might affect a patient's treatment.[123] After the patient underwent lumbar surgery, he experienced a permanent loss of his bowel and bladder control.[124] The patient sued his physician for negligence and for failure to disclose both the risk of loss of excretory functions and the physician's alcohol abuse.[125]

The court affirmed the lower court's ruling that the physician's failure to inform the patient of his personal alcohol abuse voided the surgical consent.[126] The court reasoned that the alcohol abuse created a material risk relating to the physician's ability to perform the surgery and that, had the physician disclosed this information, the patient could have opted for another type of treatment.[127] After reviewing evidence relating to the physician's heavy drinking habits and drug and alcohol dependency, the court agreed that the physician's condition increased the potential for injury and that the failure to disclose that risk violated informed consent.[128]

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117. *See id.* at 216 (noting that without obtaining such consent the physician will be committing a battery).

118. *See id.* (questioning whether the court should expand the doctrine to this degree).

119. *Id.* at 217.

120. *Id.*

121. *See id.* (questioning whether patients would have "to be informed of every fact which might conceivably affect performance in the surgical suite").

122. 578 So. 2d 1192 (La. Ct. App. 1991).

123. *See id.* at 1198 (holding that a physician violated the informed consent doctrine by not disclosing his alcohol abuse to his patient).

124. *Id.* at 1194.

125. *Id.*

126. *Id.* at 1196, 1198.

127. *Id.* at 1196.

128. *Id.* at 1198. The district court based its decision on medical testimony about alcoholism, testimony from the physician's former wife about his alcohol use, and pleadings from his divorce, which detailed his substance problems. *Id.* at 1197. The physician denied having an alcohol problem and maintained that the medical review board suspended his license on the basis of hearsay. *Id.*

Thus, the present case law shows that courts have treated the issue of whether a patient can claim that a physician's substance abuse voided his or her consent differently.[129] Whether a patient will prevail on such a claim remains a gray area of informed consent.

2. *HIV and AIDS Status*

Whether physicians have a duty to disclose their Human Immunodeficiency Virus (HIV) or Acquired Immune Deficiency Syndrome (AIDS) status to their patients varies from jurisdiction to jurisdiction.[130] A Maryland appeals court acknowledged that, when proper techniques are used, medical science suggests an extremely low risk of transmitting HIV during surgery.[131] The court did, however, note that the seriousness of the risk should be evaluated along with the risk's probability.[132] Therefore, although the risk of contracting the AIDS virus from a surgeon is low, if the patient does become infected he or she will almost certainly die.[133] Cases involving HIV exposure often consist of a patient who seeks damages for an injury consisting of the fear of contracting AIDS and the physical symptoms of that fear in the absence of evidence that he or she actually contracted the disease.[134]

In *Faya v. Almaraz*,[135] two patients sued the estate of a surgeon who had operated on them without telling them he was HIV-positive.[136] Neither woman could allege that due to some accident or incident during the operation the AIDS virus had entered their bloodstream.[137] The Maryland appeals court held that even though the patients could not allege actual transmission of the disease, the patients could recover for the fear and mental distress they experienced as a result of their anxiety

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129. *Compare* Albany Urology Clinic, P.C. v. Cleveland, 528 S.E.2d 777, 781 (Ga. 2000) (holding no cause of action for a physician's failure to reveal drug use), *with* Hidding v. Williams, 578 So. 2d 1192, 1198 (La. Ct. App. 1991) (holding a cause of action exists for a physician's failure to reveal his alcohol abuse).

130. *Compare* Faya v. Almaraz, 620 A.2d 327, 339 (Md. 1993) (finding that a physician's failure to disclose HIV status to his patients resulted in a cause of action based on lack of informed consent), *with* K.A.C. v. Benson, 527 N.W.2d 553, 561-62 (Minn. 1995) (finding that where there are no compensable damages resulting from the HIV exposure, there can be no claim for nondisclosure).

131. *Faya*, 620 A.2d at 333.

132. *Id.*

133. *Id.*

134. Kerins v. Hartley, 33 Cal. Rptr. 2d 172, 174 (Ct. App. 1994). Patients frame their complaints in a number of ways, but their causes of action may include failure to obtain informed consent, intentional infliction of emotional distress, battery, negligent misrepresentation, breach of fiduciary duty, and fraud. *Faya*, 620 A.2d at 330.

135. 620 A.2d 327 (Md. 1993).

136. *See id.* at 333 (noting that while both women alleged multiple counts of misconduct, their complaints centered on the surgeon's failure to disclose his illness).

137. *Id.* at 330-31. The lower court, holding that the women had no actionable claim, characterized the women's claimed injury as the "fear that something that did not happen could have happened." *Id.*

about contracting AIDS.[138] However, the court limited the women to a "legitimate window of mental anxiety," noting that they could recover for the fear and physical manifestations of that fear only for the time period between learning of the surgeon's illness and learning of their own HIV-negative test results.[139]

However, in *K.A.C. v. Benson*,[140] the Minnesota Supreme Court held that no claim exists when a patient seeks damages solely out of the fear of contracting AIDS, when the patient demonstrates no actual exposure to the virus.[141] Both the claim for battery and for negligent nondisclosure failed on the grounds that there were no "compensable damages recognized by law."[142]

Cases involving physicians' health status in the areas of HIV and substance use pose risk management challenges for hospitals.[143] A hospital may need to take on a greater role in setting internal standards for informed consent and monitoring physicians' credentials in order to protect themselves from negligence claims.[144]

3. *Qualifications*

Another questionable area that has emerged in the sphere of a physician's personal information is the degree to which a patient has a right to know about a physician's experience or lack thereof in performing an operation.[145] Clearly, if a patient asks a physician about his or her experience with a certain procedure, the physician has a duty to disclose the information.[146] Absent inquiry by a patient, however, the question has arisen: does a physician have a duty to disclose his or her experience and qualifications?[147]

A Washington appeals court has questioned how far this duty would go because, theoretically, "the physician's own health, financial situa-

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138. *Id.* at 337.

139. *Id.* at 337, 339. The court noted that medical evidence demonstrated a 95% certainty that a person will, if infected, test positive for HIV within six months of exposure. *Id.* at 337 (citing figures from U.S. DEP'T OF HEALTH AND HUMAN SERVICES, VOLUNTARY HIV COUNSELING AND TESTING: FACTS, ISSUES, AND ANSWERS (1991)).

140. 527 N.W.2d 553 (Minn. 1995).

141. *Id.* at 560.

142. *Id.* at 561.

143. *Risk Analysis: Informed Consent*, *supra* note 7, at 4.

144. *Id.*

145. *See* II THE PHYSICIAN'S PERSPECTIVE ON MEDICAL LAW 410 (Howard H. Kaufman & Jeff L. Lewin eds., 1997) (suggesting that patients may be increasingly seeking this type of information).

146. Canterbury v. Spence, 464 F.2d 772, 783 n.36 (D.C. Cir. 1972). However, this court rejected the idea that "the patient should ask for information before the physician is required to disclose. Caveat emptor is not the norm for the consumer of medical services." *Id.* at 783 n.36.

147. *See id.* (noting that the "[d]uty to disclose . . . is a duty to volunteer, if necessary, the information the patient needs for [an] intelligent decision").

tion, [or] even medical school grades could be considered material facts a patient would want to consider in consenting to treatment by that physician."[148] In *Whiteside v. Lukson*,[149] a patient sued her physician after an operation to remove her gallbladder resulted in numerous complications.[150] When the patient agreed to undergo the procedure, the physician did not tell her that he had never performed the procedure on a person before.[151] Although the jury found that the physician's failure to disclose his experience with the procedure resulted in a failure to obtain the patient's informed consent, the court granted the physician's motion for a judgment notwithstanding the verdict.[152] The court followed the "traditional approach" and found that a physician's degree of experience in performing a particular operation is not a material fact for liability issues in a claim for failure to obtain informed consent.[153]

However, other jurisdictions have found that a physician's experience regarding a procedure is an element that will demonstrate to the patient all of the viable treatment options and therefore should be disclosed.[154] One patient, after undergoing surgery for an aneurysm which left her an incomplete quadriplegic,[155] sued her surgeon for failing to disclose that he had only performed six surgeries for aneurysms after completing his residency training, and that he had never operated on one as complex or large as hers.[156]

Although the surgeon argued that requiring him to disclose such information transformed his duty to inform the patient about the risks of the surgery into a duty to reasonably perform the surgery, the court disagreed.[157] Following jurisdiction precedent regarding the informed consent statute, the court found that disclosure was not limited by the plain language of the Wisconsin statute to the disclosure of "the availability of all alternate, viable medical modes of treatment" and "the

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148. Whiteside v. Lukson, 947 P.2d 1263, 1265 (Wash. Ct. App. 1997).

149. 947 P.2d 1263 (Wash. Ct. App. 1997).

150. *Id.* at 1264.

151. *Id.* The physician had learned the procedure by practicing on pigs, but by the time he did the patient's surgery, he had performed the operation on two other people. *Id.*

152. *Id.*

153. *Id.* at 1265; *see also* Thomas v. Wilfac, Inc., 828 P.2d 597, 601 (Wash. Ct. App. 1992) (rejecting the assertion that the physician was required to inform his patient of his medical qualifications).

154. Johnson by Adler v. Kokemoor, 545 N.W.2d 495, 498 (Wis. 1996).

155. *Id.* at 499. After surgery, the patient could not walk or control her excretory functions, and her vision, speech, and upper body coordination were impaired. *Id.*

156. *Id.* at 497, 499.

157. *Id.* at 504. The surgeon argued that the duty to inform should be thought of as a "bright line rule" that requires only the disclosure of significant risks attendant to the procedure. *Id.* The court, however, followed the reasoning of the *Canterbury* Court, which stated that in informed consent, "there is no bright line separating the significant from the insignificant." *Id.* at 505 (quoting Canterbury v. Spence, 464 F.2d 772, 788 (D.C. Cir. 1972)).

benefits and risks of these treatments."[158] The court held that along with personal experience, the physician should have disclosed his risk statistics, as compared to other surgeons who performed the same surgery, and the availability of other more capable medical care providers.[159]

B. DUTY TO DISCLOSE FINANCIAL INTERESTS IN A PATIENT'S CARE

An area that has received increasing attention is whether and to what extent a physician has a duty to disclose financial interests in a patient's care.[160] Patients who seek to litigate a physician's failure to inform them of financial interests may have to contend with federal regulations dealing with health care.[161] The days of a physician practicing medicine as a sole practitioner on a fee-for-service system have evolved into physicians who work for larger organizations, such as managed care groups and sports teams.[162] Exactly what these changes mean for a physician's obligations of disclosure is gradually being defined through case law, as illustrated in the following sections.

1. *Research Interests*

The earliest and best known case involving informed consent and a breach of a physician's fiduciary duty is *Moore v. Regents of the University of California.*[163] The court held that for a physician to obtain informed consent and satisfy his fiduciary duty, he had to disclose research or economic personal interests independent from the patient's health.[164] The patient suffered from leukemia, and the defendant surgeon recommended a splenectomy.[165] The surgeon was aware that the patient's blood contained valuable substances that he could use for certain scientific and commercial ventures.[166] After obtaining the patient's consent for surgery, the physician worked with the Regents of the University of California, a genetics institute, and a pharmaceutical

158. *Id.* at 501, 505 (citing WIS. STAT. § 448.30).

159. *Id.* at 498.

160. *See generally* Bobinski, *supra* note 39, at 301-02.

161. *See* Krause, *supra* note 16, at Part IV.C.2 (noting that managed care organizations have used the Employee Retirement Income Security Act (ERISA), which preempts state laws that relate to any employer benefit plan, to avoid tort suits by patients).

162. *Id.* at Part II.A.

163. 793 P.2d 479 (Cal. 1990). The court noted that a physician who has research interests in a patient's care runs the risk of having conflicting loyalties that may result in performing tests or procedures that serve the research interests and not the patient. *Id.* at 484.

164. *Id.* at 485.

165. *Id.* at 481.

166. *Id.*

company to create and patent a cell line[167] from the patient's white blood cells.[168] The physician retained the patient's spleen after surgery as well as obtaining other tissue and blood samples over the course of the next seven years for this purpose.[169]

The court reasoned that although informed consent questions typically occur when a physician does not properly disclose all medical risks of a procedure, the doctrine could also encompass situations in which a physician fails to disclose personal interests.[170] The court concluded that when a physician has a research interest in a patient, this interest could create conflicting loyalties.[171] This conflict is something that a reasonable patient would want to know about before consenting to treatment.[172] Even though the patient needed the surgery for legitimate medical purposes, the physician still had an obligation to inform his patient about his underlying personal interests.[173] The patient, not the physician, should determine the true motivations of the physician.[174]

A recent suit by the parents of children whose genetic material was used to create a test for Canavan disease presents many of the same issues as *Moore*.[175] Parents of affected children allowed researchers to take pieces of their children's brains after they had died in order to develop a prenatal test for the disease.[176] The hospital where the test was developed patented the gene, and it began charging royalties as well as

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167. *Id.* at 481-82. One type of Moore's white blood cells overproduced a certain protein involved in regulating the body's immune system, allowing the researchers to more easily identify its genetic material. *Id.* at 482 n.2. Once identified, the researchers could isolate the genetic material and develop a culture or cell line that would continually reproduce. *Id.*

168. *Id.* at 480-81.

169. *Id.* at 480-81. Of the patient's thirteen allegations (conversion, lack of informed consent, breach of fiduciary duty, fraud and deceit, unjust enrichment, quasi-contract, bad faith breach of the implied covenant of good faith and fair dealing, intentional infliction of emotional distress, negligent misrepresentation, intentional interference with prospective advantageous economic relationships, slander of title, accounting, and declaratory relief), ultimately, he only succeeded in stating a cause of action for lack of informed consent and breach of fiduciary duty. *Id.* at 482 n.4, 485.

170. *Id.* at 483. The court in *Moore* focused on three principles:

> First, "a person of adult years and in sound mind has the right, in the exercise of control over his own body, to determine whether or not to submit to lawful medical treatment." Second, "the patient's consent to treatment, to be effective, must be an informed consent." Third, in soliciting the patient's consent, a physician has a fiduciary duty to disclose all information material to the patient's decision.

Id. at 483 (citations omitted).

171. *Id.* at 484.

172. *See id.* (reasoning that knowing about a conflicting loyalty, as a material element to a decision for treatment, is a prerequisite to informed consent).

173. *Id.* at 486.

174. *Id.* at 485 (citing Cobb v. Grant, 502 P.2d 1, 10 (Cal. 1972)).

175. Peter Gorner, *Parents Suing over Patenting of Genetic Test*, CHI. TRIB., Nov. 19, 2000, at C1. Affecting mainly Jewish children, Canavan disease is a rare neurological disorder that causes the brain to slowly deteriorate. *Id.*

176. *Id.*

limiting the availability of the test.[177] Families who gave tissue samples are suing for control of the gene on the basis that their rights were violated by the researchers' actions.[178] The plaintiffs seek to block Miami Children's Hospital's commercial use of the gene, so those tests can be given for free once again.[179]

2. *Physician Incentives and Gag-Clauses*

In the past, when medicine was largely delivered on a fee-for-service system, physicians received compensation corresponding to the amount of services they provided.[180] Informed consent claims of this era tended to focus on the fact that the physician failed to disclose risks associated with a certain treatment.[181] However, the delivery of healthcare today is furnished largely through Health Maintenance Organizations (HMOs).[182] Providers in HMOs generally receive more compensation for keeping costs down or, in other words, for providing fewer services.[183] Therefore, informed consent actions today have begun to focus on the physician's failure to adequately inform a patient about certain treatment options.[184]

HMOs sometimes use so-called "gag clauses"[185] to control how their employee physicians deliver medical care and also what information they tell their patients.[186] When physicians are bound by gag-clauses, patients may allege that because all treatment options were not presented, the physician breached his or her fiduciary duty.[187] The American Medical Association's Council on Ethical and Judicial Affairs (Council) supports the patient's right to know about a possible conflicts of interest between patient care and health care costs.[188] The Council has stated that managed-care physicians have a duty to disclose financial incentives and restrictions placed on them by the HMOs.[189]

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177. *Id.*
178. *Id.*
179. *Id.*
180. ROSOFF, *supra* note 16, § 17.01(2)(d)(i).
181. *Id.*
182. *Id.*
183. *See id.* (postulating that as physicians try to keep costs down they may downplay certain options that they would rather not, for cost purposes, provide).
184. *Id.*
185. Krause, *supra* note 16, at Part III.A. Gag clauses are explicit attempts by managed care organizations to restrict what treatment options a physician can inform their patients about. *Id.*
186. *See* Roger Parloff, *The HMO Foes*, AM. LAW., July/Aug. 1996, at 80.
187. Weiss v. CIGNA Healthcare, Inc., 972 F. Supp. 748, 751 (S.D.N.Y. 1997).
188. *See* Council on Ethical and Judicial Affairs, American Medical Association, *Ethical Issues in Managed Care*, 273 J.A.M.A. 330 (Jan. 25, 1995) (stating that both the physician and the managed care organization have disclosure duties to patients).
189. *Id.*

In a suit for non-disclosure or informed consent, physicians will face more liability than their managed care employers because of federal preemption in the Employee Retirement Income Security Act (ERISA).[190] Cases in which patients accuse their HMOs and HMO physicians of failing to disclose financial incentives often become enmeshed in these ERISA preemption issues.[191] ERISA has traditionally preempted claims against HMOs due to its regulation of state claims that relate to healthcare plans and its system of standards for plan providers and provisions of remedies for plan participants.[192] Under ERISA, a patient cannot have a jury trial or advance a negligence claim, and recovery is limited to the benefits denied.[193] Because of these restricted remedies for breaches of fiduciary duty and ERISA's preemption of state claims challenging a plan's administration, ERISA acts as barrier for many patients' claims against their HMOs.[194] Because the physician ultimately makes the health care decisions, he or she will most likely shoulder the responsibility for final determinations regarding treatment, not the insurer.[195]

In *Weiss v. CIGNA Healthcare, Inc.*,[196] a New York District court dismissed a class action suit by patients who claimed that their HMO breached its fiduciary obligations under ERISA by failing to disclose its physician compensation arrangements.[197] Although the patients argued that the financial arrangements in question would cause physicians to breach their ethical duties to patients, the court found this argument too speculative to support a cause of action.[198] The court did, however, allow the patients' claim to move forward on the allegations that the HMO exercised inappropriate discretionary authority over what medical information the physicians could reveal to patients.[199] The court noted that "a

190. *See generally* 29 U.S.C. § 1144(a) (1994). A New York appeals court held that a medical malpractice claim based on a physician's delay in treating a patient, which ultimately led to his death, in order to refer the patient to an out-of-plan specialist was not preempted by ERISA. Nealy v. US Healthcare HMO, 711 N.E.2d 621, 622-23 (N.Y. 1999). Although the plaintiff's cause of action was related to a patient's treatment under a managed care organization, the physician could not escape liability under ERISA by construing his actions as relating to plan administration. *Id.* at 625.

191. Pegram v. Herdrich, 530 U.S. 211, 233-35 (2000).

192. David Schultz & Tracey Galinson, *Suits Against Managed Care Providers May Elude ERISA*, NAT'L LAW J. (July 6, 1998), at B9

193. Krause, *supra* note 16, at Part IV.C.2.

194. *Id.*

195. Wickline v. State, 239 Cal. Rptr. 810, 819 (Ct. App. 1986) (noting that the physician must advocate for the best interest of his or her patient even in the face of intimidation by an insurer). In this case, the patient was insured through the California medical assistance program. *Id.* at 812.

196. 972 F. Supp. 748 (S.D.N.Y. 1997).

197. *Id.* at 753. The court noted that if Congress had intended a disclosure requirement of physician compensation arrangements, it could have outlined such a requirement in an ERISA provision. *Id.* at 754.

198. *Id.* at 752.

199. *Id.* at 751.

physician has an independent duty to provide full information to his or her patients, a duty which 'is not altered by limitations in the coverage provided by the patient's managed care plan.'"[200] Thus, if proven, the alleged gag-clauses, which restricted a physician's ability to tell a patient about non-covered treatments, were held to constitute a breach of the HMO's duty under ERISA to manage the health plan "solely in the interest of the participants." [201]

In *Shea v. Esensten (Shea I)*,[202] a patient died after suffering a heart attack.[203] Although the patient had recently visited his primary care physician and presented symptoms of heart problems, including a family history of cardiac trouble, the physician did not refer him to a cardiologist.[204] The patient's widow sued the HMO her husband belonged to for failing to disclose the financial incentive system it provided to its physicians to minimize referrals to specialists.[205] The United States Court of Appeals for the Eighth Circuit agreed that knowledge of financial incentives that affect a physician's decisions to refer patients to specialists is material information requiring disclosure, and it reversed the lower court's dismissal of the claim for breaching a fiduciary duty.[206]

In *Shea v. Esensten (Shea II)*,[207] the patient's widow pursued her claim of negligent misrepresentation against the physicians for failure to disclose their conflict of interest under their contract with the HMO.[208] The United States Court of Appeals for the Eighth Circuit reversed the district court's dismissal of the misrepresentation claim as preempted by ERISA.[209] The court held that allowing the tort claim to proceed against the physicians would not impact any element of the ERISA plan.[210] Furthermore, Minnesota professional ethical standards mandate a disclo-

200. *Id.* (quoting Council on Ethical and Judicial Affairs, American Medical Association, *Ethical Issues in Managed Care*, Council Report, 273 J.A.M.A. 330 (Jan. 25, 1995)).

201. *Id.* at 751.

202. 107 F.3d 625 (8th Cir. 1997).

203. *Id.* at 626.

204. *Id.*

205. *Id.* at 627. According to the patient's widow, if the patient had known of the incentives designed to minimize referrals, he would have seen a specialist on his own accord. *Id.*

206. *Id.* at 627-28. The court stated that a "patient necessarily relies on the doctor's advice about treatment options, and the patient must know whether the advice is influenced by self-serving financial considerations created by the health insurance provider." *Id.* at 628.

207. 208 F.3d 712 (8th Cir. 2000).

208. *Id.* at 715-16. The complaint was originally brought as a state tort action, but the defendants, the managed care organization, moved the case to federal district court. *Id.* at 715; *see also Shea*, 107 F.3d at 627. In the state claim, the Minnesota Supreme Court affirmed the lower court's refusal to admit evidence regarding the managed care incentives. Shea v. Esensten, 622 N.W.2d 130, 132 (Minn. Ct. App. 2001). The court stated there was no evidence to link the incentives to patient care. *Id.* at 135-36.

209. *Shea*, 208 F.3d at 718-19.

210. *Id.* at 718.

sure of conflicts of interest.[211] Thus, a patient who files suit against an HMO for the failure to disclose the financial physician incentives and gag-clauses will have to deal with the challenges that ERISA presents.[212]

3. *Pharmaceutical Kickbacks*

Another informed consent issue involves physicians who accept compensation from pharmaceutical companies for prescribing certain prescription drugs.[213] In *D.A.B. v. Brown*,[214] the government indicted a doctor for participating in a scheme to prescribe patients a growth hormone drug in return for compensation from the drug distributor, and six patients and their parents sued the doctor for failing to disclose the kickback arrangement.[215] Although the patients claimed that the physician should be held liable for breaching the law of fiduciaries and for statutory fraud, the Minnesota appellate court found that the doctor's duty to disclose the compensation scheme meant the case should be analyzed in terms of informed consent.[216] The court declined to recognize a new tort based on the breach of fiduciary duty to encompass the acts of a physician who receives compensation for prescribing a product.[217] Although the court recognized that a physician should provide advice to patients without "self-serving financial considerations," any breach of fiduciary duty emerges from the doctor-patient relationship, and a complaint properly arises from that medical care.[218]

4. *Team Physicians*

In *Krueger v. San Francisco Forty-Niners*,[219] a professional football player sued his former employer after relying on the treatment and advice of the team doctors relating to an injured knee that left him with a permanent, crippling arthritic condition.[220] After injuring his knee while playing football, the patient received treatments, designed to decrease the

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211. *Id.* at 717.

212. *See, e.g.*, Weiss v. CIGNA Healthcare, Inc., 972 F. Supp. 748 (S.D.N.Y. 1997).

213. D.A.B. v. Brown, 570 N.W.2d 168, 171 (Minn. Ct. App. 1997).

214. 570 N.W.2d 168 (Minn. Ct. App. 1997).

215. *Id.* at 169. The patients also sued the manufacturer and the distributor of the drug. *Id.*

216. *See id.* at 171 (noting that because the heart of the scheme involved the medical diagnosis, treatment, and care of patients, the complaint must be framed as one for medical malpractice).

217. *See id.* (stating that to hold otherwise would permit every malpractice action to be pleaded as a breach of fiduciary duty and circumvent the statute of limitations for malpractice claims).

218. *See id.* at 172 (noting that the patient's complaint would fail as a malpractice claim because it alleged no actual injury and because the events occur beyond the statute of limitations).

219. 234 Cal. Rptr. 579 (Ct. App. 1987). This case was ordered not published. Under Rule 977(a)(1) of the California Rules of Court, the opinion has persuasive, but not precedential, value.

220. *Id.* at 581-82. Charles Krueger played for the San Francisco Forty-Niners from 1958 to 1973, during which time he suffered from numerous injuries; however, only the injury to his knee was at issue in this suit. *Id.* at 580.

pain and swelling, from the team doctors who failed to advise him of the potential risks associated with the treatments.[221] After being hit in a game, a piece of the patient's knee broke off and dislodged in the joint.[222] However, the team doctors never informed him that by continuing to play he risked permanent knee damage.[223]

In the patient's suit against the team for fraudulent concealment, the court found that the physicians failed to make full disclosure as to the patient's condition.[224] The physician claimed that he did not conceal any information from the patient and that he believed the patient knew the extent of his injury.[225] However, the court focused, not on whether the physicians had *withheld* any information from the patient, but rather whether they had failed to make a complete *disclosure* of his condition.[226] The court stated that the physician's claim that he did not purposely withhold any information from his patient was not an excuse for failing to make a complete disclosure.[227] Noting that no evidence was presented that the patient had ever received information regarding the risks of continuing to play on his damaged knee, the court found that the physicians failed to make adequate disclosure to the patient.[228]

The patient, in order to satisfy the elements for fraudulent concealment, had to establish that the defendants concealed the information in order to induce the plaintiff to perform or to abandon a course of action.[229] The court found that the patient established that the team had a compelling financial interest in keeping the patient playing football, which satisfied the intent requirement.[230] The court held that the patient

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221. *Id.* at 581. The physicians aspirated the fluid from the knee and then injected cortisone and novocaine into the knee; however, the patient was never advised that repeated treatments could lead to knee damage. *See id.*

222. *Id.*

223. *Id.* Although the trial court found that the patient would have continued to play football even if he had known the severity of the injury, the appeals court considered this conjecture and accepted the patient's testimony that, had he known of his condition, he would have retired. *Id.* at 583, 585.

224. *See id.* at 583. *Compare id. with* Sherwin v. Indianapolis Colts, Inc., 752 F. Supp. 1172, 1179 (N.D.N.Y. 1990) (dismissing a similar claim for fraud and negligent misrepresentation by a professional football player because it was subject to arbitration pursuant to the collective bargaining agreement between the National Football League Players Association and the National Football League Management Council).

225. *Krueger*, 234 Cal. Rptr. at 583.

226. *Id.* The court noted that "[a] physician cannot avoid responsibility for failure to make full disclosure by simply claiming that information was not withheld." *Id.*

227. *Id.* at 584.

228. *Id.* at 583-84.

229. *Id.* at 584. The case considers the duties of both the San Francisco Forty-Niners and the physicians together, apparently because the team's medical staff was treating him. *Id.* at 583.

230. *Id.* at 584.

was entitled to rely on the physicians to make a full disclosure of medical information.[231]

Thus, a team physician has a duty to disclose relevant medical information to team members.[232] A sports player is entitled to rely on the physician's advice without concern that the physician is placing the team's interest above patient care.[233] This duty would likely apply to school sports as well as professional sports.[234]

IV. INFORMED CONSENT: LEGISLATIVE RESPONSE

Some state legislatures have passed laws requiring managed care organizations to disclose physician reimbursement information to patients,[235] and the federal government has expressed concern about the use of financial incentives in the health care industry.[236] The North Dakota legislature has acted to protect the physician-patient relationship from encroachment by HMOs' contractual provisions that might harm a patient.[237] These protections extend to protecting the communications between the patient and physician from interference by the plan provider,[238] prohibiting incentives to health care providers to withhold medically needed treatment,[239] and prohibiting health insurance providers from

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231. *Id.*

232. *See* Matthew J. Mitten, Annotation, *Medical Malpractice Liability of Sports Medicine Care Providers for Injury to, or Death of, Athlete*, 33 A.L.R. 5th 619, § 4(d), at 635 (noting that in actions against team physicians for lack of disclosure, traditional principles of informed consent apply).

233. *Krueger*, 234 Cal. Rptr. at 584.

234. *See* Margaret Cronin Fisk, *New Century, New Causes*, NAT'L L. J., Nov. 27, 2000, at A1.

235. *See* Bobinski, *supra* note 39, at 323-25; *see also* Krause, *supra* note 16, at 371 ("By the end of 1998, most states had enacted laws banning the existence of such clauses in MCO [managed care organizations] contracts, and otherwise addressing perceived impediments to patient (and provider) rights.").

236. Bobinski, *supra* note 39, at 323-24 (noting that the federal government has enacted some protections for Medicaid and Medicare patients).

237. N.D. CENT. CODE § 26.1-04-02 (1995) (unfair methods of competition or unfair and deceptive acts or practices prohibited). The prohibited practices are defined in section 26.1-04-03 of the North Dakota Century Code.

238. *Id.* § 26.1-04-03(15)(a) (Supp. 1999) (Interference with certain medical communications). The code provides:

> An entity offering a health plan may not restrict or interfere with any medical communication and may not take any of the following actions against a health care provider solely on the basis of a medical communication:
> (1) Refusal to contract with the health care provider;
> (2) Termination of or refusal to renew a contract with the health care provider;
> (3) Refusal to refer patients to or allow others to refer patients to the health care provider; or
> (4) Refusal to compensate the health care provider for covered services that are medically necessary.

Id.

239. *Id.* § 26.1-04-03(17) (Supp. 1999) (incentives to withhold medically necessary care). The code states:

> An entity may not offer a health care provider, and a contract with a health care

retaliating against a health care provider who advocates for a patient.[240] As the issues surrounding informed consent and the disclosure of managed care information continue to result in litigation, legislatures may enact more statutes further defining the way in which managed care providers disseminate information to their patients.[241]

The benefits of a patient being fully informed must be balanced with practical considerations.[242] In an effort to provide patients with access to information about hospitals and HMOs, New York recently passed legislation that requires the release of "report cards" to the public.[243] For HMOs, these report cards will detail information about the satisfaction and enrollment of members, certification rates of physicians, and access to services.[244] Because many of the schemes for paying physicians in managed care organizations are very complex, one must question whether providing this information will truly inform patients.[245] One should not forget that the reason HMOs have become so prevalent is because, as health care costs continually rise, HMOs help keep those costs down.[246]

Some states have enacted laws that make physician profiles available to patients over the Internet or by toll free numbers.[247] These profiles typically contain factual data, medical malpractice claims, disciplinary history, and criminal history.[248] Advocates of these publicly available profiles assert that unless a patient knows this type of information, he or she cannot really make an informed decision to consent to treatment.[249]

> provider under a health plan may not contain, an incentive plan that includes a specific payment made to, or withheld from, the provider as an inducement to deny, reduce, limit, or delay medically necessary care covered by the health plan and provided with respect to a patient. This subsection does not prohibit incentive plans, including capitation payments or shared-risk arrangements, that are not tied to specific medical decisions with respect to a patient. . . .

Id.

240. *Id.* § 26.1-04-03(18) (Supp. 1999). This statute protects a health care provider who advocates for a patient in an insurance program or procedure or who reports a health insurance provider for endangering a patient. *Id.* The health insurance provider cannot refuse to contract with the health care provider, terminate or refuse to renew a contract, refuse to allow the patient to be referred, or refuse to compensate the health care provider. *Id.*

241. *See* Bobinski, *supra* note 39, at 359-60.

242. *See* Henry T. Greely, *Direct Financial Incentives in Managed Care: Unanswered Questions*, 6 HEALTH MATRIX 53, 82 (1996).

243. *See* Kenneth N. Rashbaum & Hannah K. Kiernan, *The Patient Health Information and Quality Improvement Act of 2000: Health Care Consumer Beware—or Befuddled?*, MEALEY'S MANAGED CARE LIABILITY REP., Dec. 8, 2000 (citing N.Y. PUB. HEALTH LAW § 2995-a (Consol. 2000)).

244. *Id.*

245. Greely, *supra* note 242, at 82.

246. *See* Pegram v. Herdrich, 530 U.S. 211, 218-19 (2000) (providing a general background on HMOs).

247. Rashbaum & Kiernan, *supra* note 243. These states include Massachusetts, New York, Connecticut, Texas, Florida, and California. *Id.*

248. *Id.*

249. *Id.*

However, critics respond that this data may be misleading.[250] For example, the New York law requires a listing of settlement claims by number of claims, meaning that a patient would not know the circumstances surrounding the case.[251] It also lists any criminal convictions, including those unrelated to the practice of medicine.[252] Whether these profiles will truly inform a patient or merely give him or her a clouded picture of a physician is yet unclear.[253] The conflict between the privacy of a physician and the right of a patient to be informed of all of the relevant facts related to his or her treatment will likely develop into judicial challenges in the future.[254]

V. CONCLUSION

The idea that a doctor has something other than the best interests of his or her patients at heart goes directly to the core of the theories behind informed consent.[255] A patient should be able to receive advice from his or her doctor without wondering what ulterior motive the doctor may have for providing or not providing that advice.[256] At the same time, society must ask how much information a patient needs to truly be informed.[257] Will doctors be required to fill out questionnaires detailing aspects of their personal and professional lives?[258] It is necessary to strike a balance between a patient who is adequately informed and a doctor who is not so busy worrying about disclosure that he or she cannot practice medicine. As medical care becomes in many ways more depersonalized, these issues have the potential to make a deeply personal impact on doctors, patients, and the legal medicine field in general.

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250. *Id.*

251. *See* N.Y. PUB. HEALTH LAW § 2995-a (Consol. 2000). *But see* MASS. GEN. LAWS ANN. ch. 112, § 5 (West Supp. 2001) (listing settlement claims in graduated categories that indicate the significance of the claims).

252. *See* N.Y. PUB. HEALTH LAW § 2995-a. *But see* MASS. GEN. LAWS ANN. ch. 112, §5 (listing only felonies and serious misdemeanors).

253. Rashbaum & Kiernan, *supra* note 243.

254. *Id.*

255. Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 483 (Cal. 1990).

256. *Id.* at 484-85.

257. *Cf.* Canterbury v. Spence, 464 F.2d 772, 787-88 (D.C. Cir. 1972). The court proclaimed that "[t]here is no bright line separating the significant from the insignificant: the answer in any case must abide by a rule of reason." *Id.* at 788.

258. *Cf. id.* at 788. In *Canterbury*, the court found answers to the gray areas of disclosure by reasoning that "[w]henever nondisclosure of particular risk information is open to debate by reasonable-minded men, the issue is for the finder of facts." *Id.*