

Informed Patients go *Homeo* Happy: Applying the Doctrine of Informed Consent to Homeopathic Practitioners

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I. INTRODUCTION

Imagine a young female college student suffering from systemic lupus erythematosus.¹ Symptoms from her disease, such as depleted energy, rheumatoid arthritis,² chronic pleurisy,³ and pericarditis⁴ are regularly treated with synthetic steroid medications.⁵ As a precaution, she also takes a maintenance medication.⁶ These medications present grueling side effects, including mood swings, weight gain, bone depletion, and erosion of the retina. The student decides to try an alternative method of treatment with a homeopathic practitioner.

The homeopathic treatment eliminates the use of steroids and the maintenance medications. The homeopath prescribes specially formulated tablets and liquids proposed to treat the ailments caused by her disease. The student continues to develop symptoms of pleurisy, and returns to see the homeopath. A cocktail of vitamin B with laticane is administered intravenously with a diagnosis of probable pneumonia.⁷ The homeopath then instructs the student to go home and get some rest.

Two days later, the student develops a dangerously low blood oxygen level due to excessive fluid in the lungs. She is taken to the emergency room

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1. Systemic lupus erythematosus is an auto-immune inflammatory disease that causes inflammation of connective tissues and organs. Young women make up the majority of the population effected by Lupus. Female children and older males and females can also be affected. THE MERCK MANUAL OF MEDICAL INFORMATION 231-33 (3d ed. 1997).

2. Rheumatoid arthritis is also an auto-immune disease causing inflammation of joints, mostly in the hands and feet, which results in sever pain and destruction of the joint interior. *Id.* at 227.

3. Inflammation of the pleura, a membrane that enables the lungs to move smoothly during each breath, causes pleurisy. *Id.* at 150, 205.

4. Acute pericarditis is an inflammation of the pericardium. The condition is caused by inflammation which causes fluid and blood products to fill the pericardial space. The condition is painful and comes on suddenly. *Id.* at 104. "The pericardium is a flexible, two-layered sac that envelops the heart." *Id.*

5. Corticosteroids, such as prednisone, are used to treat severe disease. THE MERCK MANUAL OF MEDICAL INFORMATION, *supra* note 1, at 233.

6. In order to suppress the immune system, immunosuppressive drugs such as azathioprine or cyclophosphamide are given. *Id.*

7. Pneumonia is an infection of the air sacs filling the lungs and the tissue around them. *Id.* at 194.

and placed in the intensive care unit. The fluid in the lungs becomes so severe that the student is placed on a ventilator. She lies there for three weeks, developing acute respiratory distress syndrome⁸ and pancreatitis.⁹

Prior to the student's treatment, the homeopath failed to advise the student of the risks that developed and of the alternative treatments for lupus regularly employed by conventional medical doctors. Had she received this information, she would have pursued a different course of treatment. This description of inadequate treatment and resulting complications, which describes real events experienced by the author, embodies the necessity for homeopathic practitioners to retain the informed consent of all patients.

The practice of homeopathy is generally classified under the broad term of Complementary and Alternative Medicine ("CAM").¹⁰ CAM includes practices such as "homeopathic, naturopathic, chiropractic and herbal medicine; Ayurveda; meditation; prayer; qi gong; and bio-electromagnetic medicine."¹¹ This paper is limited to the discussion of homeopathy treatment and the duties required of homeopathic practitioners. The practitioners of homeopathy, like other followers of CAM, are governed by the rules and principles of their fellow homeopaths rather than by those controlling other schools of medicine.¹² The rationale is that homeopaths cannot be expected to practice to the standard of any other school because they are not trained in that field and can only be answerable for the knowledge falling within their particular niche of homeopathic medicine.¹³

While the majority of states do not have laws or regulations governing homeopaths, a small minority have implemented separate licensing boards for

8. Acute respiratory distress syndrome (also called adult respiratory distress syndrome) is lung failure from various disorders that cause fluid to accumulate in the lungs (pulmonary edema). *Id.* at 164.

9. "Acute pancreatitis is a sudden inflammation of the pancreas that may be mild" or potentially fatal. *Id.* at 504.

10. See John Lunstroth, *Voluntary Self-Regulation of Complementary and Alternative Medicine Practitioners*, 70 ALB. L. REV. 209 (2006) (defining the term "Complementary and Alternative medicine"). The term has a variety of definitions. See e.g., Ted J. Kaptchuk & David M. Eisenberg, *Variety of Healing, A Taxonomy of Unconventional Healing Practices*, 135 ANNALS INTERNAL MED. 196 (2001) (describing the difficulty in defining alternative medicine and attempting to define the term). This umbrella term includes practices including, but not limited to, acupuncture, aroma therapy, energetic healing, healing practices utilizing food, food supplements, nutrients, and the physical forces of heat, cold, water, touch and light. MINN. STAT. ANN. § 146A.01(4) (West 2006).

11. J. Brad Kallmyer, M.D., *A Chimera In Every Sense: Standard of Care for Physicians Practicing Complementary and Alternative Medicine*, 2 IND. HEALTH L. REV. 225, 226-27 (2005) (citing Nat'l Ctr. for Complementary and Alternative Medicine, Health Information: What Is CAM?, <http://www.nccam.nih.gov/health/whatiscam/> (last visited Mar. 27, 2007)).

12. 61 AM. JUR. 2D *Physicians, Surgeons, Etc.* § 195 (2007).

13. *Id.*

homeopaths.¹⁴ A few states have also passed legislation to protect a patient's right to access alternative remedies from licensed physicians.¹⁵ It is unclear, however, whether states that have codified the doctrine of informed consent intended the statute to apply to homeopaths.¹⁶ Though there exists a limited amount of case law imposing a common law duty on homeopathic practitioners to adequately disclose information to their patients, this lack of common law authority should not be construed as a reflection of the homeopaths' pristine record giving no reason for litigation.¹⁷ In fact, this demonstrates the importance of holding the homeopaths to the doctrine of informed consent and requiring them to meet the standard only by disclosure of conventional medical treatment. This will protect patient autonomy by supplying a remedy to an inadequately informed patient who otherwise may not have had an option for recovery.

All patients should have a right to full disclosure of the risks inherent in homeopathic treatment, as well as information about available conventional medical treatment. Those who hold themselves out as medical healers should be held to the same informed consent requirements as any conventionally-licensed medical doctor. Had the homeopath informed the student of the risks involved in foregoing conventional treatment for her symptoms, the student would have been able to make an informed and intelligent decision regarding the course of her medical destiny. Holding a homeopathic practitioner responsible for performing his or her duties in accordance with the doctrine of informed consent is crucial to the protection of patients like the young female student and the unsuspecting and uninformed public as a whole.

Homeopathic practitioners should be required to obtain informed consent before performing any treatment on a patient in order to protect the public and individual patient autonomy. Homeopathic practitioners should be held to the standard of care of traditional medical doctors by requiring them to inform patients of the risks of any proposed treatment, as well as alternative treatments and procedures that would be available from licensed medical doctors.

14. These states include Arizona and Connecticut. *See, e.g.*, ARIZ. REV. STAT. ANN. §§ 32-2901-2951 (2006); CONN. GEN. STAT. § 20-12n (West 2007).

15. *See* Legal Issues: State Laws, <http://www.faim.org/states.htm> (last visited May 4, 2007). These states include Alaska, Colorado, Georgia, Indiana, Massachusetts, New York, North Carolina, Ohio, Oklahoma, Texas and Washington.

16. *See, e.g.*, LA. REV. STAT. ANN. § 37:1262(2)(2007). The definition of "physician" in Louisiana is limited to a M.D. or D.O. *Id.* Also, the Tennessee informed consent statute refers to the parties as plaintiff and defendant and spells out the applicable community standard for a defendant within their professional practice when treating a "patient." TENN. CODE. ANN. § 29-26-118 (West 2007). "Patient" has been defined as any person receiving treatment from a "therapist", who is one who provides therapy whether licensed by the state or not. TENN. CODE. ANN. § 29-26-2038 (West 2007).

17. *See infra*, notes 36-53 and accompanying text.

Part II of this paper discusses the background and history of homeopathic medicine. Part III explains the regulation of the profession among various states. Part IV explains the common law doctrine of informed consent. Part V describes the general standards of care applicable to medical practitioners compared to homeopaths. Part VI proposes the application of the doctrine of informed consent to homeopaths. Part VII explains how the states should go about applying the doctrine to homeopaths.

II. THE PRACTICE OF HOMEOPATHY

A. *The History and Development of Homeopathy*

Homeopathy is “a system of medical practice that treats a disease . . . by the administration of minute doses of a remedy that would in healthy persons produce symptoms of a disease treated.”¹⁸ Homeopathy is different from the conventional or allopathic¹⁹ medical treatment in that allopathy “employ[s] remedies which affect the body in a way *opposite* from the effect of the disease treated.”²⁰ Samuel Hahnemann, M.D.²¹ built the system of homeopathy “on the theory that large doses of certain drugs given to a healthy person will produce certain conditions which, when occurring spontaneously as symptoms of a disease, are relieved by the same drug in small doses.”²²

Technology is not used in the diagnosis process or formulation of homeopathic remedies.²³ Homeopathic treatment prescribes plant, animal, and mineral based substances.²⁴ These treatment methods are considered resolu-

18. WEBSTER'S NEW COLLEGIATE DICTIONARY 577 (9th ed. 1984).

19. The term “allopathy” is controversial. See, e.g., Patrick L. Sheldon, *The Truth About Homeopathy: A Discussion of the Practice and the Dangers That Inhere*, 8 QUINNIPIAC HEALTH L.J. 289, 323 (2005) (stating “[s]ome commentators argue that allopathy is a term that has been misapplied to conventional medicine ever since the time of Hahnemann”).

20. *In re Guess*, 393 S.E.2d 833, 834 (1990) (citing SCHMIDT'S ATTORNEY'S DICTIONARY OF MEDICINE A-147) (holding that physician's departure from standards of acceptable and prevailing medical practice did not have to pose threat to patients or public in order for physician's license to practice medicine to be revoked).

21. German Physician Samuel Hahnemann, M.D. (1755-1843) developed the principles of homeopathy in response to what he believed to be dangerous medical practices. See WILLIAM G. ROTHSTEIN, *AMERICAN PHYSICIANS IN THE NINETEENTH CENTURY: FROM SECTS TO SCIENCE* 232-33 (1972); Michael H. Cohen, *Holistic Health Care: Including Alternative and Complementary Medicine in Insurance and Regulatory Schemes*, 38 ARIZ. L. REV. 83, 111 (1996).

22. *Guess*, 393 S.E.2d at 834 (citing STEDMAN'S MEDICAL DICTIONARY 654 (24th ed. 1982)).

23. See Lunstroth, *supra* note 10, at 216.

24. See, e.g., Nat'l Ctr. for Homeopathy, <http://www.homeopathic.org/meds.htm> (last visited Mar. 18, 2007).

[t]he substances may be made from plants such as aconite, dandelion, plantain; from minerals such as iron phosphate, arsenic oxide, sodium chloride; from animals such as the

tions to the causes of the underlying disease as opposed to the symptoms.²⁵

Hahnemann developed three principles encompassing the goals and methodology of homeopathy.²⁶ The first principle states, “the medicinal effect of a substance can be measured by giving the substance to a healthy human.”²⁷ Second, “disease is known by assessing the signs and symptoms presented by the patient . . . generally speaking, all of the symptoms and signs a person presents with are caused by one disease.”²⁸ Finally, “[t]he third principle is the ‘law of similars’” where the evaluation of the patient occurs, symptoms the patient suffers are noted, and the homeopath compares the symptoms suffered with the symptoms of a healthy human who was treated with various remedies.²⁹ The remedy for the disease is selected from the comparison.³⁰

Hahnemann’s development of homeopathic treatment in Germany evolved over fifty years.³¹ Originally, the patient was prescribed a plant, animal or mineral based “remedy” for consumption.³² Hahnemann began diluting remedies for optimal effectiveness after he observed that higher doses caused adverse effects, which manifested as additional symptoms.³³ Thus, a precise scientific method for dilution developed and is utilized today in formulation of homeopathic pharmacopoeia.³⁴ Homeopathic treatment first

venom of a number of poisonous snakes, or the ink of the cuttlefish; or even from chemical drugs such as penicillin or streptomycin. These substances are diluted carefully until little of the original remains.

Id.

25. See Sheldon, *supra* note 19, at 290.

26. See Lunstroth, *supra* note 10, at 216.

27. *Id.*

28. *Id.*

29. *Id.*

30. *Id.*

31. See ROTHSTEIN, *supra* note 21, at 152-53.

32. *Id.*

33. See Lunstroth, *supra* note 10, at 217.

34. See Sheldon, *supra* note 19, at 293 (stating “[d]ilutions of homeopathic remedies are designated by Roman numerals) (citing Stephen Barrett, *Homeopathy: The Ultimate Fake*, QUACKWATCH, <http://www.quackwatch.org/01QuackeryRelatedTopics/homeo.html> (last visited Mar. 25 2007)).

Homeopathic products are made from minerals, botanical substances, and several other sources. If the original substance is soluble, one part is diluted with either nine or ninety-nine parts of distilled water and/or alcohol and shaken vigorously (succussed); if insoluble, it is finely ground and pulverized in similar proportions with powdered lactose (milk sugar). One part of the diluted medicine is then further diluted, and the process is repeated until the desired concentration is reached. Dilutions of 1 to 10 are designated by the Roman numeral X (1X = 1/10, 3X = 1/1,000, 6X = 1/1,000,000). Similarly, dilutions of 1 to 100 are designated by the Roman numeral C (1C = 1/100, 3C = 1/1,000,000, and so on). Most remedies today range from 6X to 30X, but products of 30C or more are marketed.

Barrett, *supra*. The Food and Drug Administration only regulates the marketing and sale of Homeopathic Pharmacopoeias, recognizing:

appeared in the United States in 1825.³⁵

B. Regulations of Homeopathy in the U.S.

This section will discuss the regulation of homeopathy through legislation in Minnesota and Arizona as well as the judicial imposition of the common law doctrine of informed consent. As opposed to the majority of states that have no laws regulating homeopathic medicine, Minnesota and Arizona have taken two distinct regulatory approaches. Arizona has taken a minority approach by developing a licensing board for homeopaths.³⁶ Minnesota has statutorily defined homeopaths as unlicensed and enacted guidelines for the unlicensed homeopath.³⁷

The state of Minnesota has model legislation regulating the practice of CAM.³⁸ Non-licensed CAM practitioners, including homeopaths, are recognized and governed by statute.³⁹ The statute imposes a duty to inform patients of their rights guaranteed by Minnesota law through a written form and prominent displays of information, which includes⁴⁰ the degree of training of the practitioner and disclosure of Minnesota's lack of any educational

as official the drugs and standards in the Homeopathic Pharmacopoeia of the United States and its supplements (Sections 201 (g)(1) and 501 (b), respectively). Until recently, homeopathic drugs have been marketed on a limited scale by a few manufacturers who have been in business for many years and have predominantly served the needs of a limited number of licensed practitioners. In conjunction with this, homeopathic drug products historically have borne little or no labeling for the consumer.

Today the homeopathic drug market has grown to become a multimillion dollar industry in the United States, with a significant increase shown in the importation and domestic marketing of homeopathic drug products. Those products that are offered for treatment of serious disease conditions, must be dispensed under the care of a licensed practitioner. Other products, offered for use in self-limiting conditions recognizable by consumers, may be marketed OTC.

This document provides guidance on the regulation of OTC and prescription homeopathic drugs and delineates those conditions under which homeopathic drugs may ordinarily be marketed in the U.S. Agency compliance personnel should particularly consider whether a homeopathic drug is being offered for use (or promoted) significantly beyond recognized or customary practice of homeopathy. If so, priorities and procedures concerning the agency's policy on health fraud would apply.

U.S. FDA, *Sec. 400.400 Conditions Under Which Homeopathic Drugs May Be Marketed*, available at http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg400-400.html, FDA/ORA COMPLIANCE POLICY GUIDES MANUAL (2006).

35. See Lunstroth, *supra* note 10, at 218.

36. See generally ARIZ. REV. STAT. ANN. §§ 32-2901-2951 (West 2006).

37. See MINN. STAT. ANN. § 146A.11 (West 2007).

38. *Id.* California has a similar statute. See CAL. BUS. & PROF. CODE § 2053.6 (West 2005).

39. MINN. STAT. ANN. § 146A.01 (West 2007) (defining "complementary and alternative health care practices").

40. *Id.* § 146A.11.

standard for non-licensed homeopaths.⁴¹ If the homeopath is licensed by another state board, they are governed by the rules and regulations of that licensing board.⁴²

Arizona has a separate licensing board which governs homeopathic practitioners.⁴³ The licensing board examines and regulates the practice of homeopathy through statutory guidelines.⁴⁴ While these statutory guidelines require the informed consent of a patient when a homeopath uses experimental treatment, there is no regulatory statute that explicitly imposes a general duty of disclosure on the licensed homeopath.⁴⁵

In terms of the development of case law regarding the licensing and control over homeopathic medicine by a state, courts have only heard cases involving CAM practitioners in general, rather than practitioners who deal exclusively with homeopathy.⁴⁶ Although the practitioners involved in these cases were not alternative practitioners of homeopathy, they all practiced alternative treatments also falling under the umbrella term of CAM.

Although the courts have imposed a doctrine of informed consent on CAM providers, the issue of assumption of the risk clouds the possibility of a sufficient remedy for the injured patient.⁴⁷ In *Schneider v. Revici*, a CAM physician treated a breast cancer patient with various nutritional remedies.⁴⁸ The patient signed a release form prior to treatment.⁴⁹ Despite the alternative treatment the cancer spread and the patient brought a malpractice claim against the CAM physician.⁵⁰ The court found the patient fifty percent at fault for assuming the risk of the alternative treatment.⁵¹ Although there was not an informed consent claim against the CAM physician, *Schneider* represents the possibility of decreased liability for CAM physicians due to assumption of the risk by the patients represented through signed consent forms and adequate documentation of discussion concerning risks and benefits of the proposed alternative treatment.⁵²

41. *Id.*

42. *See id.*

43. *See* ARIZ. REV. STAT. ANN. §§ 32-2901 to 2951 (West 2006). Connecticut also has licensing boards governing homeopaths. *See* CONN. GEN. STAT. § 20-12n (West 2007).

44. *Id.*

45. *See generally* ARIZ. REV. STAT. ANN. § 32-2901-2951 (West 2006).

46. *See* *Moore v. Baker*, 989 F.2d 1129 (11th Cir. 1993); *Schneider v. Revici*, 817 F.2d 987 (2d Cir. 1987); *Charrel v. Gonzales*, 660 N.Y.S.2d 665 (N.Y. App. Div. 1998).

47. *E.g.*, *Schneider*, 817 F.2d at 995-96.

48. *Id.* at 989-90

49. *Id.*

50. *Id.* at 990.

51. *Id.*

52. *Schneider*, 817 F.2d at 995-96

The available case law suggests that courts expect CAM practitioners to disclose all risks of alternative treatment in addition to the risks of refusing conventional treatments.⁵³ Homeopaths are categorized as CAM practitioners and should therefore be held to the same standards of disclosure as a conventional doctor to protect themselves as well as their patient's autonomy and society's faith in their professed school of medicine.

III. THE DOCTRINE OF INFORMED CONSENT

The common law doctrine of informed consent is founded on the protection of individual autonomy.⁵⁴ Today, the doctrine of informed consent is based on the theory of negligence, but the doctrine of informed consent originated as a battery claim.⁵⁵ The actions were limited to claims against physicians for treatments to which the patient did not consent.⁵⁶ This section will provide a background to the underlying rationale of the doctrine and explain its modern development into a negligence-based claim.

A. *Background of the Doctrine*

The doctrine of informed consent mandates that patients be able to determine their own medical destiny after all proper disclosure by their physician.⁵⁷ As explained by Justice Cardozo, "[e]very human being of adult years and sound mind has the right to determine what shall be done with his own body."⁵⁸

Traditionally, claims for lack of informed consent were brought as a claim of battery.⁵⁹ The definition of a tortious battery is "an intentional and legally unpermitted physical contact with ('touching' of) another person."⁶⁰ When patients were subjected to treatment for which they did not consent, their recourse was to file a battery claim.⁶¹

53. See *Moore*, 989 F.2d 1129; *Schneider*, 817 F.2d 987; *Charrel*, 660 N.Y.S.2d 665.

54. William J. Curran, *Preface to the Second Edition* in FAY A. ROZOVSKY, CONSENT TO TREATMENT A PRACTICAL GUIDE xxxi, xxxi-iv (2d ed. 1990).

55. RUTH R. FADEN ET AL., A HISTORY AND THEORY OF INFORMED CONSENT 27 (1986).

56. See *Fox v. Smith*, 594 So. 2d 596, 604 (Miss. 1992) (stating "[m]edical and surgical procedures that involve touching a patient's person, even the simplest manipulation of a limb, must be properly authorized or the person performing the procedure will be subject to an action for battery"). For example, the patient consents to the operation of the right leg and the physician operates on the left leg.

57. See *Sherwood v. Carter*, 805 P.2d 452, 457 (Idaho 1991).

58. *Schloendorf v. Soc'y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914) (holding hospital not charged with notice that surgeons were operating without patient's consent because it appeared that such physician knew an operation was to be performed).

59. See ROZOVSKY, *supra* note 54, at 6-7.

60. See FADEN, *supra* note 55.

61. See *Lane v. United States*, 225 F.Supp. 850, 852 (E.D. Va. 1964) (claiming operation which had

The historical rule required patients to give their informed consent before physicians were legally entitled to commence treatment.⁶² The first reported case utilizing this principle was the late eighteenth-century English case of *Slater v. Baker & Stapleton*,⁶³ which held two medical practitioners liable for re-breaking a patient's already-healing leg without his consent.⁶⁴ The rule at the time of this case was that "the nonconsensual and unprivileged touching of another person was battery."⁶⁵ At this time, physicians historically saw the requirements for consent as a minimal requirement.⁶⁶ Physicians believed very little or no information at all needed to be given to the patient before the patient gave permission to proceed with treatment.⁶⁷

A limit on the theory of battery is that the patient may only recover when there has been unconsensual touching,⁶⁸ which made the theory of battery ill-suited for consent-based recovery.⁶⁹ Some courts have found the limitation of the battery theory to situations involving nonconsensual touching to be inconsistent with the doctrine of informed consent.⁷⁰ Informed consent cases do not involve nonconsensual touching, but rather the failure of a physician to inform his patient of the material facts surrounding the consensual treatment.⁷¹

A claim for battery is most commonly reserved for an instance when the patient has consented to one operation and another operation is performed.⁷² The law of battery has been classified as over-inclusive in situations where a physician may fail to disclose an uncommon risk inherent in the proposed treatment.⁷³ On the other hand, the patient may have no cause of action when she has consented to a treatment based on minimal information concerning

been planned for plaintiff's left knee was performed on right knee by mistake); *Hively v. Higgs*, 253 P. 363, 365 (Or. 1927) (claiming removal of plaintiff's tonsils was without authority).

62. PAUL S. APPELBAUM ET AL., *INFORMED CONSENT, LEGAL THEORY AND CLINICAL PRACTICE* 35 (1987).

63. *Slater v. Baker & Stapleton*, (1767) 95 Eng. Rep. 860 (K.B.).

64. See APPELBAUM, *supra* note 62, at 36.

65. *Id.*

66. *Id.*

67. *Id.*

68. See FADEN, *supra* note 55, at 139.

69. Ken Marcus Gatter, *Protecting Patient Physician Discourse: Informed Consent and deliberative Autonomy*, 78 OR. L. REV. 941, 950 (1999).

70. See, e.g., Suzanne K. Ketler, Comment, *The Rebirth of Informed Consent: A Cultural Analysis of the Informed Consent Doctrine After Schreiber v. Physicians Insurance Co. of Wisconsin*, 95 NW U. L. REV. 1029, 1037 (2001) (stating "[a]s the Schreiber court put it, 'a doctor's performance of an unauthorized treatment [does] not intuitively coincide with the 'intentional anti-social nature of battery' nor [does] it adequately reflect the fact that patients 'consent' on some level whenever they see a doctor").

71. *Id.*

72. DAN B. DOBBS, *THE LAW OF TORTS* 654 (2000).

73. See Gatter, *supra* note 69, at 951.

highly likely risks or complications.⁷⁴ Due to these inadequacies, the modern doctrine of informed consent has transformed into a theory of negligence.

B. The Modern Doctrine

The majority of jurisdictions have held that the theory of negligence most adequately applies the principles of the doctrine of informed consent.⁷⁵ The focus of the doctrine is on patients and their capacity⁷⁶ to give informed and voluntary consent to a physician.⁷⁷ The courts made this transition because they recognized that even a physician working in good faith may breach a duty to a patient to fully disclose the proposed treatment.⁷⁸ The physician is charged with the responsibility of disclosing information, including any risks, benefits or alternatives, about a proposed treatment.⁷⁹ Patients have the right to refuse all treatment or to withdraw any consent given at anytime prior to treatment as well as to refuse any suggested or recommended alternative treatment.⁸⁰ Patients can also refuse any suggested or recommended alternative treatment.⁸¹

In order to prevail in an action for lack of informed consent under a negligence theory, a patient must show three main elements.⁸² First, the patient must show a failure to disclose based on the standard within that jurisdiction.⁸³ Second, the patient must show injury as a consequence of the failure to disclose.⁸⁴ Finally, the patient must show that a reasonable patient, or that particular patient,⁸⁵ in the same or similar circumstances, would have

74. *Id.*

75. See ROZOVSKY, *supra* note 54, at 9 (citing TEX. STAT. ANN. art. 4590i (1979) (stating “the only theory on which recovery may be obtained is that of negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent”). The statute limits the methods of recovery to negligence, which supports the idea that negligence law is the most appropriate theory of recovery for informed consent cases.

76. Patients must have the legal and mental capacity to consent to treatment. This topic is outside the scope of this paper. See *id.* at 13.

77. See Jeremy Sugarman, *Informed Consent, Shared Decision-Making, and Complementary and Alternative Medicine*, 31 J.L. MED & ETHICS 247 (2003) (stating there is a model to follow when properly obtaining a patient's informed consent).

78. See Sharon Nan Perley, Note, *From Control Over One's Body to Control Over One's Body Parts: Extending the Doctrine of Informed Consent*, 67 N.Y.U. L. REV. 335, 335-39 (1992).

79. *Id.* at 340.

80. See ROZOVSKY, *supra* note 54, at 35 (stating that informed consent is a process and not a form). See also Kallmyer, *supra* note 11.

81. See *id.* and accompanying text.

82. *Id.* at 11.

83. *Id.*

84. *Id.*

85. The standard varies among the jurisdictions. The informed consent section provides an explanation of each standard. See *infra* notes 90-114 and accompanying text.

refused the treatment.⁸⁶ The standard of proof for the elements of informed consent is preponderance of the evidence. Some states have codified the doctrine of informed consent,⁸⁷ while others have developed the standards for the doctrine through case law.⁸⁸ The doctrine focuses on the reasonableness of the disclosure by the physician rather than the reasonableness of the treatment.⁸⁹

C. Explanation of the Standards for Disclosure and Causation

To succeed in a claim for lack of informed consent, the patients must prove that they were not adequately informed and that the lack of disclosure caused their injury. The causation element requires that plaintiff patient would have chosen no treatment or a different course of treatment had the alternatives and material risks been made known to him.⁹⁰ There is a causal connection between the physician's duty to disclose and the injury suffered by the patient when proper disclosure by the physician would have resulted in a decision by the patient to forgo the treatment and ultimately avoid the injury.⁹¹ This section will explain the duty to disclose imposed by the doctrine of informed consent and the doctrine's requirement of causation of injury.

1. The Duty to Disclose

i. The Reasonable Patient Approach

A number of jurisdictions apply the patient standard for the required duty of disclosure.⁹² The patient standard requires disclosure of all risks the patient

86. *Id.*

87. See ALASKA STAT. § 09.55.556 (1976) (establishing informed consent liability and defenses to malpractice claims based on informed consent). MISS. CODE ANN. §§ 41-41-3, 41-41-5, 41-41-7, 41-41-9 (West 1991) (specifying who may consent to medical procedures, implied consent under emergency situations, consent by court order, etc.).

88. *Canterbury v. Spence*, 464 F.2d 772, 791 (D.C. Cir. 1972).

89. 61 AM. JUR. 2D *Physicians, Surgeons, Etc.*, § 152 (2006).

90. *Scott v. Bradford*, 606 P.2d 554, 558 (Okla. 1980) (holding that the subjective causation standard should be applied but still implementing a reasonable person disclosure standard). The use of the subjective standard for causation has been criticized because courts implement a subjective standard with causation, and then an objective standard for disclosure. This undermines the effectiveness of implementing the subjective standard because the focus ultimately shifts from the actual patient to the reasonable patient when determining what the physician should have disclosed.

91. *Id.*

92. See Armand Arabain, *Informed Consent: From the Ambivalence of Arato to the Thunder of Thor*, 10 ISSUES L. & MED. 261 (1994) (citing cases from Iowa, Louisiana, Maryland, Massachusetts, Pennsylvania, South Dakota, Utah and Vermont that have adopted the reasonable patient standard).

would consider to be material.⁹³ The determination of whether or not a risk is material requires a focus on the facts surrounding the case.⁹⁴

The measure for disclosure of information is through the needs of the patient.⁹⁵ To allow physicians, rather than patients, to determine what information must be disclosed to a patient is in direct conflict with underlying principle of patient sovereignty. This standard focuses not on what the physician believes the patient needs to know in order to make an informed decision, but what the reasonable patient needs to hear to make an informed and intelligent decision regarding the treatment.⁹⁶ This paper will focus on the objectively reasonable physician standard adopted by a majority of jurisdictions.⁹⁷

ii. The Reasonable Physician Approach

The reasonable physician standard requires the reasonable physician, or other healthcare provider to disclose what a reasonable physician, or other healthcare provider would disclose under the same or similar circumstances.⁹⁸ The liability of a physician is determined by the acceptable practices of disclosure as adopted by their peers in the particular medical profession.⁹⁹

The modern doctrine of informed consent requires more than just obtaining the patient's permission.¹⁰⁰ The physician has a duty to provide a "comprehensive disclosure of information, including the risks and benefits of

93. See FADEN *supra* note 55, at 135-36.

94. *E.g.*, MARSHALL S. SHAPO, PRINCIPLES OF TORT LAW 130 (2d ed. 2003) (stating that one court held in an operation for the removal of wisdom teeth, the .001 risk of permanent loss of feeling in a portion of the case was not material, however the same court then held that the chance of one to three out of a thousand that a sterilization procedure would fail was a material fact because the woman suffered complications with pregnancy in the past).

95. *Wheeldon v. Madison*, 374 N.W.2d 367, 374 (S.D. 1985) (holding measuring performance of physician's duty to disclose risk is conduct which is reasonable under circumstances).

96. *Adler v. Kokemoor*, 545 N.W.2d 495, 501 (Wis. 1996) (holding evidence that surgeon should have advised patient of possibility of undergoing surgery at tertiary care facility with more experienced surgeon in better-equipped facility was properly admitted).

97. See Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 916-17 (1994).

98. See *Brandon v. Karp*, 490 N.Y.S.2d 490, 492 (1982) (holding that absent expert testimony that defendants violated applicable standard of care, defendants were not liable for medical malpractice on grounds of lack of informed consent).

99. See, *e.g.*, *In re Swine Flu Immunization Prod. Liab. Litig.*, 533 F. Supp. 567, 574 (1980) (holding that county health department's habit and routine practice of obtaining signed consent forms prior to administering vaccine was sufficient to establish that plaintiff received information concerning the vaccine and the information received was sufficient to enable her to make an informed consent to be vaccinated but plaintiff, who had history of problems with back and left leg prior to swine flu immunization, failed to meet her burden of proving causal connection between her left foot drop and the swine flu vaccine).

100. *Ketler*, *supra* note 70, at 1037.

alternative forms of treatment as well as the risks and benefits of no treatment at all.”¹⁰¹ The doctrine of informed consent does not require disclosure of risks already known by the patient or risks which are common knowledge.¹⁰² Further, “the primary duty of a physician is to do what is best for his patient and that a physician may withhold adequate disclosure of information . . . where the disclosure would be detrimental to a patient’s total care and best interests.”¹⁰³ The burden is on the plaintiff to show that he was inadequately informed, and that the failure to disclose was the proximate cause of the injury suffered.¹⁰⁴ A physician’s failure to adequately disclose information to the patient must result in injury to the patient.¹⁰⁵

2. Causation

The element of causation requires “that the plaintiff patient would have chosen no treatment or a different course of treatment had the alternatives and material risks of each been made known to him.”¹⁰⁶ The plaintiff does not have a claim if disclosure would not have changed her decision to undergo the treatment which caused her injury.¹⁰⁷

A minority of jurisdictions follow the subjective patient standard, relying on evidence of what the specific patient would have done had they been presented with all of the material facts.¹⁰⁸ In these jurisdictions, the jury is charged with the responsibility of assessing the credibility of the plaintiff’s

101. *Id.*

102. *See* Yeates v. Harms, 393 P.2d 982, 991 (1964) (holding evidence of whether or not the hospital had duty to call another physician during surgeon’s unavailability when plaintiff complained of pain was insufficient to take case against hospital to jury).

103. *See* Nishi v. Hartwell, 473 P.2d 116, 119 (1970) (holding that uncontradicted testimony that patient who was dentist was suffering from hypertension and suffered severe pain and that physicians were afraid that disclosure of possible side effect from use of medium in performing thoracic aortography might have adverse effect on patient, and that failure to disclose possible side effect at time general disclosure as to surgical procedure was given to patient did not render physicians liable to patient who became paralyzed from use of medium).

104. Laurent B. Frantz, Annotation, *Modern Status of Views as to General Measure of Physician’s Duty to Inform Patient of Risks of Proposed Treatment*, 88 A.L.R.3d 1008 (1978).

105. *See* DOBBS, *supra* note 72, at 657.

106. *Scott v. Bradford*, 606 P.2d 554, 558 (1979).

107. *Id.*

108. *See* Reidesser v. Nelson, 534 P.2d 1052, 1054-55 (1975) (holding that doctrine of *res ipsa loquitur* was inapplicable since plaintiffs had failed to establish negligence of the surgeon, that negligence on part of a physician must be established by expert medical testimony unless the negligence is so grossly apparent that a layman would have no difficulty in recognizing it, that since wife had given her informed consent, any liability of surgeon for failure to disclose that development of a uretrovaginal fistula was a risk to be incurred in undergoing hysterectomy was to be for malpractice, that no breach of duty in such regard had been established and that no damage could be said to have proximately resulted from failure to disclose unless wife would not have had the operation had the disclosure been made).

testimony.¹⁰⁹ Courts have recognized that this standard places the physician at the mercy of the patient, and after that patient has suffered injury which could alter the patient's decision-making power at trial.¹¹⁰ One court, in justifying the application of this standard, adopted the rationale that the physician is always encouraged to protect himself from liability by adequately informing all of his patients.¹¹¹ However, most courts have denied that justification.

The common law and statutory law have moved toward the objective standard for causation. A landmark case in the development of informed consent was *Canterbury v. Spence*.¹¹² In that case the court implemented an objective standard of "what a prudent person in the patient's position would have decided if suitably informed of all perils bearing significance."¹¹³ In jurisdictions which have applied this standard the element of causation has been crucial in determining the outcome of cases.¹¹⁴ Application of the majority view is crucial to cases involving homeopathic practitioners because the objectively reasonable juror is able to hear all surrounding facts and circumstances to make a determination without having any close relationship with the homeopathic practitioner.

IV. GENERAL STANDARDS OF CARE APPLICABLE TO PRACTITIONERS

Informed consent is critical to the standard of care analysis for homeopathic practitioners. The duty to disclose is founded on the protection of patient autonomy and materializes when a patient makes an informed decision regarding her medical treatment.¹¹⁵ However, the majority of states do not have regulatory boards governing homeopathic practitioners.¹¹⁶ These practitioners are treating patients without any regulatory scheme or common law doctrines imposing duties such as informed consent. Homeopathic practitioners are able to develop their own practices and standards which are outside the scope of conventional medical treatment because they are governed by the standard of care of another homeopathic practitioner.¹¹⁷

One example of the formation and implementation of homeopathic practice outside the standard of care of a conventional medical physician is in

109. See FADEN, *supra* note 55, at 34.

110. *Scott*, 606 P.2d at 559.

111. *Id.*

112. 464 F.2d 772 (D.C. Cir. 1972).

113. *Id.* at 791.

114. See FADEN, *supra* note 55, at 34.

115. See FADEN, *supra* note 55.

116. The only states that do have separate licensing boards for homeopaths are Arizona, Nevada, and Connecticut.

117. See 61 AM. JUR. *Physicians, Surgeons, Etc.* 2D § 195.

the *Charell v. Gonzalez* case.¹¹⁸ While few reported cases involving the liability of homeopathic practitioners exists, this court imposed the requirement of obtaining informed consent on a homeopathic practitioner.¹¹⁹ In *Charell*, a cancer patient decided to pursue alternative treatment with a homeopathic practitioner.¹²⁰ The patient chose to undergo an alternative nutritional program and to forgo conventional chemotherapy without disclosure of the risks of that decision.¹²¹ The jury found the alternative medical practitioner fifty-one percent at fault for the failure to adequately inform the patient of the risks of pursuing the alternative treatment and other available alternatives.¹²²

V. IMPOSING THE DOCTRINE OF INFORMED CONSENT ON HOMEOPATHIC PRACTITIONERS

Homeopathic practitioners should be required to obtain informed consent before performing any treatment on a patient in order to protect the public and individual patient autonomy. Homeopathic practitioners should be held to the standard of care of traditional medical doctors with regard to informed consent. Specifically, they should be required to inform patients of the risks of any proposed treatment, as well as alternative treatments and procedures that would be available from licensed medical doctors.

Regardless of the circumstances surrounding the relationships, homeopaths should be required to disclose all risks of the homeopathic treatment as well as inform the patient of conventional treatments that are available. One theory suggests that homeopaths and their patients have a closer relationship than conventional medical doctors and their patients.¹²³ Some believe that there is less likely to be any feeling of resentment when a treatment is unsuccessful because the homeopath and the patient work together.¹²⁴ Homeopaths are often more sympathetic to the feelings of the patient.¹²⁵ Also, many vulnerable homeopathic patients seek out homeopaths as a last resort for treatment because they are terminally ill.¹²⁶ A homeopathic practitioner should be required to tell his patient of the alternative treatments offered by

118. 660 N.Y.S.2d 665 (1997).

119. *See id.* at 667-69.

120. *Id.* at 667.

121. *Id.*

122. *Id.*

123. *See* Aimee Doyle, *Alternative Medicine and Medical Malpractice*, 22 J. LEGAL MED. 533, 550 (2001).

124. *Id.*

125. *See* Sheldon, *supra* note 19, at 312.

126. *See Charell*, 660 N.Y.S.2d at 667-68.

the competing conventional school of medicine. This includes alternatives which may even pose more risks than the treatment proposed.

Homeopathic practitioners should not be able to escape the challenges that conventional medical physicians bear in satisfying their duty to disclose. Homeopaths should be held to the reasonable patient objective standard when disclosing material risks to their patients. The “natural” aspect of homeopathic treatment presents a unique problem for practitioners because patients may assume that the treatments are risk free. The recent recognition of organic products, including for example produce and dairy products, could cause a person to assume that a naturally-based or organic product is by its very nature safer than any other. Therefore, it is even more important for homeopathic practitioners to obtain consent in order to ensure that the patient understands the material facts concerning her treatment. It is unfair to allow the unlicensed homeopath free reign to practice with no imposition of a duty of informed consent to his patient, when the licensed and extensively-educated physician is held to such a higher duty. The homeopath should be required to have knowledge and expertise of a proposed treatment and be capable of administering it safely and appropriately. This requirement includes an adequate and complete disclosure of the risks, benefits, and alternatives of the proposed treatment.

It is imperative to strike a balance between patient autonomy and medical paternalism. The risk of medical paternalism is much higher with homeopathy than with conventional medicine because of the unique trusting relationship which develops between the homeopath and the patient. In Colorado, a naturopath¹²⁷ injected a child with hydrogen peroxide as treatment for his cancer.¹²⁸ After commenting to the patient’s desperate parents that “No Irish kid’s going to die on my watch,” the naturopath administered a vitamin cocktail intravenously.¹²⁹ The child’s blood oxygen level dropped, his skin turned a grayish tint and he died nine days later.¹³⁰ This is an example of how untrained people could mislead the public. The naturopath provided a false glimpse of hope to an uninformed patient and his family. Homeopathic practitioners should not be able to take life-altering or life-ending steps to provide treatment without adequately informing patients. The homeopath must always enable patients to make their own informed decisions to protect the principle of individual patient autonomy. The goal of the doctrine is

127. Dan Wilcock, *RX for Confusion: Colorado’s Lack of Regulation Leaves Alternative Physician on Risky Ground*, COLO. SPRINGS INDEPENDENT, Jan. 19, 2006, available at www.csindy.com/csindy/2006-01-19/cover.html.

128. *Id.*

129. *Id.*

130. *Id.*

furthered by courts holding homeopaths to the standard of disclosure of a conventional doctor because the methods and practices have been closely interpreted by United States courts, as opposed to the slight number of cases addressing CAM practices.¹³¹ This small amount of judicial review establishes the importance of enforcing a standard for informed consent because the courts and society are walking on unlitigated ground and the true propensity for injury unknown.

Courts should apply the objective standard for causation in informed consent cases against homeopaths. The element of causation would be much easier to prove to a jury when the courts apply the objective standard. Application of this standard gives the uninformed and injured patient a possible remedy. A reasonable juror is more likely to see—had the patient been aware of the material risks surrounding homeopathic treatment and the available conventional treatment—the reasonable patient would have decided not to undergo the homeopathic treatment. The court should apply this standard to allow the reasonable juror to assess the situation and to determine if she would have avoided the injury suffered.

The patient must show that she would have chosen another treatment had she been advised of the risks inherent in homeopathic treatment. There also must be evidence to support any contention that the injury suffered is a loss incurred from not pursuing any other treatment as a result of the failure to disclose the availability of the treatment. The conventional treatment must be supported by evidence demonstrating its effectiveness and the likelihood the patient would or would not have benefited from the treatment.

VI. HOW STATES SHOULD APPLY THE DOCTRINE OF INFORMED CONSENT TO HOMEOPATHS

In states without statutes codifying the doctrine of informed consent, courts should apply the common law doctrine of informed consent to homeopathic practitioners. Even if a homeopath is unlicensed and not regulated by any specific medical board, the homeopath should be held to the same standard of disclosure as a licensed conventional physician as a matter of common law. As with conventional physicians, homeopaths treat citizens who have a well founded right under common law to have all material facts in front of them prior to a decision concerning medical treatment. Even Minnesota, which regulates the medical profession much more thoroughly than other states, does not impose a regulatory duty on homeopathic practitioners to

131. Edzard Ernst, *Informed Consent in Complementary and Alternative Medicine*, 161 ARCH. INTERN. MED. 2288 (2001).

obtain informed consent.¹³² In fact, the state requires the patient to sign a form called the patient Complementary and Alternative Healthcare Client Bill of Rights, however, this document does not go as far in protecting patients as informed consent does.¹³³ The focus should be on the process of disclosure and the patient's understanding, as opposed to a basic form.¹³⁴ The duty to disclose is met only after a process of interaction between the physician and the patient.

States with informed consent statutes that clearly apply only to licensed medical doctors, should amend their statutes to include unlicensed and licensed homeopaths.¹³⁵ Alternatively, courts should impose a similar duty on homeopathic practitioners as a matter of common law. In states such as Arizona, where homeopaths are licensed, the courts should still impose the common law doctrine to the licensed homeopath. The homeopaths could only meet their burden of disclosure if, after a reasonable determination that the patient should see a conventional physician, the homeopath informs the patient of the availability of the conventional treatment and the risks of continuing alternative treatment.

Licensed professionals should all be included in the state's informed consent statute. All states should develop governing boards and mandate licensure requirements for homeopaths. These requirements should include accredited homeopathic schooling. Any homeopath practicing in any state without a license should be charged with practicing medicine without a license.

Chiropractors also fall under the CAM classification.¹³⁶ They are licensed professionals who, just as the case with the ordinary physician, will be held liable for medical malpractice when injury occurs because of substandard treatment.¹³⁷ Chiropractors and other drugless healers, including homeopaths, have been held to the standard of care in the treatment of their patients as "possessed and used by prudent, skillful, and careful practitioners of the same school and not that of a medical doctor or specialist."¹³⁸ Just as these CAM practitioners are licensed and regulated, homeopaths as CAM practitioners should be licensed and regulated by the states as well.

132. MINN. STAT. ANN. § 146A.11 (West 2007).

133. *See id.*

134. *See id.*

135. *See supra* note 16 and accompanying text.

136. Annotation, *Liability of Chiropractors and Other Drugless Practitioners for Medical Malpractice*, 77 A.L.R. 4TH. 273 (1989).

137. *Id.*

138. *Id.*

Homeopaths have been held liable for medical malpractice for breach of the duty to disclose and a resulting injury due to substandard treatment.¹³⁹ However, they are only held to the standard of another homeopathic practitioner.¹⁴⁰ All states should codify the common law doctrine of informed consent and include homeopaths in the imposition of liability. The homeopaths should be held to the same standard of informed consent as a licensed medical physician because the patient must be informed not only of what another homeopath in the community may deem material, but as what a conventional medical physician would deem material. The patient should not be forced to undergo conventional treatment, but be informed and able to make the decision to forego the treatment.

Proponents of homeopathy may argue that homeopaths are unable to inform their patients of the risks inherent in refusing the conventional treatment because homeopaths are not trained in the conventional medical field. However, requiring the unlicensed homeopath to recommend the patient to a licensed physician if there is a reasonable likelihood the patient needs to be seen by a licensed conventional physician eliminates any concern that the homeopath be required to diagnose an ailment which he is unqualified to detect.¹⁴¹ There is not a need for specific diagnosis, but only the reasonable determination that the patient should seek conventional treatment from a licensed physician.

VII. CONCLUSION

Homeopathic practitioners should be required to obtain informed consent before performing any treatment on a patient. In order to protect the public and individual patient autonomy, homeopathic practitioners should be held to the standard of care of traditional medical doctors with regard to informed consent, requiring them to inform patients of the risks of any proposed treatment, as well as conventional treatments and procedures that are available from licensed medical doctors.

The courts should apply the reasonable physician standard for disclosure to homeopathic practitioners. States should require homeopaths to be licensed and regulated by a state board. However, if homeopaths are not licensed, the court should apply the common law doctrine of informed consent and require adequate disclosure of available conventional treatment. The element of causation should be determined through the objective standard of the reasonable patient. The courts should determine if the harm suffered could have

139. *See Charell*, 660 N.Y.S.2d at 668.

140. *Id.*

141. MINN. STAT. ANN. § 146A.11 (West 2007).

been avoided had the reasonable patient been presented with all material risks and the alternative conventional treatment. Furthermore, states should include homeopathic practitioners in their informed consent statutes. In the alternative, states that limit informed consent to licensed medical physicians should apply the common law doctrine of informed consent to homeopathic practitioners.

This proposal is not intended to defeat the homeopathic school of thought, but is instead intended to establish a judicial standard which can be adopted by states and the judicial system as a whole to protect a vital state interest and the health and safety of young students like the female suffering from lupus. A classic fundamental right in this country is liberty and each citizen should be entitled to all material risks and alternatives concerning their medical treatment. There should not be one institution of medicine, such as homeopathy, which is able to place any persons liberty interest on hold due to a lack of common law development or statutory formulation.