

1990

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### Recommended Citation

Hunter L. Prillman, *A Physician's Duty to Inform of Newly Developed Therapy*, 6 J. Contemp. Health L. & Pol'y 43 (1990).

Available at: <https://scholarship.law.edu/jchlp/vol6/iss1/6>

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# A PHYSICIAN'S DUTY TO INFORM OF NEWLY DEVELOPED THERAPY

*Hunter L. Prillaman\**

## I. INTRODUCTION

As medical science develops, new drugs, devices and treatments are constantly being created for the use of the medical profession. Similarly, new knowledge about disease and the functions of the human body is constantly being discovered and disseminated. This condition of constant change creates an important practical question that the medical practitioner must answer: when, under theories of malpractice and informed consent, does a physician have a duty to inform a patient of a newly developed or controversial alternative therapy, different from the therapy the physician recommends for the patient? A satisfactory answer to this question will require an approach somewhat different from that used in the usual situation involving the absence of informed consent to a medical procedure. This article will propose that although a physician may properly be required to inform a patient of all medically acceptable alternative treatments, even if the application of a professional standard of care would not require such disclosure, the use of a professional standard is nevertheless essential to establish what treatments are medically acceptable.

## II. MALPRACTICE AND INFORMED CONSENT

In analyzing the duty to inform patients of new medical treatments, it is important to distinguish between the theories underlying causes of action for malpractice and for failure to obtain informed consent to medical treatment. A claim for malpractice is made out when the patient is harmed as a result of a physician's failure to render care in accordance with that which would have been rendered by other physicians practicing in the community.<sup>1</sup> This standard is a "professional" one in that the physician's conduct is measured in relation to what would have been considered proper by other professionals

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1. 61 AM. JUR. 2D *Physicians, Surgeons, and Other Healers* § 205 (1981).

in the field, and not by an objective standard of reasonableness. Thus, in evaluating whether a physician should have recommended or used a newly developed medical treatment, this professional standard of malpractice will be applied. There can, of course, be complications with this rule. For example, there may be disputes about whether the relevant community consists of local practitioners or members of a specialty on a national basis.<sup>2</sup> It may also be that a particular standard of practice will be considered so outrageous or deficient that a court may disregard the professional standard and find the practice to be negligent as a matter of law.<sup>3</sup> Nevertheless, the basic standard of behavior for the rendering of medical treatment is established by the professional community, and not by external authority.

There is a sharp division under state law, on the other hand, as to the elements of a cause of action for failure to obtain informed consent to a medical treatment or procedure. Older cases based the duty to obtain informed consent on the idea that an unconsented touching was actionable battery,<sup>4</sup> although this has now generally been recognized as an archaic way of thinking about the issues involved, and the focus has shifted to the patient's rights of self-determination. The cause of action is also often stated in terms of negligence rather than battery. For example, Minnesota courts have

recognized a cause of action for medical malpractice due to negligent nondisclosure of a significant risk of treatment or alternative treatment plan. . . . To make out such a claim, a plaintiff must establish a duty on the part of the physician to know of a risk or alternate treatment program. He must also show a duty to disclose the risk or alternate treatment plan by evidence establishing that a reasonable person in what the physician knows or should have known to be the patient's position would likely attach significance to that risk or alternative in formulating his decision to consent to treatment. He further must show breach of that duty, causation, and damage.<sup>5</sup>

Modern cases take one of two approaches to the duty to obtain informed

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2. In *Logan v. Greenwich Hospital Association*, 191 Conn. 282, 465 A.2d 294 (1983), the court abandoned the limitation of the physician's standard of conduct to physicians practicing in the state in favor of a national standard, since medical literature is equally available to all physicians.

3. Thus, where a glaucoma test was simple, inexpensive, reliable and risk-free, it was negligence for an ophthalmologist to fail to administer the test to persons under the age of 40, even though it was not routinely administered to such persons by others in the profession. *Gates v. Jensen*, 92 Wash. 2d 246, 595 P.2d 919 (1979). See also 61 AM. JUR. 2D *Physicians, Surgeons, and Other Healers* § 211 (1981).

4. 61 AM. JUR. 2D *Physicians, Surgeons, and Other Healers* § 197 (1981).

5. *Cornfeldt v. Tongen*, 295 N.W.2d 638, 640 (Minn. 1980) (footnote omitted).

consent. In certain states, a professional standard is applied here as well. In other words, a physician has a duty to inform his or her patients of the same risks of, and alternatives to, the proposed medical treatment as would other physicians practicing in the community. In essence, this form of the cause of action is a subset of malpractice. Thus, in *Ziegert v. South Chicago Community Hospital*,<sup>6</sup> the court applied a "reasonable medical practitioner" standard of informed consent, and held that there must be expert medical testimony of the necessity to inform patients of possible alternatives.<sup>7</sup> Thus, although the claim of failure to obtain informed consent may be treated as a cause of action separate from malpractice, all of the defendant doctor's behavior with regard to the patient will be measured by the same standard, that of adherence to the level of care given by other practitioners in the relevant community.

On the other hand, many states apply a "lay" standard of informed consent, requiring the physician to inform the patient of all the information a reasonable patient would wish to know in making an informed decision as to whether to undergo the proposed therapy. This approach protects the patient's right of personal autonomy and control of his or her body, wholly apart from the physician's duty not to commit malpractice. Indeed, under either approach to informed consent, the treatment proposed by the physician may be entirely proper and may even be properly rendered, but still may result in liability if consent was inadequate. The difference is that with the lay standard, different standards of behavior are used to measure the duty not to commit malpractice and the duty to obtain informed consent.

A typical formulation of the lay or "prudent patient" standard of informed consent is as follows:

In Pennsylvania, a physician is liable to his or her patient if (1) the physician fails to disclose any risk in the recommended treatment, or the existence of any alternative method of treatment, that a reasonable person would deem material in deciding whether to undergo the recommended treatment; (2) the patient would have foregone the recommended treatment had he or she known of the undisclosed information; and (3) as a result of the recommended treatment, the patient actually suffers an injury the risk of which was undisclosed, or the patient actually suffers an injury that would not have occurred had the patient opted for one of the un-

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6. 99 Ill. App. 3d 83, 425 N.E.2d 450 (1981).

7. *Id.* at 92-93, 425 N.E.2d at 458-59. *See also* *Guebard v. Jabaay*, 117 Ill. App. 3d 1, 12-13, 452 N.E.2d 751, 759-60 (1983) (where doctor did not disclose alternative treatment which plaintiff's expert testified was preferable, jury question was created as to whether failure to inform was proximate cause of plaintiff's harm).

disclosed methods of treatment.<sup>8</sup>

While some courts hold that the patient must prove subjectively that "full disclosure of the material risk or alternative would have altered her decision to consent to treatment,"<sup>9</sup> others apply an objective test, requiring a showing that a reasonable person would have made a different choice if informed of the risk or alternative.<sup>10</sup> In practice, of course, it is difficult to refute an injured plaintiff's claim that he or she would have chosen a different course of treatment if fully informed. Accordingly, the subjective test is likely to benefit plaintiffs, while the reasonable patient test is likely to benefit defendants.

It is also worth noting that the injury required under an informed consent claim is not necessarily an injury resulting from negligent or improper medical treatment. As will be described more fully *infra*, the injury may even be a fully expected outcome of the recommended medical treatment. The crucial factor is that it would have been avoided if the plaintiff had chosen an undisclosed alternative treatment.

Both the professional and lay standards of informed consent are part of the general evolution of attitudes about the relationship between the medical profession and medical patients, including the growing belief that patients are entitled to more information about their health, as well as a real and informed role in decisions about their medical treatment. As general levels of education and public awareness of health issues have increased, patients have become dissatisfied with the paternalism of much traditional medical practice and have sought more power for themselves in the relationship. This change in attitude finds expression in the law of informed consent.

### III. DUTY TO INFORM OF ALTERNATIVE TREATMENTS

Under either the professional or lay approach to informed consent, the physician has the duty to inform the patient of appropriate alternative treat-

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8. Neal v. Lu, 365 Pa. Super. 464, 478, 530 A.2d 103, 111 (1987) (citations omitted). See also Festa v. Greenberg, 354 Pa. Super. 346, 511 A.2d 1371 (1986), *app. denied*, 515 Pa. 580, 527 A.2d 541 (1987); Holt v. Nelson, 11 Wash. App. 230, 523 P.2d 211 (1974), *review denied*, 84 Wash. 2d 1008 (1974); Salis v. United States, 522 F. Supp. 989 (M.D. Pa. 1981) (Pennsylvania law).

9. Spencer v. Seikel, 742 P.2d 1126, 1129 (Okla. 1987). The mother of a hydrocephalic child born with virtually no brain claimed she should have been informed of the alternative of abortion. The court found that the doctor had no duty to inform her that abortions at her stage of pregnancy were legal in other states although not in Oklahoma; she knew about the hydrocephalus and about the existence of abortion in general. *Id.*

10. Duff v. Yelin, 721 S.W.2d 365, 372 (Tex. Ct. App. 1986) (Even if plaintiff was not informed of alternatives, the jury must find that "a person of ordinary prudence would have refused the surgical procedure under the same or similar circumstances if the alternatives to surgical treatment had been disclosed."), *aff'd*, 751 S.W.2d 175 (1988).

ments (in addition to the alternative of no treatment) and to describe the benefits and risks of those treatments. This duty does not require, of course, that the physician describe every conceivable alternative to every detail of the treatment he or she intends to provide. "Disclosure of alternative treatment means disclosure of alternatives for the particular patient and not a recital of medical casebook theory."<sup>11</sup> On the other hand, the "decision involves choosing among medically acceptable options, not simply accepting or rejecting the medically preferable option."<sup>12</sup> Thus, this rule affects the doctor-patient relationship even more profoundly than the duty to disclose the risks of the recommended treatment, since it in effect obligates the physician to defend to the patient the choice of treatment in contrast to other medically feasible treatments. The rule goes beyond ensuring that the patient understands the dangers of the treatment recommended and assumes a role for the patient in the choice of treatment.

As mentioned above, the cause of action for lack of informed consent is conceptually distinct from that for malpractice. The nature and extent of compensable injuries differ as well. A patient may recover for a physician's failure to disclose alternative treatments even if the chosen treatment is not negligently performed. Thus, in *Smith v. Karen S. Reisig, M.D., Inc.*,<sup>13</sup> in which the patient's bladder was punctured during a hysterectomy and in which she had not been informed of the alternative of hormone therapy, the court held:

In cases such as this, where liability is premised upon the physician's failure to inform of non-surgical alternatives, one of the elements of damage is the injury and expense caused by the surgery itself, including any complications which may arise, whether resulting from defective treatment or not, and without regard to whether the complication was a risk to be disclosed. This is so

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11. *Dunham v. Wright*, 423 F.2d 940, 946 (3d Cir. 1970).

12. APPELBAUM, LIDZ, & MEISEL, INFORMED CONSENT - LEGAL THEORY AND CLINICAL PRACTICE 54 (1987). See also *Archer v. Galbraith*, 18 Wash. App. 369, 378-79, 567 P.2d 1155, 1161 (1977), review denied, 90 Wash. 2d 1010 (1978) ("While it may be that the testimony as a whole indicated that the prudent course of action was to remove the nodule surgically, this decision was not a decision to be made by the physician but by the patient. The totality of the evidence permits an inference that had the patient been informed of the alternative treatment, though risky, a reasonably prudent patient would have chosen that course." (citation omitted)); *Cobbs v. Grant*, 8 Cal. 3d 229, 242-43, 502 P.2d 1, 10, 104 Cal. Rptr. 505, 513-14 (1972) ("In many instances, to the physician, whose training and experience enable a self-satisfying evaluation, the particular treatment which should be undertaken may seem evident, but it is the prerogative of the patient, not the physician, to determine for himself the direction in which he believes his interests lie. To enable the patient to chart his course knowledgeably, reasonable familiarity with the therapeutic alternatives and their hazards becomes essential.").

13. 686 P.2d 285 (Okla. 1984).

because the patient is required to establish that the surgery would not have been performed if the alternatives had been disclosed.<sup>14</sup>

Indeed, it appears from the language of the court that even if the recommended treatment were entirely "successful" (in that the results were as the physician intended), the physician could still be liable for failure to disclose an alternative treatment which by its nature might have caused less injury to the patient.<sup>15</sup>

On the other hand, the physician does not commit an actionable wrong simply because he or she chooses between medically acceptable alternatives.<sup>16</sup> The choice between alternative treatments will be evaluated under the professional standard of malpractice. It is the failure to disclose the alternative, not the failure to recommend it, which results in liability under an informed consent theory.

Courts have struggled, and sometimes stumbled, in their attempts to specify the limits of the physician's duty to inform of alternative treatments. The difficulty is, of course, much reduced if a professional standard of informed consent is followed, since the jury will decide the issue by comparing the testimony of competing medical experts. Whether other practitioners in the relevant community would have disclosed the alternative is usually a fairly direct yes-or-no question. Under the lay standard, however, the determination to be made by the jury is a more difficult one, since it involves a consideration of what a reasonable person would want to know under the circumstances. This decision requires analysis beyond simply weighing the credibility of the opinions of opposing experts on community standards. Furthermore, the court must instruct the jury as to what constitutes a medically acceptable alternative before the jury can decide whether a reasonable patient would have wanted to know about it.

In attempting to define what constitutes an alternative treatment, courts have attempted to impose various restrictions on the concept. Thus, in *Logan v. Greenwich Hospital Association*,<sup>17</sup> the patient's gall bladder was punctured during a needle biopsy of the kidney, and the patient complained that the doctors had not mentioned the possibility of performing an open biopsy. The trial court, in applying the lay standard of informed consent, instructed

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14. *Id.* at 288-89.

15. For example, even a successful surgery might cause significant pain and leave a patient physically impaired in some respect. If the therapeutic result could have been achieved by another undisclosed method, the pain and impairment might be compensable injuries.

16. *Young v. United States*, 574 F. Supp. 571, 581 (D. Del. 1983) ("Where among physicians and surgeons of ordinary skill and learning more than one method of treatment is recognized as proper, it is not negligence for a physician or surgeon to adopt one such method instead of another."); *Harrigan v. United States*, 408 F. Supp. 177, 185 (E.D. Pa. 1976).

17. 191 Conn. 282, 465 A.2d 294 (1983).

the jury that "[a]n alternative that is more hazardous is not a viable alternative."<sup>18</sup> In reversing the lower court, the appellate court held that this instruction "wholly relieves physicians of any obligation to discuss alternatives with their patients and substitutes merely a duty to recommend the safest procedure"<sup>19</sup> and that all "viable" alternatives must be disclosed "even though some involve more hazard than others."<sup>20</sup> Although perhaps the lower court's ruling might be correct if the alternative treatment were more hazardous and provided no benefits different from those provided by the recommended treatment, this is rarely the case in reality. More often, competing treatments have different risk-benefit balances, and there is often controversy within the medical profession about what the respective risks and benefits are. Thus, a simple rule that "more hazardous" alternatives need not be disclosed would not succeed in practice.

Courts have also struggled with the question of what constitutes an alternative treatment. For example, in *Kalsbeck v. Westview Clinic, P.A.*,<sup>21</sup> the decedent had pneumonia, and the issue was whether he should have been hospitalized sooner and should have been subjected to more tests. The court held:

The doctrine [of informed consent] applies when the patient must choose between two or more medically accepted alternative methods of treatment.

The flaw underlying appellant's theory is that, rather than constituting alternative methods of treatment, the choices available to Kalsbeck were *additional* treatments. Had Dr. Haight disclosed all of the potential risks confronting Kalsbeck, Kalsbeck might have opted to be hospitalized. Perhaps he would have wanted Dr. Haight to take a culture. He might have wanted to be given additional antibiotics. But Dr. Haight would still have administered the treatment that he did give Kalsbeck, from the injection of Bicillin, to the taking of the blood sugar, to the advice that he check back with the doctor if there was no improvement in the next two days. The doctrine of informed consent does not apply to situations where the patient's decision is whether to submit to treatments in addition to the basic treatment given. Rather, it applies only to situations where the choice is between two or more distinct, alternative methods of treatment.<sup>22</sup>

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18. *Id.* at 293, 465 A.2d at 301.

19. *Id.*

20. *Id.* at 295, 465 A.2d at 302. One doctor had testified that an open biopsy was "viable" and that it did have some advantages. *Id.*, 465 A.2d at 301.

21. 375 N.W.2d 861 (Minn. Ct. App. 1985).

22. *Id.* at 869.

This holding ignores medical reality, and in effect immunizes from any duty to give informed consent those physicians who recommend the most conservative treatment. The alternatives which should be revealed must include alternative *courses* of treatment if the rule is to have any meaning. It cannot make any difference that one of the courses of treatment is a lesser included part of another course of treatment. This theory was implicitly recognized in *Keogan v. Holy Family Hospital*,<sup>23</sup> in which a doctor gave a 37-year-old man with chest pain a "resting EKG" but did not inform him of a "treadmill EKG" or of angiography. The court ruled that the doctor had a duty to disclose alternative diagnostic procedures once he was aware of a physical abnormality in the patient, and that the doctor was negligent as a matter of law for his failure to disclose.<sup>24</sup> Thus, alternate courses of treatment should include alternate means of diagnosis and evaluation, as well as alternate medical and surgical therapies.

Courts have also struggled with how different a treatment must be in order to be considered an alternative. In *Masquat v. Maguire*,<sup>25</sup> the plaintiff claimed she was not informed of other methods of performing a sterilization by tubal ligation that might be more easily reversed. The court held:

Ms. Masquat consented to the tubal ligation operation. Although various methods were available to do the ligation the difference between them was not so significant as to vitiate consent. The appellants' expert testimony showed that there was some difference in successful reversals depending on which ligation method was used. The testimony, however, did not demonstrate any causal linkage between some unrevealed risk and the injuries complained of. Therefore, the differences did not go to the nature of the operation and a general consent to the surgery was sufficient.<sup>26</sup>

This decision appears to depart from the idea that the purpose of the informed consent rule is to protect the patient's right to make informed decisions about her medical treatment. Clearly, the different ligation methods were all medically acceptable alternatives. Why should not the jury be permitted to determine if a reasonable person would want to know about those alternatives in making a decision about treatment? Similarly, in *Wachter v.*

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23. 95 Wash. 2d 306, 622 P.2d 1246 (1980).

24. *Id.* at 314, 622 P.2d at 1252-53 (quoting *Gates v. Jensen*, 92 Wash. 2d, 246, 251, 595 P.2d 919, 923 (1979)). *But see* *Thornton v. Anest*, 19 Wash. App. 174, 574 P.2d 1199 (1978) (holding without explanation that a doctor is not required to disclose feasible alternative means of diagnosis as opposed to treatment.). *See also* Wainess, *Physician's Duty to Inform Patients Who Refuse "Treatment,"* 32 MED. TR. T.Q. 444 (1986).

25. 638 P.2d 1105 (Okla. 1981).

26. *Id.* at 1107.

*United States*,<sup>27</sup> the doctor failed to inform the patient of the possible use of the internal mammary artery for a coronary bypass operation instead of the saphenous vein. The court held that the internal mammary artery (IMA) procedure was not a "medically significant alternative," and further stated:

[T]he IMA procedure was not in general use, was not then known among surgeons to produce better results, and was not the subject of any definitive study showing it would be better than a saphenous vein graft . . . [T]his case presents only a choice of tactical surgical approaches, rather than a choice among treatment modalities, and, thus, it presents no issue of lack of informed consent.<sup>28</sup>

Leaving aside for the moment the question of whether the procedure was sufficiently accepted to make it an alternative which must be revealed, there is no obvious dividing line between a "tactical surgical approach" and a "treatment modality." Indeed, if different tactical surgical approaches had significantly different degrees or types of risk, would not a reasonable patient wish to be informed of those differences? A standard of general applicability is needed, rather than one which depends on mere semantics.

Thus, both the issue of whether "additional" treatment is alternative treatment and whether an "insignificant" difference is an alternative treatment should be treated in the same way. *Any* medically acceptable variation from the recommended course of treatment, no matter how minor, should constitute an alternative treatment. The crucial question should always be whether a reasonable patient would deem the information about the alternative treatment material in deciding whether to undergo the recommended treatment. Although there may be cases in which the difference is so insignificant that a court should rule as a matter of law that the alternative need not have been disclosed, the whole purpose of the lay standard is to vindicate the patient's right to make an informed decision based on information he or she would find material. It is for the jury to determine if any particular item of information meets this standard. Possibly the courts in *Kalsbeck*, *Masquat* and *Wachter* believed that no reasonable jury could have believed the asserted alternatives to be material. If so, they should have explicitly based their rulings on that ground, rather than obscuring the definition of alternative treatment.

There may be circumstances, of course, in which a physician will be relieved of the obligation to disclose an alternative treatment. For example, if the physician believes that disclosure will be harmful to the particular patient, most formulations of the rule permit silence.<sup>29</sup> A similar question is

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27. 689 F. Supp. 1420 (D. Md. 1988), *aff'd*, 877 F.2d 257 (4th Cir. 1989).

28. *Id.* at 1423-24.

29. 61 AM. JUR. 2D *Physicians, Surgeons, and Other Healers* § 191 (1981).

whether a physician should be allowed to take into account the particular patient's economic status in determining what alternative treatments to describe. Does it make sense, for example, to explain an expensive treatment offered in an exclusive clinic in Vienna to an indigent patient from an American inner city? On the other hand, should doctors make the cost-benefit analyses required in determining whether a patient can afford a treatment, or should such decisions always be left to the patients themselves?<sup>30</sup> Even these questions, however, may be restated in terms of the general requirement to disclose that information which a reasonable patient, under the circumstances of the patient in the particular case, would want to know.

#### IV. WHAT MAKES AN ALTERNATIVE TREATMENT "ACCEPTED"?

As can be seen from the case law described above, the essential criterion for determining whether an alternative treatment must be disclosed is that the treatment be "medically acceptable." The difficulty is in defining what makes a particular treatment, especially a new one, acceptable, and to whom it must be acceptable. In terms of a doctor's duty to disclose, this issue can be broken down into two parts. First, what criteria, objective or subjective, make a particular treatment acceptable? Second, are there additional factors which create (or excuse) the particular physician's duty to know about the treatment?<sup>31</sup>

Every new medical treatment, whether it be surgery, drug therapy, or another more exotic technique, begins as an experimental treatment.<sup>32</sup> Some courts have held that there is no duty to offer patients treatments which are still experimental. For example, in *Del Valle Rivera v. United States*,<sup>33</sup> the

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30. In the malpractice context, the failure to provide a new form of treatment solely because of its cost may be found to be negligent. For example, a plaintiff reportedly recovered damages from District of Columbia General Hospital when the hospital did not provide a CAT scanner for cost reasons. See Mehlman, *Rationing Expensive Lifesaving Medical Treatments*, 1985 WIS. L. REV. 239, 287 (1985).

31. "[T]he courts must consider the process whereby medical discoveries are diffused. Even after the therapeutic value of a new resource is demonstrated, its value may not be known to practitioners." *Id.* at 296 (footnote omitted).

32. "Another set of conditions that sometimes limits the availability of medical treatments is the transition of a treatment from experimental to accepted status. After it is invented, a new therapeutic or diagnostic tool or technique is refined, and its advantages and drawbacks are communicated to and evaluated by the medical community. During this period, the availability of the resource is often sharply restricted, in part by law. Experimental new drugs and medical devices, for example, are not widely available until they are approved for safety and effectiveness by the Food and Drug Administration, a process which usually takes years. Furthermore, federal health care reimbursement programs and private insurance plans do not reimburse health care providers for experimental treatments, and this generally curtails their availability." *Id.* at 242 (footnote omitted).

33. 630 F. Supp. 750 (D.P.R. 1986).

court found no duty to offer "sclerotherapy," a treatment "being utilized on an experimental basis in some stateside medical centers," because it was not "an available developed therapy" at times material to the action.<sup>34</sup> Such cases do not go very far in solving the problem, however, since "experimental" is simply a label and must itself be defined. Furthermore, court rulings that a physician did not commit malpractice by failing to apply an experimental treatment<sup>35</sup> do not necessarily answer the different question of whether a doctor has a duty to inform his patients of the existence of the experimental treatment.

Thus, either clear objective criteria or rational procedures are needed to determine when, in the course of a new treatment's development, it becomes sufficiently "acceptable" to create a duty of disclosure. There are several "objective" criteria which could be used to evaluate the acceptability of new treatments. They are only objective, however, in the sense that they depend on the acceptance of the judgment of some entity outside the court.

For example, it could be argued that once a drug is approved by the Food and Drug Administration for a particular indication, from the point that use becomes an accepted treatment it must be revealed to patients for whom it might be indicated. Of course, this rule would recognize the expertise of the FDA as decisive in questions of medical judgment. Thus, it ignores the possibility that even though the FDA approves of a drug, a majority of experts in the field might still believe that its acceptability was still unproven. Should such opposition suffice to remove the duty to disclose? The FDA might approve a new drug as "safe and effective" for use with a particular condition, even though safer and more effective drugs were already available. If no different benefits were provided by the new drug, it might not be considered "medically acceptable" for treatment of the condition as long as the better drugs remained available. Another problem is that some drug treatments become generally accepted even before the FDA approves the drug for the particular use. This situation occurs most often when a drug approved for some uses is found to be effective for other complaints as well. The drug is commercially available and physicians may prescribe it even though the drug company may not be permitted to market it for the new use.<sup>36</sup> Thus, an "FDA approval" rule might still fail to cover all medically

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34. *Id.* at 755-56.

35. *Garrett v. United States*, 667 F. Supp. 1147, 1162-63 (W.D. La. 1987) ("This court will not find malpractice in the treating physician's failure to adopt a 'controversial' treatment modality which is not commonly accepted in the medical profession. . . . This court would violate the long-established standard of care for physicians if it held a doctor liable for failing to use experimental and unproven treatment on one of his patients.").

36. An example is the wide use of propranolol for angina pectoris, despite the absence of FDA approval for that use. R. MERRILL & P. HUTT, *FOOD AND DRUG LAW* 462 (1980).

acceptable drug treatments, and might presumptively categorize some treatments as acceptable despite overwhelming disagreement by the medical profession.<sup>37</sup>

A second possible source of acceptance of a new medical treatment is official acceptance by a professional medical organization, such as the American Medical Association or a medical specialty association.<sup>38</sup> Like the "FDA approval" rule, this rule would permit courts to defer to the professional organization's expertise without the necessity of examining the reasonableness of its conclusions. Since these organizations do not have governmental status, accepting their approval as decisive would be merely to accept majority rule of the profession as decisive. Such an approach would place the interest of patients in conflict with the professional organization's interest in protecting the members of the profession. It would also exclude treatments supported by groups dissenting from the association's view, and would involve association politics in the establishment of a legal standard.

Another possible objective criterion is recognition of the treatment as accepted in the most recent leading textbooks of the relevant specialty. There are several problems with this approach. First, expert opinion testimony would be required to establish which textbooks are the leading ones, and thus acceptance of the treatment would simply be based on the opinions of the textbook's authors. Second, it is impossible to keep textbooks up to date. No major, general textbook is updated on more than a yearly basis, and many specialty textbooks are updated even less frequently.<sup>39</sup> A year is much too long in today's rapidly changing realm of medical science. Finally, textbooks are likely to discuss only established, accepted treatments. Therefore, the failure to mention an alternative does not indicate whether it is explicitly disapproved or simply too new to have been included in the latest edition.

A similar rule would be to require that the acceptance of the new treatment be demonstrated through articles in medical journals.<sup>40</sup> The leading

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37. Other governmental entities may also issue statements as to appropriate medical treatments. See, e.g., CENTERS FOR DISEASE CONTROL, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, 1985 SEXUALLY TRANSMITTED DISEASES TREATMENT GUIDELINES (1985).

38. For example, the American Medical Association Division of Drugs and Technology, in conjunction with the American Society for Clinical Pharmacology and Therapeutics, publishes drug evaluations with the purpose being "[t]o provide physicians and other health care professionals with up-to-date, unbiased information on the *clinical* use of drugs." DIVISION OF DRUGS AND TECHNOLOGY, AMERICAN MEDICAL ASSOCIATION DEPARTMENT OF DRUGS, DRUG EVALUATIONS iii (6th ed. 1986).

39. For example, an interval of four years occurred between revisions of *CANCER: PRINCIPLES & PRACTICE OF ONCOLOGY* (V. Devita, Jr., S. Hellman & S. Rosenberg eds. 1989) [hereinafter cited as *CANCER*], the leading oncology textbook.

40. This approach was at least implicitly accepted in *Wachter v. United States*, 689 F. Supp. 1420 (D. Md. 1988), *aff'd*, 877 F.2d 257 (4th Cir. 1989).

peer-reviewed journals are the primary fora for the discussion and dissemination of medical advances throughout the medical profession. As with textbooks, however, expert testimony will still be needed to establish which journal articles are conclusive and to interpret their findings.<sup>41</sup>

Another possible consideration is whether the treatment is accepted for reimbursement by insurance carriers. Insurance policies usually limit reimbursement to medical treatment which is "reasonable and necessary" for treatment of the disease or "in accordance with generally accepted professional medical standards."<sup>42</sup> However, it seems that while this might be a relevant consideration for a patient in deciding whether to undergo the treatment, it is not necessarily good evidence of whether the treatment is an appropriate medical treatment. Indeed, insurance carriers may refuse to reimburse certain new treatments because of their enormous cost, even though they might be effective. There is little reason to leave the authority to accept new medical treatments in the hands of those with an economic incentive to withhold acceptance.<sup>43</sup>

The possible criteria described above attempt to define a treatment as "acceptable" by looking at external indicia such as support in the medical literature or approval by some decisionmaker with conclusive power. Another possible criterion would be that the treatment in question must be "accepted" (as opposed to "acceptable") as an appropriate treatment by some substantial percentage of practitioners in the relevant specialty.<sup>44</sup> Although some of the other criteria mentioned above (especially professional organization approval) would be useful or perhaps even presumptively decisive in establishing this criterion, expert opinion would be necessary, particularly if

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41. Of course, reliance on literature or other professional reports is not alone sufficient to protect a physician from patient claims. For example, in *Ahern v. Veterans Administration*, 537 F.2d 1098 (10th Cir. 1976) (New Mexico law), a patient with rectal cancer was exposed to extremely high doses of radiation, on the basis of one paper read at a conference suggesting high radiation treatments for bladder cancer. The court held that the treatment was experimental, and that informed consent was not obtained: "[I]n order for a physician to avoid liability by engaging in drastic or experimental treatment, which exceeds the bounds of established medical standards, his patient must always be fully informed of the experimental nature of the treatment and of the foreseeable consequences of that treatment." *Id.* at 1102.

42. Monaco and Burke, *Insurance as Gatekeeper - Part Two: Policy Obstacles in Unproven Methods Litigation*, 20 FORUM 400, 404 (1985).

43. Monaco and Burke argue that insurance companies, "as part of their quasi-public nature" have a responsibility to act as "gatekeepers" to exclude illegitimate claims, and that they should carefully define their exclusions, including naming "the professional groups whose opinions will be held definitive." *Id.* at 404, 416. One may well question whether this "quasi-public" role is really compatible with an insurance company's profit motive.

44. One court has held that a patient has the right to be informed about an alternative "means of therapy pursued by a respectable segment of the medical profession." *Archer v. Galbraith*, 18 Wash. App. 369, 378, 567 P.2d 1155, 1161 (1977).

the substantial percentage required were to be something less than a majority. How sizable or respectable must the minority accepting the treatment be before other practitioners are obligated to disclose it? What if the doctor in question believes in good faith that the doctors who accept the treatment are quacks?<sup>45</sup> On the other hand, it is easy to imagine opposed schools of thought as to a particular treatment which might nonetheless recognize the intellectual respectability of the opposing school. For example, controversy exists as to whether, in treating breast cancer in its early stages, "breast preservation utilizing local excision and radiation therapy" is preferable to a radical mastectomy.<sup>46</sup> In such cases, it appears quite clear that a patient should be informed that reasonable minds disagree as to the proper treatment for the disease; indeed, it is probably the most important situation calling for such information.<sup>47</sup>

The problems inherent in all the possible criteria are intensified when the issue of the doctor's duty to know of a particular accepted treatment is added into the calculation. For example, individual doctors cannot be expected to follow closely the actions of the FDA in approving all new drugs. On the other hand, drug companies can be expected to act expeditiously in informing doctors of the availability of their new drugs. Physicians may have a duty to pay careful attention to such communications. Similarly, if textbooks and journals are to establish the acceptance of a new treatment, it must be recognized that there is a tremendous amount of such material available. If a doctor is to be held responsible for keeping up with "the literature," what journals and textbooks is he or she obligated to read? The problem is the same if the criterion is acceptance by a substantial percentage of practitioners. The individual practitioner must somehow learn of the treatment and its level of acceptance. Furthermore, what if a physician is aware of a new treatment for some particular reason different from those listed above? For example, a doctor affiliated with a hospital might be aware

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45. Consider, for example, the scientific dispute over the use of laetrile in the treatment of cancer. J. PATTERSON, *THE DREAD DISEASE: CANCER AND MODERN AMERICAN CULTURE* 277 (1987); J. Henney, *Unproven Methods of Cancer Treatment*, in *CANCER: PRINCIPLES & PRACTICE OF ONCOLOGY* 2338 (V. DeVita, Jr., S. Hellman & S. Rosenberg eds. 1985). Note also that some states, including New York, recognize by statute that certain non-traditional therapies are in some sense valid, for example, chiropractic therapy. N.Y. EDUC. LAW §§ 6550-6556 (McKinney 1985). Must medical doctors inform patients of the chiropractic alternative even if they believe it is invalid?

46. See *CANCER*, *supra* note 39, at 1229-30. "From the available data, it seems clear that both mastectomy and breast preservation utilizing local excision and radiation therapy are acceptable alternatives for the treatment of early breast cancer." *Id.* at 1230.

47. *Id.* "Today, both alternatives must be discussed with the patient; only through this discussion can an informed patient receive information and guidance sufficient to permit her to reach a reasonable decision." *Id.*

that a new cancer treatment was being tested there. It is conceivable that although the doctor might not have a duty to know about a new treatment, he or she might have an obligation to inform patients of it anyway if he or she in fact knows about it.

As mentioned previously, if a professional standard of informed consent is employed, the problems described above will rarely arise, and the entire doctor-patient interaction will be judged by the same standard of behavior. Such an approach does not, however, grant the same importance to the patient's right to self-determination as does the lay standard.

## V. CONCLUSION

The discussion above suggests that even if a "lay" approach to informed consent is utilized, it cannot be effectively extended to determine what alternative treatments are medically acceptable, although it may be used to require medically acceptable treatments to be revealed. Application of a "lay" approach to permit a jury to determine whether a reasonable patient would have considered the treatment to be medically acceptable would mean that a physician would never know what alternatives he or she might have to describe, and might lead to the description of even "quack" treatments for fear that a future jury might find that a reasonable patient would have wanted to know about those treatments. This danger is real, especially in those situations in which there is a committed, if eccentric, minority of physicians believing in the efficacy of the controversial treatment. Furthermore, a practitioner might feel obligated to waste time scouring even the most obscure literature for fear of missing a report of an "accepted" new treatment. Many of these same dangers exist if any of the "objective" criteria used above are applied as decisive factors, particularly when the problem of communication is added. Even the "substantial percentage of practitioners" test holds this threat if a jury is permitted to decide what percentage is substantial.

Instead, the standard for medical acceptability should be based on the perception of the reasonable practitioner. It would not necessarily be whether a reasonable practitioner would inform a patient of the alternative, but whether the reasonable practitioner would believe that the treatment was a "medically acceptable" alternative, that is, whether it was accepted as an appropriate treatment by a significant number of reputable experts in the field. All of the factors described above - FDA approval, discussions in the literature, the availability of information about the treatment, good-faith belief the treatment was quackery, individual knowledge of a new treatment - could potentially be used by experts in forming their opinions as to whether

the practitioner was reasonable in his or her evaluation of whether or not the treatment was medically acceptable. Some courts have implicitly recognized this approach, requiring expert testimony to establish viable alternative treatments and their accompanying risks, even in jurisdictions applying the lay standard of informed consent. Thus, in *Stelle v. St. Paul Fire & Marine Insurance Co.*,<sup>48</sup> a doctor performed a hysterectomy without informing the patient of the possibility of more conservative treatment. The court held:

In order to show that the alternative procedure in this case was "material" information, the patient would have to prove that it is an accepted medical treatment. A physician, of course, would be under no duty to disclose alternative procedures which were not accepted as feasible. Hence, expert medical testimony was necessary in this case to establish the feasibility of the procedure.<sup>49</sup>

It should be emphasized that the standard is not whether the individual doctor believes the treatment is feasible or advisable, but whether he or she is aware that it is accepted by other experts in the field. It should be left to expert testimony to explore the number and respectability of those accepting the treatment, as well as the other factors which might contribute to the analysis. Although the physician would still be in danger (as is probably inevitable) from the opinions of unscrupulous or extremist experts, he or she would be able to appeal to a professional standard for the evaluation of the expert testimony. Under such a standard, a physician could avoid the danger of having to describe the theories of quacks or to explain treatments too new to have a track record, but could still be held to have a duty to keep up with the relevant literature and other sources of information, and to inform patients of new treatments as they met the criteria of acceptance.

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48. 371 So.2d 843 (La. App. 1979), *cert. denied*, 374 So.2d 658 (La. 1979).

49. *Id.* at 849 (citation omitted). See also *Neal v. Lu*, 365 Pa. Super. 464, 480-81, 530 A.2d 103, 112 (1987); *Sard v. Hardy*, 281 Md. 432, 451, 379 A.2d 1014, 1025 (1977) (doctors performed tubal ligation without describing alternate methods of ligation and other forms of sterilization including vasectomy; expert testimony was not required to prove standard of informed consent but was necessary to prove risks and alternatives); *Adams v. Richland Clinic, Inc.*, 37 Wash. App. 650, 681 P.2d 1305 (1984); *Miller v. Kennedy*, 11 Wash. App. 272, 522 P.2d 852, 861 (1974) (Expert testimony is necessary to establish that an alternative treatment is "feasible" but not to establish whether it must be disclosed: "There is no need to prove what other doctors might tell their patients in similar circumstances."), *aff'd*, 85 Wash. 2d 151, 530 P.2d 334 (1975); *Getchell v. Mansfield*, 260 Or. 174, 489 P.2d 953 (1971).