Informed Consent in the Prescription Drug Context: The Special Case

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Medical patients rarely bring suit against prescribing physicians on an informed consent theory in the context of prescription drug therapy.\(^1\) By contrast, patients frequently file suit against their physicians for failure to obtain an informed consent to surgery and other bodily invasive medical treatments.\(^2\) Yet physicians employ prescription drugs far more frequently than any other therapy,\(^3\) and prescription drugs result in a proportionally larger number of side effects and related injuries.\(^4\) Moreover, physicians appear to disclose to patients little, if any, information about the risks of serious side effects or about alternative treatments.\(^5\) One would therefore expect to see many more prescription drug claims litigated under the theory of lack of informed consent.\(^6\) The fact that so few prescription drug claims

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\(^1\) The number of reported appellate decisions, including cases involving prescription drug injections given by the treating physician and therefore involving no written prescription, is probably less than 20. See infra notes 8–9.


\(^3\) See infra notes 96–101 and accompanying text.

\(^4\) See infra notes 96–152 and accompanying text.

\(^5\) See, e.g., R. Mendelsohn, MALE PRACTICE: HOW DOCTORS MANIPULATE WOMEN 36–37 (1982) (arguing that oral contraceptives have been prescribed as if they were no more hazardous than chewing gum). Not only are physicians quick to prescribe drugs, they do so without providing their patients with much, if any, information about potentially dangerous side effects. One physician argued in his own defense that while he agreed that patients should be told about side effects, physicians should not give patients so much information as to scare them. “In other words, it is all right to tell a [patient] that a drug might make her nauseous, but . . . don’t tell her . . . that it might also cause convulsions, heart failure, or anaphylactic shock!” Id. at 59. Other commentators have found that physicians believe that patients are too ignorant to make their own medical decisions and increased disclosure only heightens patients’ fears. See J. Katz, THE SILENT WORLD OF DOCTOR AND PATIENT 83 (1984); see also Boyer v. Smith, No. 80-12190-6, slip op. at 2 (C.P. Bucks County, Pa., Jan. 28, 1985), aff’d, 497 A.2d 646 (Pa. Super. 1985); 2 President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Making Health Care Decisions [hereinafter cited as 2 President’s Commission] 167 table 5–4 (1982) (only 23% of physicians polled think informed consent means that the patient understands treatment risks); infra notes 91–132, 162–211 and accompanying text.

\(^6\) The dearth of appellate decisions might be explained in part by the fact that, although in prescription drug cases prescribing physicians are often named as defendants, the primary target is
are brought might suggest that patients' rights, normally protected by the doctrine of informed consent, are not adequately protected when patients undergo prescription drug therapy.

To understand the current law of informed consent in the area of prescription drugs, one must look to the separate and divergent development of the law of informed consent generally. Currently, courts adopt one of two models of informed consent: the medical-community model and the patient-oriented model (objective-patient model). The medical-community model, adopted by a majority of jurisdictions, determines the existence and scope of a physician's duty to inform by the standard of practice of physicians in the medical community. A significant number of jurisdictions, however, determine the existence and scope of the physician's duty to inform based on the information a reasonable patient would find material in deciding whether or not to undergo the proposed therapy. However, both models employ a reasonable patient standard for determining proximate cause: that is, whether the patient would have consented to the therapy had the physician adequately disclosed pertinent information.

In the prescription drug context, however, courts have almost universally applied the medical-community standard to determine the existence and scope of the physician’s duty to inform and have thereby ignored patients’ rights. This extreme judicial deference to medical autonomy in the prescription drug context largely results from the courts’ failure to examine the unique factors present in prescription drug therapy.

Evaluation of the general doctrine of informed consent is the starting point for determining whether, and how, the doctrine might apply to prescription drug therapy. This article demonstrates that, unlike the decision to undergo surgery (the more typical informed consent situation), the process of prescribing drugs contains numerous considerations, many of which are inherent in and unique to prescription drug therapy. The presence of these considerations dictates that courts accord even greater significance to the need for patient participation in prescription drug therapy than that accorded in the more typical consent to surgery situation. Moreover, in light of the many unique considerations involved, courts need to examine their ready deference to physicians’ autonomy, which results in total exclusion of patient participation and the abrogation of patients’ rights of self-determination and bodily integrity.

This article argues that when the patient would have refused the surgery, Id. The court held that the physician’s duty is to make a full disclosure of all material risks incident to the treatment, the materiality of which is to be determined by the finder of fact. Id. at 558. This is consistent with the Canterbury standard, but the Scott standard differs sharply with regard to causation. In Scott, the relevant causation inquiry is whether the particular patient, and not the reasonable patient, would have consented to the treatment had she been fully informed. Id. at 559.

11. See supra note 8; infra notes 27–32 and accompanying text. One exception to the adoption of the medical-community standard in prescription drug cases can be found in Hamilton v. Hardy, 37 Colo. App. 375, 549 P.2d 1099 (1976), where the court applied an objective standard.

12. See infra notes 96–152 and accompanying text.

13. "Typical" is used in the sense that court decisions concerning informed consent far more often involve surgery or bodily invasive exploratory testing than they do prescription drug situations.

14. See infra notes 96–152 and accompanying text.

15. See infra notes 64–69 and accompanying text.

16. One goal of informed consent is to allow patients to make decisions that affect their own bodies. This goal can be met only when courts afford adequate protection to patients' rights of "self-determination" and "bodily integrity." This premise was first stated in Schloendorff v. Society of N.Y. Hosp., 211 N.Y. 125, 105 N.E. 92, 93 (1914) ("[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body."). The doctrine of informed consent protects the "physical integrity of the individual." Cooper v. Roberts, 220 Pa. Super. 260, 286 A.2d 647, 649 (1971). Beginning with the premise of self-determination, the common law recognized that individuals are masters of their own bodies. Natanson v. Kline, 186 Kan. 383, 350 P.2d 1093, 1104 (1960). Physicians could not substitute their own judgment for that of patients. Id. at 1104. Respect for the patient's right of self-determination therefore demands that the courts, and not the medical profession, set the standards by which physicians must obtain patients' consent prior to the commencement of medical therapy. Canterbury v. Spence, 464 F.2d 772, 784 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972); see also infra notes 219–230 and accompanying text. In Scott v. Bradford, 606 P.2d 554, 559 (Okla. 1979), the court reemphasized the importance of allowing individual patients to make their own decisions, regardless of the unreasonableness of the decision, else "a patient's right of self-determina-
physician prescribes drug therapy, the only reasonable guarantee of a patient’s right of bodily integrity and self-determination is for courts to apply a subjective, individual-patient standard of disclosure in conjunction with a presumption of proximate cause. Finally, the article proposes a duty/disclosure scheme that alters the objective-patient model of informed consent to accommodate the unique aspects of prescription drug therapy and to give full force and effect to the patient’s rights.

I. THE GENERAL LAW OF INFORMED CONSENT

The modern doctrine of informed consent finds its roots in the common law doctrine that adults have a right to determine what will be done with their bodies. To effect the common law rights of self-determination and bodily integrity, modern courts have fashioned the doctrine of informed consent. On a state constitutional level, several jurisdictions have broadly worded privacy protections, which may not require state action, and therefore, lend themselves to interpretations embracing the rights of self-determination, bodily integrity, and personal dignity.

Courts developed the doctrine of informed consent to ensure the protection of patients’ rights, and have fashioned alternate informed consent models: the medical-community model and the objective or reasonable-patient model ("objective-patient model"). Although the objective-patient model provides, at least to some extent, protection for the patient’s right to 

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17. See infra notes 240–46 and accompanying text.
18. See infra notes 247–81 and accompanying text.
19. See supra note 16 and accompanying text.
20. True consent is an informed exercise of choice. To make this choice, the patient must have knowledge of the factors involved, including the alternatives to, and the risks of, the proposed therapy. Average patients have little or no understanding of medicine and must look to their physicians to provide the information necessary for decisionmaking. Providing the patient the opportunity to make this knowledgeable choice is the goal of informed consent and sets the parameters of the physician’s duty to disclose. See, e.g., Canterbury v. Spence, 464 F.2d 772, 780 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972); Lane v. Candura, 6 Mass. App. 377, 376 N.E.2d 1232, 1235–36 (1978) (court held that patient had right to make her own decision concerning life-saving treatment, regardless whether the decision is wise or unwise).
21. See, e.g., Cal. Const. art. I, § 1 ("All people are by nature free and independent and have inalienable rights. Among these are enjoying and defending life and liberty, acquiring, possessing, and protecting property, and pursuing and obtaining safety, happiness, and privacy."); Pa. Const. art. I, § 1 (all people "have certain inherent and indefeasible rights, among which are those of enjoying and defending life and liberty, of acquiring, possessing and protecting property and reputation, and of pursuing their own happiness"); Wash. Const. art. I, § 7 ("No person shall be disturbed in his private affairs, or his home invaded, without authority of law."). For a discussion of Washington’s privacy protection in the context of protecting the individual’s right to refuse medical treatment, see Comment, Artificial Nutrition and the Terminally Ill: How should Washington Decide?, 61 WASH. L. REV. 418 (1986).
choose, neither model adequately protects the patient’s dignitary interest.22 In attempting to fashion workable models, the courts have focused far too much attention on the narrow question of the physician’s duty to warn. Instead, courts should examine and emphasize the larger question of the physician’s obligation to communicate sufficient information to permit the patient to make an informed choice. Courts have lost sight of the importance of allowing individual patients to make their own decisions, a concept that lies at the core of every patient’s right to self-determination.23 Rather than emphasizing the individual’s right to choose, courts have adopted a highly deferential attitude towards the medical profession that permeates the entire field of informed consent.

A. Protecting the Patient’s Right to Choose: Current Models

In general, courts apply the doctrine of informed consent in cases that concern bodily invasive procedures such as surgery,24 exploratory diagnostic techniques,25 and radiation treatment.26 Courts apply either the medical-community or the objective-patient model to determine whether a patient gave an informed consent to one of these invasive procedures. Each model includes standards for determining the three essential doctrinal elements of informed consent: whether the physician had a duty to disclose; the scope of that duty (what procedure-specific information must be disclosed); and, if the duty was breached, whether the breach proximately

22. At least one court has observed that the objective-patient standard severely limits the protection granted an injured patient. Scott v. Bradford, 606 P.2d 554, 559 (Okla. 1979). The Scott court stated that “[t]o the extent the plaintiff, given an adequate disclosure, would have declined the proposed treatment, and a reasonable person in similar circumstances would have consented, a patient’s right of self-determination is irrevocably lost.” Id. (emphasis in original); see also McPherson v. Ellis, 305 N.C. 266, 273, 287 S.E.2d 892, 897–99 (1982) (the subjective standard allows consideration to be given to the particular quirks and idiosyncrasies of the individual); Katz, Informed Consent—A Fairy Tale?—Law’s Vision, 39 U. Pa. J. L. Rev. 137, 140, 163 (1977); Seidelson, Medical Malpractice: Informed Consent Cases in “Full Disclosure” Jurisdictions, 14 DUQ. L. Rev. 309, 319–20 (1976).

23. See supra notes 16, 21 and accompanying text.


caused the patient's injury (that is, whether the patient would not have consented to the procedure had adequate disclosure been made).

The medical-community model is the most widely accepted model for evaluating claims alleging the lack of informed consent. Under this model, courts use the practice of the local community of physicians as the standard for determining the existence and scope of the individual physician's duty to disclose.\(^\text{27}\) The patient has no right to know about therapeutic risks unless the medical community collectively has determined to disclose those risks.\(^\text{28}\) Physicians breach their duty to inform by failing to disclose the alternatives and risks that practitioners in the medical community would have disclosed.\(^\text{29}\) However, even when a breach occurs, patients must demonstrate that the failure to inform proximately caused their injuries. To do so the patient must prove that the hypothetical reasonable patient would not have agreed to take the drug had the physician made the required disclosure.\(^\text{30}\) Therefore, the proximate cause determination does not depend on what choice the particular patient would have made.\(^\text{31}\)

Although the proximate cause component of the medical-community model takes a more patient-oriented approach than the physician-oriented duty and scope components, courts that ignore the concerns and desires of the particular patient in favor of the hypothetical patient cannot effect the patient's right of self-determination and bodily integrity. In most cases, therapeutic preferences of hypothetical patients do not represent the unique concerns of particular, individual patients.\(^\text{32}\)

Because of the overly deferential aspects of the medical-community model, a significant number of jurisdictions have adopted the reasonable-patient perspective for evaluating the three components of the informed

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\(^{27}\) See supra note 8.

\(^{28}\) See Kaiser v. Suburban Transp. Sys., 65 Wn. 2d 461, 464, 398 P.2d 14, 16 (1965) (to determine what warnings are to be given with a prescription drug, a court should look to what the medical community usually discloses); Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093, 1106 (1960) ("The duty of the physician to disclose . . . is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances.").


\(^{30}\) See Canterbury v. Spence, 464 F.2d 772, 791 (D.C. Cir.) ("If adequate disclosure could reasonably be expected to have caused [a prudent person in the patient's position] to decline the treatment . . . causation is shown, but otherwise not."). cert. denied, 409 U.S. 1064 (1972). As to proximate cause, both the medical-community and objective-patient models apply the reasonable-patient standard. See infra notes 32, 42, and accompanying text.

\(^{31}\) See supra note 22.

\(^{32}\) The reasonable-patient approach has been criticized as "backtracking on . . . [the] theory of self-determination." Scott v. Bradford, 606 P.2d 554, 559 (Okla. 1979). The basic rights to know and to decide are the reasons for adopting a full-disclosure rule. Id.
The most notable adoption of an objective-patient model came in *Canterbury v. Spence*, where the court recognized the importance of protecting the patient's dignitary interest and attempted to develop its model accordingly. The objective-patient model developed out of courts' recognition that physicians, given their medical knowledge and perspective, tend to view the therapeutic choice with certainty. Typically, the physician can see only one reasonable course of therapy in a given situation, and therefore sees no need to discuss with the patient the possible alternatives and the potential risks.

Patient-oriented courts assume that if left with the freedom to choose, physicians would usually decide not to share the information necessary for patients to make their own therapeutic choices. This presumption of non-disclosure is another reason why patient-oriented courts reject the medical-community model in favor of the objective-patient model to informed consent doctrine. The court held that fundamental to American jurisprudence is the premise that "every human being of sound mind has a right to determine what shall be done with his own body." The court went on to define true consent as an informed exercise of choice that requires the patient to have knowledge of the risks of and alternatives to the proposed treatment.

The scope of the physician's duty to disclose was governed by an objective-patient standard in *Canterbury*. This standard requires the physician to disclose all information potentially affecting the patient's decision. With respect to scope of disclosure, the court did not want to place the burden on the physician to know what each particular patient would consider relevant; therefore, the physician was only required to disclose what the average, reasonable patient would consider material under the circumstances. As to proximate cause, *Canterbury* also adopted the objective-patient standard. Causation would be found only where a reasonable patient would have refused treatment had adequate disclosure been made. The court rationalized its adoption of an objective standard by reasoning that the adoption of a purely subjective patient standard would place the physician at the mercy of the patient's self-serving hindsight testimony.

The court observed that "[t]o the physician, whose training enables a self-satisfying evaluation, the answer may seem clear, but it is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie." Judge Robinson observed that:

"The reality of any discernible custom reflecting a professional concensus on communication of option and risk information to patients is open to serious doubt. We sense the danger that what in fact is no custom at all may be taken as an affirmative custom to maintain silence, and that physician-witnesses to the so-called custom may state merely their personal opinions as to what they or others would do under given conditions."
The patient’s rights of bodily integrity and self-determination require that the patient receive the information necessary to make an informed therapeutic decision. In order to guarantee that the patient receives the necessary information, patient-oriented courts have decided that the judiciary has the responsibility for determining when the duty to inform attaches, rather than allowing the community of physicians to make that determination.

Optimally, the duty to inform ought to require the physician to disclose therapeutic alternatives and risks and all other information that would be material to the particular patient’s opportunity to make an informed choice. This optimal standard is subjective, rather than objective, because it requires the disclosure of information significant to the particular patient’s decision. Nevertheless, the “reasonable patient” courts uniformly back away from the subjective individual-patient standard in order to protect the medical profession at the expense of individual patient’s rights of self-determination and bodily integrity.

Objective-patient model courts, like their medical-community model counterparts, reject a subjective-patient standard for determining proximate cause. Courts almost universally apply the objective-patient, proximate cause test in informed consent cases by requiring the trier of fact to answer the following question: Would a “reasonable” patient have consented to the medical procedure if the physician had made an adequate disclosure of the alternatives to and the risks associated with the proposed treatment? The objective-patient standard fails to protect the right of

37. Id. at 783–84.
38. The duty to disclose “is a duty imposed by law which governs [the physician’s] conduct in the same manner as others in a similar fiduciary relationship. To hold otherwise would permit the medical profession to determine its own responsibilities to the patients in a matter of considerable public interest.” Cooper v. Roberts, 220 Pa. Super. 260, 286 A.2d 647, 650 (1971) (quoting Berkey v. Anderson, 1 Cal. App. 3d 790, 82 Cal. Rptr. 67, 78 (1970)); see also Canterbury v. Spence, 464 F.2d 772, 784 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972) (“Respect for the patient’s right of self-determination on particular therapy, demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves.”) (footnotes omitted).
39. See, e.g., Canterbury, 464 F.2d at 787 (“Optimally for the patient, disclosure of a risk would be mandatory whenever the patient would deem it significant to his decision.”); Cooper v. Roberts, 220 Pa. Super. 260, 286 A.2d 647, 650 (1971) (primary interest of informed consent is that of “having the patient informed of all the material facts from which he can make an intelligent choice as to his course of treatment, regardless of whether he in fact chooses rationally”).
41. Canterbury, 464 F.2d at 787 (determining that a subjective standard of disclosure would unfairly require the physician to “second-guess” the patient, “whose ideas on materiality could hardly be known to the physician”); Cooper v. Roberts, 220 Pa. Super 260, 286 A.2d 647, 650 (1970) (subjective standard would require physicians to be mindreaders). But see infra notes 65–70, 76 and accompanying text.
"subjective" patients to make their own therapeutic choices. Nevertheless, of the currently available informed consent models, the objective-patient model is preferable. It effects a more thoughtful and thorough doctrine of informed consent that expressly recognizes the need to protect the patient’s rights of bodily integrity and self-determination. Courts that have adopted the objective-patient model have recognized, at least implicitly, that patient idiosyncrasies affect a patient’s ability to make an informed choice.

However, in backing away from a subjective-patient standard for determining proximate cause, courts have compromised the rights of individual patients. Both of the currently available informed consent models deny patients the opportunity to hold their own peculiar values and to make their own informed choices. This almost universal failure by the courts to protect the patient’s dignity arises out of the automatic deference courts assign to judgments made by the medical profession. Unless courts recognize and evaluate the underlying causes of this automatic deferential response to medical authorities, which is incompatible with the concept of

42. See supra notes 22, 32 and accompanying text; infra note 70 and accompanying text.
43. McClellan, Informed Consent to Medical Therapy and Experimentation, 3 J. LEGAL MED. 81, 103 (1982). Professor McClellan views the Canterbury approach, see supra note 35, as the best accommodation between concerns for human integrity and respect for professional expertise. Id. Much of the criticism of Canterbury misses the point because it focuses on a single value or goal. Id. The Canterbury approach views the problem systematically and comprehensively in light of fundamental values and practicalities. Id.
44. See supra notes 38–40 and accompanying text.
45. In Canterbury, the court explained its refusal to adopt a subjective-patient standard by observing that:
when causality is explored . . . with a professedly uninformed patient, the question whether he actually would have turned the treatment down if he had known the risks is purely hypothetical . . . And the answer . . . hardly represents more than a guess, perhaps tinged by the circumstance that the uncommunicated hazard has in fact materialized. Canterbury, 464 F.2d at 790 (footnotes omitted). For a discussion of the physician’s duty to communicate in a subjective-patient model, see infra notes 266–68 and accompanying text. But see infra note 90.
46. Violations of a person’s dignitary interest necessarily involve an interference with the right to self-determination. J. Katz, supra note 5, at 79. Dignitary interest violations are not limited to those involving physical harm; lack of informed consent is itself a violation. “The additional presence of physical harm only adds injury to insult.” Id. In Canterbury, the court accepted the traditional requirement that the undisclosed risk must materialize for liability to attach. 464 F.2d at 790. By failing to attach legal consequence to the unpardonable omission, however, the court severely limits protection of the dignitary interest. Courts do not have to infringe patients’ dignitary interests in order to preserve the traditional requirement that risks must materialize before a claim is actionable. Courts could strike a fairer balance between protection of patients’ dignitary interests and the preservation of the traditional tort scheme by maintaining physical injury as an element of plaintiff’s claim in order to protect physicians from harassment suits, see infra notes 90, 274–80 and accompanying text, but at the same time recognize the needs and interests of the particular, subjective patient in shaping the duty, scope, and proximate cause standards. See infra notes 264–81 and accompanying text.
patient self-determination, there is little prospect that the patient's digni-
tary interest can be effectively protected.

B. Deference to the Medical Community

Judicial deference to the medical profession is endemic in the entire field
of informed consent.\textsuperscript{47} Considering that courts have little difficulty impos-
ing legal standards upon other professions and specialist groups,\textsuperscript{48} it is
remarkable that they are so willing to have the medical profession deter-
mine for itself the existence and scope of the duty to disclose information to
patients.\textsuperscript{49} To examine the judicial response to informed consent in pre-
scription drug cases, one must understand why courts defer to the medical
profession generally.

There are four general reasons why courts defer to the medical profession:
(1) lack of understanding of the knowledge and practice of medicine, which
creates a judicial fear of destroying the physician-patient relationship; (2) a
belief shared with society at large that physicians know what is best for their
patients; (3) a belief that physicians already tell patients all that patients need
to know; and (4) reluctance to interfere with the application of an esoteric
body of knowledge. While these reasons interact at different times and
manifest themselves in various forms in both of the existing informed
consent models, each reason for judicial deference must be examined
individually in order to understand its full impact on the judiciary.

It appears that judges believe that they lack familiarity with and under-
standing of the practice of medicine and its concomitant body of knowl-
edge.\textsuperscript{50} Consequently, courts are reluctant to impose legal standards that
would pose unique and difficult questions regarding medical practice.\textsuperscript{51}
Instead, judges have based the legal standard for physicians' behavior on

\textsuperscript{47} J. KATZ, supra note 5, at 49, 82–84; S. SAGOV, THE ACTIVE PATIENT'S GUIDE TO BETTER
MEDICAL CARE 125 (1976); Comment, Informed Consent: From Disclosure to Patient Participation in
Medical Decisionmaking, 76 NW. U.L. REV. 172, 176 (1981). See generally Shapiro, Limiting Physi-
cian Freedom to Prescribe a Drug For Any Purpose: The Need for F.D.A. Regulation, 73 NW. U.L.

\textsuperscript{48} See McClellan, supra note 43, at 94–95.

\textsuperscript{49} See supra notes 8, 28, and accompanying text; infra notes 61–63 and accompanying text; see

\textsuperscript{50} See, e.g., Frankfurter, A Lawyer's Dicta on Doctors, The George W. Gay Lecture upon
Medical Ethics at Harvard Medical School, HARV. MED. ALUMNI BULL. 12, 17 (July 1958) (“I am not
competent to have any views on the very difficult problem of the relations between the medical
profession and society.”).

\textsuperscript{51} J. KATZ, supra note 5, at 82 (“What are the risks and benefits of the proposed treatment and of
no treatment? Which ones did physicians have to be aware of? How much are they required to know
about them? Which ones are they required to disclose?”).
actual medical practices, rather than on a judicially derived theory.\textsuperscript{52} It is generally recognized that the majority of patients tend to exhibit a deferential attitude toward their physicians.\textsuperscript{53}

Judges may also believe, like much of the rest of society, that doctors know better than patients what is good for them.\textsuperscript{54} Apparently, courts fear that patients are incapable of participating in medical decisionmaking.\textsuperscript{55} Courts also fear that imposing changes on the traditional physician-patient relationship will interfere with patients' unquestioned faith in their doctors,

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\item \textsuperscript{52} Id. at 69; see also Katz, supra note 22, at 140; McClellan, supra note 43, at 95.
\item \textsuperscript{53} T. Preston, supra note 49, at 66–67 (physician-patient relationship is similar to that of parent-child, where the child-like patient does what the physician says with few avenues for appeal). But see 2 President's Commission, supra note 5, at 140 table 4-7 (only 38% of the public believes the physician has the right to withhold information if it might make the patient unwilling to undergo the treatment); id. at 239 table 8-1 (43% of the public wants the final decision to be up to them; 38% want the final decision to rest with the physician); Roter, Physician-Patient Communication: Transmission of Information and Patient Effects, 32 Md. St. Med. J. 260, 260 (1983). For discussion of "paternalism", see J. Katz, supra note 5, at 27 (doctors feel patients lack the capacity to make final decisions); Katz, supra note 22, at 140; Comment, Warnings and the Pharmaceutical Companies: Legal Status of the Package Insert, 16 Hous. L. Rev. 140, 163 (1978) (physician views the patient as a sick child).
\item \textsuperscript{55} See Katz, supra note 22, at 148 (doctors believe patients are not emotionally equipped to make final decisions and judges will not intrude); see also J. Katz, supra note 5, at 59 (concern for protecting patient's best interests prevailed over protecting patient's rights of self-determination and liberty); 2 President's Commission, supra note 5, at 137 table 4-4 (only 17% of physicians think all their patients want a candid disclosure). In the court's view, doctors know what the patients' best interests are better than the patients do. But cf. id. at 136 table 4-3 (94% of the public wants to know everything about their medical condition even if it is unfavorable); Andrews, Informed Consent Statutes and the Decision-making Process, 5 J. Legal Med. 163, 171, 178 (1984) (doctors misjudge patients' ability to understand); Roter, supra note 53, at 260 (doctors underestimate patients' knowledge).
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In the prescription drug context, the courts have created a legal role for the physician vis-a-vis the patient and the drug manufacturer. See Łukaszewicz v. Ortho Pharmaceutical Corp., 510 F. Supp. 961, 963 (E.D. Wis. 1981). American courts universally hold that in the case of prescription drugs, the manufacturer's duty to warn is satisfied by proper warnings to a physician because the patient cannot obtain the drug except through the physician.\textsuperscript{56} Id. This implies that the physician is sufficiently knowledgeable about pharmacology to play his part as the learned intermediary between patient and manufacturer. See Dixon, Drug Product Liability: Information for Safety, Trial, November 1980, at 62, 65–66; Pruzan, Prescription Drug Liability in the Context of Washington Law, 9 Gonz. L. Rev. 707, 718 (1974); Rheingold, Products Liability—The Ethical Drug Manufacturer's Liability, 18 Rutgers L. Rev. 947, 987 (1964); Note, Tort: Unavoidably Unsafe Drugs—An Oklahoma Modification, 20 Okla. L. Rev. 252, 256 (1976).

While it has been argued that physicians have a duty to educate themselves about the pharmacology of drugs, and the courts base the physician's learned intermediary role on the assumption that physicians in fact have pharmacological expertise and knowledge about particular drugs, there is evidence that physicians are not sufficiently knowledgeable about either pharmacology in general or particular drugs. See, e.g., R. Mendelsohn, supra note 5, at 65 (doctors prescribe tranquilizers freely, but as one study of Librium demonstrated, half of the doctors asked to identify the active ingredient could not do so).

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\end{footnotesize}
which will undermine the prospects for a cure. Thus, judicial deference indicates that judges fear that a legal standard will unduly affect, and perhaps destroy, the practice of medicine as it currently exists.

Judges tend to believe that their legal rulings on informed consent simply condone the usual behavior of physicians, in effect creating a presumption of due care. Because of this belief, courts assume that physicians, as part of providing due care, ordinarily disclose facts sufficient for informed consent. Therefore, courts set the standard of disclosure by reference to the "reasonable medical practitioner." The judicial faith in physicians' willingness and desire to disclose and share aspects of decisionmaking with patients results from courts' failure to understand the tradition of physician autonomy and noncommunication.

Finally, courts have now developed a tradition of judicial deference, even powerlessness, vis-a-vis the medical profession. This traditional attitude is founded, in part, on an early belief that the responsibility for protecting patients from medical misadventure lay within the province of legislatures and enlightened public opinion. Modern courts have continued this deferential tradition by their reluctance to impose legal demands upon medical judgment when such demands intrude into areas believed to be "solely the province of medicine." Judicial reluctance to "interfere" in the practice of medicine may originate in a recognition that "[a]ll professions possess esoteric knowledge that, in its totality, is difficult to learn,

56. J. Katz, supra note 5, at 71. A significant number of physicians believe that by "'[filling] a patient with uncertainties, [torturing] them with potentialities, however remote,'" a physician "endangers patients' mental and physical life and 'destroys good patient care.'" Id. at 27 (footnotes omitted); see also R. Burt, Taking Care of Strangers 102-05 (1979).

57. See J. Katz, supra note 5, at xv; 2 President's Commission, supra note 5, at 200 table 6-8 (physicians feel they have duty to persuade); Meisel & Roth, What We Do and Do Not Know About Informed Consent, 246 J. A.M.A 2473, 2476 (1981) (no conclusive studies have been made on whether giving patients full disclosure will discourage them from consenting to the treatment); see also ZeBarth v. Swedish Hosp. Medical Center, 81 Wn. 2d 12, 499 P.2d 1 (1972), overruled, Miller v. Kennedy, 85 Wn. 2d 151, 530 P.2d 334 (1975) (per curiam).

58. See, e.g., Finley v. United States, 314 F. Supp. 905, 911 (N.D. Ohio 1970). The court found that a presumption of negligence does not arise from the fact that a bad or unexpected result occurs. In fact, the court held that there is a presumption of due care that the injured party must overcome. Id.

59. See, e.g., Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093, 1106 (1960). The Kline court stated:

So long as the disclosure is sufficient to assure an informed consent, the physician's choice of plausible courses should not be called into question if it appears, all circumstances considered, that the physician was motivated only by the patient's best therapeutic interests and he proceeded as competent medical men would have done in a similar situation.

Id. See also J. Katz, supra note 5, at 2-3.

60. J. Katz, supra note 5, at 3. It is not surprising that defendant physicians in prescription drug cases argue that they do not have a duty to communicate with the patient. See, e.g., Sharpe v. Pugh, 277 N.C. 598, 155 S.E.2d 108 (1967); Boyer v. Smith, No. 80-12190-6, slip op. at 5 (C.P. Bucks County, Pa., Jan. 28, 1985), aff'd, 497 A.2d 646 (Pa. Super. 1985).

61. J. Katz, supra note 5, at 36; Frankfurter, supra note 50, at 177.

understand, and master” and that “the complexity of professional knowl-
dge commands the laity to listen carefully to experts.” Courts then seem
to conclude that only experts within the profession, the persons who have
learned, understood, and mastered the esoteric knowledge, can determine
appropriate standards for the behavior of the profession.

Of the available models of informed consent, the medical-community
model represents the extreme of deference to the medical profession. In
using the practice of the community of physicians to determine both the
existence and the scope of the duty to communicate with patients, courts
ignore the vital role of the patient. Instead, courts make a variety of
assumptions, all tending toward the conclusion that patients are not capable
of participating in therapy decisionmaking and that the physician, the only
party that understands the choices, should unilaterally determine the cor-
rect therapy.64

While those assumptions have some logical appeal, it is not necessarily
accurate to infer, as this approach does, that professional knowledge
“cannot be communicated to, or understood by, patients.” Nor should
one conclude that because professionals have mastered this esoteric knowl-
dge, they should unilaterally decide how to proceed without consulting
patients, especially when alternatives exist and the success of treatment is
uncertain.65

For whatever reason, courts, even those adopting the objective-patient
model, seem to have concluded, with almost dogmatic determination, that
effective communication between physicians and patients is not possible.66
As a result, regardless of which model is employed, courts do not impose a
duty of full communication on physicians, which is to the detriment of

63. Id. at 92.
64. See Watkins v. United States, 482 F. Supp. 1006, 1012 (M.D. Tenn. 1980) (physician has duty
to use own best judgment in treating the patient); Finley v. United States, 314 F. Supp. 905, 914 (N.D.
Ohio 1970) (medical questions are a technical and specialized subject matter and require medical
experts to set the standards). Doctors believe that patients are better protected if they trust their doctors'
authority and have confidence in the medical community's altruistic dedication. J. Katz, supra note 5,
at 91.
66. J. Katz, supra note 5, at 92. In order to safeguard the autonomy of both parties, medical
decisionmaking must become a joint undertaking. Professor Katz believes that the complexity of
professional knowledge requires the laity to listen carefully to experts. He does not suggest, however,
that physicians cannot communicate with individual patients or make them understand. According to
Katz, physicians cannot dispute patients' ability to understand because the medical community has had
too little experience communicating their esoteric knowledge. Id.
67. See, e.g., Canterbury v. Spence, 464 F.2d 772, 787 (D.C. Cir.) (physicians cannot know with
complete certainty what particular patients would consider important to their decisions), cert. denied,
68. Id. at 787 (physicians, using their “medical training and experience . . . can sense how the
average, reasonable patient expectably would react”) (footnote omitted).
the particular patient, who has needs, priorities, and preferences different from those of the "reasonable" patient. Of course, in reality, the physician can ask patients about their needs and explain carefully every alternative to the proposed therapy, including no therapy, as well as the risks associated with each alternative. In this manner the physician can come to understand with reasonable certainty the facts material to the particular patient's decision to choose one therapy from various alternatives, including the one recommended by the physician.

Thus, the objective-patient model of informed consent manifests a high level of deference, although much less than that of the medical-community model. The objective-patient model moves away from deference by recognizing patients' rights of bodily integrity and self-determination. But while an objective-patient standard initially seems to protect patient rights, courts using this model ultimately defer to the medical profession. In *Canterbury v. Spence*, the court gave two reasons for applying an objective standard to the scope of the duty to disclose in the general informed consent context: physicians cannot know individual patients well enough to determine what information is material to their personal choices; and the scope of the duty to inform ought, in fairness, to be controlled by an objective rather than a subjective standard. In effect, these courts balance the individual patient's rights of bodily integrity and self-determination against a judicial interest in treating physicians fairly.

69. Scott v. Bradford, 606 P.2d 554, 559 (Okla. 1979) ("To the extent the plaintiff, given an adequate disclosure, would have declined the proposed treatment, and a reasonable person in similar circumstances would have consented, a patient's right of self-determination is irrevocably lost.") (emphasis in original); J. Katz, supra note 5, at 76 ("The belief that there is one 'reasonable' or 'prudent' response to every situation inviting medical intervention is nonsense, from the point of view of both the physician and the patient."); see also Comment, Informed Consent in Medical Malpractice, 55 Calif. L. Rev. 1396 (1967) (suggesting that there must be standards imposed by courts because each patient is mentally and emotionally unique).

70. J. Katz, supra note 5, at 78.

71. See supra note 34 and accompanying text.

72. 464 F.2d 772, 787 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972). The scope of disclosure must be objective because physicians cannot possibly know what the patient considers important, and therefore, physicians need leeway in their decisionmaking. Id.; see also Cooper v. Roberts, 220 Pa. Super. 260, 286 A.2d 647, 650 (1971). Courts adopting the objective model believe that holding physicians to a subjective standard of disclosure would be placing upon them an unreasonable burden; it would require them to be mind-readers. Cooper, 286 A.2d at 650–51. According to these courts, the subjective-patient standard "places the physician in jeopardy of the patient's hindsight and bitterness." Canterbury, 464 F.2d at 790–91. The patient's testimony would be tinged with bitterness given the fact that the uncommunicated hazard has materialized. Id. at 790; see also supra note 45, infra notes 272–74, and accompanying text. But see infra note 90.

73. See Canterbury, 464 F.2d at 787; Cooper v. Roberts, 220 Pa. Super. 260, 286 A.2d 647, 650 (1971). Courts adopting the objective model believe that holding physicians to a subjective standard of disclosure would be placing upon them an unreasonable burden; it would require them to be mind-readers. Cooper, 286 A.2d at 650–51. According to these courts, the subjective-patient standard "places the physician in jeopardy of the patient's hindsight and bitterness." Canterbury, 464 F.2d at 790–91. The patient's testimony would be tinged with bitterness given the fact that the uncommunicated hazard has materialized. Id. at 790; see also supra note 45, infra notes 272–74, and accompanying text. But see infra note 90.

74. The objective-patient standard gives "due regard [to] the patient's informational needs and [provides] suitable leeway for the physician's situation." Canterbury, 464 F.2d at 787.
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There are two major problems with this rationale. First, the courts erode a traditional common law right by balancing it against physician interests, which have no basis in the common law or in any other clearly delineated right. Secondly, courts assume that physicians cannot know what their patients think, and that physicians' conduct can be measured fairly only by an objective reasonableness standard. Both assumptions are questionable.

The assumption that physicians cannot know what information would be material to a particular patient's therapeutic choices is unjustified. Often, physicians do not know because they choose not to know. In Canterbury, the leading objective-model case, the court assumed that physicians cannot know "with complete exactitude" what is significant to particular patients. Yet the Canterbury court also recognized that because of their medical knowledge, physicians tend to see only one viable therapeutic choice in a particular situation. What the court did not consider, however, is that this medical preference strongly inhibits physicians from recognizing any necessity to communicate information to patients to facilitate a choice from among various therapeutic alternatives.

Courts' insistence on measuring the conduct of the prescribing physician by a reasonableness standard does not necessarily require that an objective...
patient standard be applied to the scope of the physician's duty to disclose.\textsuperscript{81} Apparently courts confuse the objective reasonableness standard, which a judge could instruct a jury to use in determining whether a defendant physician breached the duty to inform (did the physician make a reasonable attempt to communicate with the particular patient?), with whether it is reasonable (in the sense of fairness) to require a physician to communicate with the particular patient in order to learn the patient's subjective needs.

Courts put forth two reasons for asserting that it is unfair to require physicians to communicate effectively with individual patients. First, courts believe that it is impossible for one person to know what another person really thinks or feels.\textsuperscript{82} Much responsible medical opinion, however, disagrees strongly with the courts in this regard, maintaining that physicians can communicate, just as any other person can, but that they deliberately choose not to communicate.\textsuperscript{83} The second reason, although less clearly articulated, may be more significant: courts feel that imposing time-consuming legal requirements on the medical profession would unfairly interfere with physicians' busy practices.\textsuperscript{84}

Despite these reasons, it does not seem unfair to require a professional, who is providing a critical personal service, to take the time necessary to make that service as effective and satisfying to each individual patient as possible.\textsuperscript{85} By focusing on fairness to the physician, rather than on therapeutic effectiveness, courts misplace their concern for the relative rights of the parties. Even if a duty to communicate results in some unfairness to the physician, the burden is outweighed by the infringement of an individual's rights of bodily integrity and self-determination that results when courts fail to establish a legal, patient-oriented duty to communicate.\textsuperscript{86}

\textsuperscript{81} See infra notes 251–52 and accompanying text.

\textsuperscript{82} See supra notes 72–73.

\textsuperscript{83} See supra notes 77–78.


\textsuperscript{85} This requirement does not seem unfair for three reasons. First, the requirement to communicate is not onerous. Physicians need not try to second-guess their patients. Instead, they can, and must, improve their communication skills and inquire into their patients' particular concerns. I. Katz, supra note 5, at 78. Second, patients who are not adequately informed tend to do poorly afterwards when compared to patients who received adequate information. See infra notes 120–21, 254. Finally, increased communication leads to increased patient satisfaction which, in turn, leads to less litigation. See infra notes 253, 265.

\textsuperscript{86} See supra note 75 and accompanying text.
Courts universally apply the objective-patient standard to determine proximate cause. In considering whether the patient would have consented to the proposed therapy had the physician given the patient adequate information, courts generally fear that the "hindsight" testimony of an injured and perhaps embittered plaintiff would be unfair to the physician.

In addition, the *Canterbury* court believed that hindsight testimony would force the jury to determine a critical issue on the basis of a speculative answer to a hypothetical question. Despite this suspicion of hindsight testimony, some jurisdictions admit plaintiff's testimony on this issue, even though they determine proximate cause by whether a reasonable patient would have consented to the therapy had the physician provided adequate information about it.

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87. See *supra* notes 32, 40-42 and accompanying text.
88. See, e.g., *Canterbury*, 464 F.2d at 790-91; see also *supra* notes 45, 73 and accompanying text; *infra* notes 90, 272, and accompanying text.
89. *Canterbury*, 464 F.2d at 791. See *infra* notes 90, 272 and accompanying text.
90. Whether courts adopt a subjective or objective standard, plaintiffs' testimony regarding causation is suspect from an evidentiary point of view. See discussion of proximate cause, *infra* notes 269-82 and accompanying text.

Some commentators, as well as the majority of jurisdictions, rely on evidentiary problems to argue for the objective standard, asserting that the subjective standard would encourage self-serving hindsight testimony. See, e.g., *Liability of Health-Care Providers—Informed Consent—Physician's Duty to Disclose*, 7 *Am. J. Law & Med.* 38, 40 (1981). When the causation issue is explored at the trial with a professedly uninformed patient, whether the patient would actually have turned down the treatment if the risks were known is purely hypothetical, and the answer supplied by the patient hardly represents more than a guess, which places the physician in jeopardy of the patient's hindsight and bitterness. *Canterbury*, 464 F.2d at 90-91. One commentator argues that the subjective standard puts the fact finder in the position of deciding whether to credit a speculative answer to a hypothetical question. Seidelson, *supra* note 22, at 331; see *Niblack v. United States*, 438 F. Supp. 383, 389 (D. Colo. 1977) (subjective testimony is regarded with skepticism); Hamilton v. Hardy, 37 Colo. App. 375, 549 P.2d 1099, 1105 (1976) (subjective testimony would be, at best, self-serving and speculative); LeBlang, *Informed Consent—Duty and Causation: A Survey of Current Developments*, 18 *The Forum* 280, 287 (1982) (the objective standard protects the physician from patient bitterness).

Nonetheless, other courts besides *Canterbury* allow such testimony, and commentators support its admission. See, e.g., *Scott v. Bradford*, 606 P.2d 554, 559 (Okla. 1979) (careful practitioners can always protect themselves by insuring that each patient is adequately informed and testimony by the patient gives jurors the opportunity to evaluate the evidence and weigh the credibility of all witnesses); see also Note, *Medical Malpractice: A Subjective Approach to Informed Consent in Oklahoma*, 15 *Tulsa L.J.* 665 (1980).

Subjective testimony should be allowed in informed consent cases as a part of the totality of evidence, even though it is self-serving. *Holt v. Nelson*, 11 Wn. App. 230, 236, 523 P.2d 211, 216 (1974). The jury will recognize the self-interest underlying the plaintiff's testimony and the defense will emphasize such self-interest as a critical factor to be considered by the jury in determining the plaintiff's credibility and the weight to be given to subjective testimony. Seidelson, *supra* note 22, at 330-31.

Courts adopting the objective model argue that allowing the patient to testify gives the jury an opportunity to compare the testimony with their belief in its reasonableness, thereby strengthening the case for a wholly objective causation standard. *Canterbury*, 464 F.2d at 791.
Judicial deference to the medical profession is most striking in the prescription drug context, where courts almost universally apply the medical-community model. In deferring to the interests of the medical profession, courts ignore the essential factors that operate in the prescription drug context. By ignoring these factors, courts invariably reject the subjective-patient model. This in turn reinforces physicians' narrow view of what needs to be disclosed and denies patients information most significant to them personally. Ultimately, the failure to adopt a subjective standard and the unwarranted deference to the medical profession results in a failure to protect the patient's right of bodily integrity and self-determination. These rights are fundamental in Anglo-American law. If courts examined closely all of the important considerations permeating prescription drug therapy, it is difficult to imagine that they would allow the mere possibility of a slight economic infringement on the practice of medicine to infringe on these fundamental rights.

II. PRESCRIPTION DRUG THERAPY: THE SPECIAL FACTORS

A variety of factors either are unique to the prescription drug setting or are more prevalent and play a significantly greater role for informed consent in prescription drug therapy than for informed consent to bodily invasive procedures. While some obvious interrelationships exist between many of these factors, each can be regarded as a distinctive aspect of prescription drug therapy. Courts should recognize and consider these factors in applying the informed consent doctrine in prescription drug cases. Too often courts fail to recognize that these factors are at work or, when recognition occurs, courts disregard the actual effect these factors have in the situation at hand.

The failure to take account of these factors affects the patient's ability to make an informed therapeutic choice and leads to the continuation of unwarranted judicial deference to the medical community. Although each special factor has relevance to both courts' attitudes toward informed

91. See infra notes 153–58 and accompanying text.
92. See infra notes 96–152, 162–230 and accompanying text.
93. J. Katz, supra note 5, at 76 (arguing that it is nonsensical to believe that there is a single "reasonable" or "prudent" person response to every medical situation).
94. See infra notes 96–161 and accompanying text.
95. See infra notes 162–233 and accompanying text. Although state legislatures do not appear to have responded specifically to the prescription drug situation, lawmakers do seem to defer to the medical profession's complaints to the detriment of patients' rights and needs. See Andrews, supra note 55, at 179. Not only is inadequate attention paid to state informed consent requirements, they are not enforced. Id.; see 2 President's Commission, supra note 5, at 176 table 5-13 (an average of 76% of physicians do not know applicable informed consent standards in their state).
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consent in the prescription drug context and to the patient's decision-making process, it is helpful to divide them into two groups. First, factors such as the pervasiveness of prescription drug use, the tendency of physicians to overprescribe these drugs, and the narrow limits of physicians' pharmacological knowledge have been almost universally ignored under the medical-community model. Second, factors, such as the way in which personal idiosyncrasies are relevant to the choice of therapy, must be understood by patients in order to make an informed choice. Patients also need to know the range of treatment alternatives and to understand the risks of side effects in order to participate in the constant monitoring required during prescription drug therapy.

A. Factors That Should Limit Judicial Deference to the Medical Profession in the Prescription Drug Context

1. The Pervasiveness of Prescription Drugs

Prescription drugs are the most common treatment of all medical therapy. Ninety million Americans are estimated to take some drug each week, with the result that the United States has become a "pill-swallowing civilization." Although completely reliable statistical studies are not available regarding side effects associated with prescription drugs, available evidence, as well as reliable expert opinion, indicates that as many as 30,000 Americans die each year from an adverse drug reaction. While no

96. I President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Making Health Care Decisions 121 (1982) [hereinafter cited as I President's Commission] ("[D]rugs are the most common treatment in all medical care. Most visits to the doctor result in a prescription being written . . . "); see also R. Mendelsohn, supra note 5, at 197 (author estimates that one billion prescriptions are written in the United States every year); Wartman, Do Prescriptions Adversely Affect Doctor-Patient Interactions?, 71 Am. J. Pub. Health 1358, 1358 (1981) (prescriptions often result from the assumption that such therapy is a concrete, definable action that should be the natural outcome of the medical care visit). Overuse of drugs is epidemic because patients and clinicians rely on drugs to take care of almost all conceivable problems, most of which do not respond to pharmacologic solutions. T. Preston, supra note 49, at 133. The overriding necessity of clinical physicians is to do something. It would be very unusual for a patient to leave after a visit to the doctor without some action having been taken. Id. at 146; see also H. Lennard, L. Epstein, A. Bernstein & D. Ranson, Mystification and Drug Misuse 18-23, 25-27, 32 (1971) [hereinafter cited as H. Lennard] (describing drug use and mystification in doctor-patient relationships generally); Koch-Weser, Fatal Reactions to Drug Therapy, 291 New Eng. J. Med. 302, 303 (1974) (adverse drug effects commonly due to inappropriate pharmacology).


99. R. Mendelsohn, Confessions of a Medical Heretic 26, 39 (1979) (20,000 to 30,000 deaths
statistics exist as to the exact number of adverse reactions each year, there is little doubt that the number is in the hundred thousands. Concern about excessive use, numerous adverse reactions, and a high percentage of addiction to prescription drugs has led some medical experts to conclude that more than half of all drug prescriptions should not be written.

2. The Tendency to Overprescribe Drugs

Modern technology has made possible a large number of prescription drugs. A large body of opinion in the medical literature indicates that rapid technological development has caused the clinical practice of medicine to become overly technical, resulting in the tendency of physicians to overprescribe drugs. Aside from increased deaths and other serious yearly are attributed to adverse reactions to drugs prescribed by doctors—there is no safe drug). See also R. Mendelsohn, supra note 5, at 60–62, 74; J. Stein, Making Medical Choices 86 (1978); Koch-Weser, supra note 97, at 302 (University of Florida study found that 177 (2.9%) of 6063 patients were admitted because of drug-induced illness and that eleven of these died before discharge).

100. T. Preston, supra note 49, at 133 (drug reactions or complications are responsible for 5% of all hospital admissions in the United States, or as many as 1,500,000 persons per year, which may represent just a small part of those harmed by drugs); see also R. Mendelsohn, supra note 99, at 26.

In 1976, doctors wrote twenty-seven million prescriptions for sleeping pills—one billion doses in all. These prescriptions resulted in about 25,000 “harrowing” trips to hospital emergency rooms, including 5,000 deaths. R. Mendelsohn, supra note 5, at 60–61. Valium alone produces about 50,000 patients per year for hospital emergency rooms. Id. See generally H. Lennard, supra note 96, at 32–35. Not all adverse side effects result in death or serious injury, but most are potentially dangerous enough to warrant concern. Taken over a period of time, many drugs have nutritional side effects. Many drugs cause a loss of appetite. Antacids can lead to phosphate and vitamin D deficiencies. The oral contraceptive is especially dangerous because it usually is taken for a long period of time and can cause vitamin B, B6, and C depletions. See Roe, Drugs, Diet and Nutrition, Contemp. Nutrition, June 1978, at 2.

101. T. Preston, supra note 49, at 133–34. It has been suggested that a large part of the excessive use of prescription drugs can be attributed to physicians’ psychological need to maintain control of treatment by appearing to have the certain solution to the medical problem. H. Lennard, supra note 96, at 27, 34; see also supra notes 56, 80 and accompanying text; infra note 150 and accompanying text.

102. See S. Klaw, The Great American Medicine Show 23 (1975). The pharmaceutical industry offers the public more and more over-the-counter drugs for every conceivable human condition and continues to reinforce the erroneous redefinition of all human problems as medical ones. Id. “An inordinate number of this year’s drugs were developed to cure the damage caused by a miracle drug that was proudly announced in some previous year. Repeatedly, new drugs are sold to counter the symptoms produced by others.” R. Mendelsohn, supra note 5, at 58. The pharmaceutical industry and the medical profession maintain a very close relationship, so that it is in both groups’ interest to maintain large numbers of persons on drugs and to define more and more problems as medical in order to justify intervening with drugs. Id. at 62–63; see also supra note 96.

adverse reactions resulting directly from the overprescription of drugs,104 bacteria have developed immunities to overused antibiotics, which indirectly causes additional deaths and injuries.105

Physicians often prescribe drugs for patients who have no disease at all or who have only minor or nonemergency conditions.106 Drugs with serious side effects are regularly prescribed for patients complaining of adolescent acne, wrinkled skin, or skin rash.107 The oral contraceptive is perhaps the most well-known example of a prescription drug that has major risks of serious side effects, but is nonetheless regularly prescribed for and used by healthy patients.108 Moreover, physicians prescribe drugs too often

104. See supra notes 100–02 and accompanying text; see also R. MENDELSOHN, supra note 5, at 15.
105. S. KLAU, supra note 102, at 25.
106. 1 PRESIDENT'S COMMISSION, supra note 96, at 42 (insomnia); H. LENNARD, supra note 96, at 18–23 (anxiety); R. MENDELSOHN, supra note 5, at 60, 61, 67 (nerves); R. MENDELSOHN, supra note 100, at 27 (prednisone is prescribed for minor skin rashes, yet can damage the reproductive system); T. PRESTON, supra note 49, at 21.
107. R. MENDELSOHN, supra note 99, at 27; T. PRESTON, supra note 49, at 131. The application of drugs to the solution of primarily nonmedical problems was demonstrated in a report that concluded that 5–10% of the 62,000 school children in Omaha were described as being generally hyperactive and were being given behavior modification drugs. H. LENNARD, supra note 96, at 31. The drugs were distributed to thousands of children, apparently in disregard of Food and Drug Administration warnings that the prescribed drugs were addictive and should be used with extreme caution. Id.
108. M. MINTZ, THE PILL 11 (1970). Recent decisions in oral contraceptive cases raise important questions regarding the application of the informed consent doctrine to the prescription drug context. Two jurisdictions have held that manufacturers of oral contraceptives can no longer fulfill their duty to warn merely by providing physicians with information about side effects. Both courts held that manufacturers of oral contraceptives now must warn users directly of the risks. Lukaszewicz v. Ortho Pharmaceutical Corp., 510 F. Supp. 961, 965 (E.D. Wis. 1981); MacDonald v. Ortho Pharmaceutical Corp., 394 Mass. 131, 475 N.E.2d 65, 69, cert. denied, 106 S. Ct. 250 (1985). Both courts recognize that the general rule with prescription drugs is that the physician acts as a learned intermediary and that the manufacturer satisfies its duty to warn by providing proper warnings to the physician because the patient cannot obtain the drug except through the physician. Lukaszewicz, 510 F. Supp. at 963. However, the courts in both Lukaszewicz and MacDonald held that because of the peculiarities of the oral contraceptive, the manufacturer must warn the ultimate user of the side effects directly. The MacDonald court explained its holding as follows:

The oral contraceptive thus stands apart from other prescription drugs in light of the heightened participation of patients in decisions relating to use of "the pill"; the substantial risks affiliated with the product's use; the feasibility of direct warnings by the manufacturer to the user; the limited participation of the physician (annual prescriptions); and the possibility that oral communications between physicians and consumers may be insufficient or too scanty standing alone fully to apprise consumers of the product's dangers at the time the initial selection of a contraceptive method is made as well as at subsequent points when alternative methods may be considered. MacDonald, 475 N.E.2d at 70.

To the extent that Lukaszewicz and MacDonald eliminate the role of the physician as the learned intermediary, they raise several issues regarding patients' rights protected by the doctrine of informed consent. Both courts appear to assume that the only significant concern involving oral contraceptives is the risk of side effects inherent in their use. The courts minimize the essential role of the prescribing physician in informing patients about and discussing with them alternative forms of contraception,
for a purpose for which they were never intended. They are never intended to be used for purposes other than those for which they were designed. The most prevalent example of this questionable practice is the use of oral contraceptives to control breakthrough bleeding and irregular menstrual cycles.

Some dispute exists as to whether overprescription is caused by the medical profession or whether the patient population is overresponding to the increasing availability of prescription drugs. But whether the pressure

many of which avoid the risks of side effects associated with oral contraceptives. See infra note 135.

Application of the doctrine of informed consent requires a process of communication. The dialogue between an enlightened physician and an informed patient is as essential to the patient's choice of alternative contraception as it is to the understanding of the risks peculiar to the use of oral contraceptives. See supra note 85, infra notes 240–68, and accompanying text. Courts should be careful not to substitute products liability law, wherein the physician who is not a seller of the product cannot have any liability, for the doctrine of informed consent as the basis of the patient's claim. See RESTATEMENT (SECOND) OF TORTS § 402A (1965). Such a substitution would effectively deny patients the protection of their right of enlightened self-determination. Nevertheless, since Lukaszewicz and MacDonald view the physician and drug manufacturer as having concurrent duties based on the doctrine of informed consent and the law of products liability, respectively, they appear adequate to protect patients' rights in both contexts. Lukaszewicz, 510 F. Supp. at 563–64; MacDonald, 475 N.E.2d at 70.

109. Hearings, supra note 98, at 2140; S. Klaw, supra note 102, at 116; R. Mendelsohn, supra note 5, at 58, 65 (3/5 of prescription drugs are not prescribed for their proper use); Mendelsohn, supra note 99, at 24; J. Stein, supra note 99, at 86. In one case, the physician negligently prescribed chloromycetin, a dangerous drug with serious side effects, including aplastic anemia, to a child with minor throat ailments. The drug was not recommended by the manufacturer to be used for these conditions. The child developed aplastic anemia and died. Sharpe v. Pugh, 270 N.C. 598, 155 S.E.2d 108 (1967); see also Koury v. Follo, 272 N.C. 366, 158 S.E.2d 548 (1968). In Koury, the physician injected twice the safe dose of a drug (strep-combioric) stamped "not for pediatric use" into an infant. 158 S.E.2d at 550. The infant became totally and permanently deaf. Id. The court held that the physician should have known about this risk and that no immediate emergency existed requiring its use. Id. at 555. The problem of drugs being prescribed for purposes for which they were not intended invokes more than just physician liability and the doctrine of informed consent. The manufacturer may be strictly liable as well under the law of products liability. See supra note 108. In Incollingo v. Ewing, 444 Pa. 263, 282 A.2d 206 (1971), a child was given chloromycetin for a trivial ailment. A second physician renewed the child's prescription for chloromycetin twice without seeing the child or checking with the prescribing physician. The child subsequently died of aplastic anemia. The second physician argued that he felt chloromycetin was safe because of the representations of the Parke, Davis detailmen. 282 A.2d at 218. This overpromotion defense was also employed by the defendant physician who prescribed chloromycetin in Stevens v. Parke, Davis & Co., 9 Cal. 3d 51, 107 Cal. Rptr. 45, 507 P.2d 653 (1973). The Food and Drug Administration required Parke, Davis to give notice of chloromycetin's dangerous and serious side effects, yet Parke, Davis minimized these risks in a letter to its salesmen and had its salesmen continue concentrated promotions of the drug. 107 Cal. Rptr. at 48, 507 P.2d at 656. The court found the manufacturer negligent for "watering down" its warning and so overpromoting the drug that it was prescribed when it was not justified. 107 Cal. Rptr. at 54, 507 P.2d at 662; see also supra note 107.

110. See, e.g., Klink v. G. D. Searle & Co., 26 Wn. App. 951, 614 P.2d 701 (1980) (plaintiff was prescribed oral contraceptives because of irregular menstrual cycles, she suffered a massive bilateral stroke, and the court awarded her a million dollar verdict). Oral contraceptives can be linked to more than 50 side effects ranging from hypertension to diabetes, strokes, heart attacks, and cancer. Since women have begun taking oral contraceptives, the normal age range of breast cancer victims has gone from 45–56 to the 30's. R. Mendelsohn, supra note 5, at 120–29.
to overprescribe comes from within the medical profession,\textsuperscript{111} or is caused by patient demand\textsuperscript{112} is not the critical issue. Courts, physicians, and patients must recognize the increased number of side effects that result from overprescription. Only meaningful physician-patient communication can prevent the current overuse of drugs. Studies indicate that many patients would prefer more communication with their physician instead of the large number of drugs currently prescribed.\textsuperscript{113} If the primary cause of overprescription is patient demand, physicians have an even greater duty to communicate\textsuperscript{114} and cannot in good conscience use patient demand as the justification for overprescribing drugs.\textsuperscript{115}

3. \textit{The Need for Constant Monitoring}

Prescription drug therapy requires constant monitoring, which depends upon patient awareness of side effects and their symptoms.\textsuperscript{116} For the monitoring process to succeed, patients need to know, for example, which symptoms are significant and which are not; how to note, measure, and record symptoms; and when to report these symptoms to their treating physicians. Obviously this requires greater and more active patient participation than that demanded of patients during, or even recovering from, surgery. The fact that a time lag, and often a significant one, occurs between the inception of the drug therapy and the side effect\textsuperscript{117} reinforces the importance of constantly monitoring the therapy and treating the patient as a coparticipant in the process.\textsuperscript{118}

Physicians cannot ensure patient compliance with prescription drug therapy because the patient, not the physician, determines whether to fill the prescription and whether to follow the directions for use and monitoring.\textsuperscript{119} Patient compliance is far from perfect, but it improves when physician-patient interaction is marked more by shared information than by the physician's imposition of treatment on a passive patient.\textsuperscript{120} Although

\textsuperscript{111} \textit{Hearings, supra note 98, at 2140.}
\textsuperscript{112} \textit{Id. at 1303.}
\textsuperscript{113} Wartman, \textit{supra note 96, at 1360-61.}
\textsuperscript{114} See \textit{Hearings, supra note 98, at 1327; L. Tushinet, supra note 103, at 199.}
\textsuperscript{115} \textit{Hearings, supra note 98, at 2140.}
\textsuperscript{116} M. Belsky & L. Gross, \textit{How to Choose and Use Your Doctor} 95, 107 (1975).
\textsuperscript{117} R. Mendelsohn, \textit{supra note 5, at 58, 74; see R. Mendelsohn, supra note 99, at 25, 28.}
\textsuperscript{118} See R. Mendelsohn, \textit{supra note 5, at 58, 74; R. Mendelsohn, supra note 99, at 25, 28; see also supra notes 113-15 and accompanying text.}
\textsuperscript{120} E. Mischler, L. Amarasingham, S. Osherson, S Hauser, N. Waxler & R. Liem, Social
physicians fear otherwise, the available evidence also suggests that patients do not decline treatment merely as a result of being fully apprised of the risk of side effects.\(^\text{121}\)

4. **Limited Pharmacological Knowledge and Protection**

If the limits of medical knowledge are narrower than is generally recognized,\(^\text{122}\) the limits of pharmacological knowledge are even narrower.\(^\text{123}\) Many prescribing physicians rely heavily on pharmaceutical company salesmen (detailmen) as their primary source of information about the drugs they prescribe.\(^\text{124}\) Physicians also have problems keeping up with new drugs and the important information relating to their use.\(^\text{125}\) Despite the narrow limits of their knowledge about drugs, physicians often prescribe them automatically,\(^\text{126}\) often without obtaining information about the risks of side effects, despite readily available sources of drug information, such as the *Physicians' Desk Reference* ("PDR").\(^\text{127}\) Some commentators argue that physicians provide patients with less information about prescription drugs with serious risks of side effects than they do about minor surgery.\(^\text{128}\)

Ineffective government regulation of drugs and of the drug industry compounds the problems created by the limited nature of most physicians' pharmacological knowledge. The Federal Food and Drug Administration (FDA) has the responsibility for protecting public safety by, inter alia,
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overseeing the safety and efficacy of all drugs. However, FDA enforcement efforts appear to have little effect upon the process of prescribing drugs. While the FDA has responsibility for regulating written drug labeling, it has no authority to oversee oral presentations given by detailmen to prescribing physicians or to oversee the communications physicians make to patients when prescribing drugs. Detailmen overpromote certain drugs by, for example, emphasizing the benefits and ignoring or minimizing the risks. Physicians, in turn, rely on this information as an important source of their knowledge about the drugs they prescribe. FDA regulations do little to control these overpromotional activities. As can be expected, the patient is the ultimate victim of industry overpromotion.

129. FDA regulations concerning new drugs (21 C.F.R § 310 (1985)) and the Federal Food, Drug, and Cosmetic Act (21 U.S.C §§ 301–63 (1982)) are intended to control or to regulate only the actions of the drug manufacturer. For example, FDA regulations list specific requirements for the warnings of certain drugs, such as the oral contraceptive, and requires, among other things, the submission of a sample batch to the Commissioner of the FDA. (21 C.F.R § 310.500 (1985)). The statute deals with the application process for new drugs and requires that each application include: (1) full reports of investigations that have been made to show whether the drug is safe and effective; (2) a full list of the drug's ingredients; (3) a full description of the methods, facilities, and controls used for the manufacture, processing, and packing of such drug; (4) a sample of such drug may be required; and (5) examples of labeling proposed to be used for such drug. 21 U.S.C § 355(b)(1) (1982).

130. See supra note 109. An excellent example of overpromotion came in Stevens v. Parke, Davis & Co., 9 Cal. 3d 51, 507 P.2d 653, 107 Cal. Rptr. 45 (1973). Despite directions from the FDA to include a specified warning on the label of the drug chloromycetin, Parke, Davis minimized the risk in the labeling language, while its salesmen continued a concentrated promotion of the drug. 507 P.2d at 656, 107 Cal. Rptr. at 47–48. Parke, Davis did not include the required warning in the 1962 PDR, its detailmen personally visited doctors and urged them to use the drug without giving any verbal warnings as to the risks (although brochures left with the physician apparently included written warnings), and promotional “giveaways” (e.g., calendars and rulers) carrying the name chloromycetin carried no warnings. Furthermore, “reminder ads” published in medical journals made no reference to the possibility of harmful side effects. According to the FDA, however, Parke, Davis was required to include warnings only in advertising material that stated specific recommendations as to proper uses and dosage. 507 P.2d at 656 n.5., 107 Cal. Rptr. at 48 n.5. Thus, by this last directive the FDA arguably aided in the overpromotion of the drug. Based on the finding of overpromotion, the court held for the plaintiff. 507 P.2d at 663, 107 Cal. Rptr. at 55.

131. See Incollingo v. Ewing, 444 Pa. 263, 282 A.2d 206, 216 (1971) (a physician prescribed the extremely dangerous drug chloromycetin for even minor viral infections; he explained that he felt the drug was safe because of the representations to that effect by the Parke, Davis detailmen); supra note 130.

132. The FDA, whose duty it is to keep unsafe drugs off the market, is handcuffed by the political influence exerted by drug companies, and consequently, the protection afforded by the FDA is more illusory than real. R. MENDELSON, supra note 5, at 73, 75–76. Often, once the FDA has discovered that a drug has not met the required standards, the government is unable to remove the drug from the market without long and tedious proceedings, and the drug will continue, often for years, to be prescribed to an unknowing public. R. MENDELSON, supra note 99, at 33.
B. Factors That Affect Patient Participation and Choice

1. Range of Treatment Alternatives

One of the most significant differences between consent to prescription drugs and the typical informed consent situation involving surgery is the availability of a greater number of treatment alternatives. A physician may have a choice of eight or ten different drugs for a particular problem, as well as nondrug alternatives that may prove safer, and yet just as effective. One physician has suggested that, as a general rule, physicians lack confidence in nondrug alternatives to therapy and do not know enough about nutrition, for example, to seriously consider it as an alternative.

In many, if not most, situations where a prescription drug provides only one possible mode of therapy, an obvious alternative (although probably not often enough recognized as such) is that of no treatment. Once patients have been apprised of the drug’s risks, they might prefer no treatment or a nondrug treatment such as bed rest. Failure to present patients with the entire range of alternatives deprives them of the opportunity to make a meaningful choice, without which patients cannot exercise their right of self-determination.

2. Patient Idiosyncrasies

Patients have their own unique medical and nonmedical preferences. Although a patient’s medical idiosyncrasies, such as allergies and past medical history, play a role in both surgical and drug prescription settings, both medical and nonmedical preferences of the patient are much more important for drug prescriptions. These patient idiosyncrasies play a larger


134. See Boyer v. Smith, 497 A.2d 646, 647 (Pa. Super. 1985) (court ignored fact that defendant physician chose the most potent, and therefore, the most dangerous, drug with no discussion whatsoever with the patient about a host of available and safer alternatives); see also R. MENDELSOHN, supra note 5, at 58.

135. R. MENDELSOHN, supra note 5, at 122-23. For example, while many oral contraceptives are readily available, other, safer means of contraception that are equally as effective or nearly as effective are also available. M. Mintz, supra note 108, at 12-16.


137. See 2 PRESIDENT'S COMMISSION, supra note 5, at 167 table 5-4 (most physicians do not think that informed consent includes informing about alternative treatments or no treatment); see also supra note 116; Katz, supra note 22, at 157-58.

138. LeBlang, supra note 90, at 285; Trichter & Lewis, supra note 54, at 164 (each patient unique); supra note 93 and accompanying text; infra note 141 and accompanying text.
role in prescribing drugs than they do in the more typical surgical setting, mainly because of the complex and unique chemical reactions each individual has to prescription drugs. In addition, the heightened concern about nutrition and health, which often causes a person to stop smoking and to avoid chemical additives in foods, may also lead that person to an aversion to all drugs and to a preference for the nondrug, or least-potent-drug, alternative. By ignoring the patient's particular interests and concerns, which might have a direct bearing on the drug therapy decision, the physician ignores the individual being treated, and in effect treats only the hypothetical "reasonable" or "average" person.

3. Risks Versus Benefits

Since all drugs are dangerous, a serious question arises whether the total injuries and deaths caused by prescription drugs outweigh the cures they effect. As many as three of five drugs prescribed are estimated not to

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140. Information about side effects may have different significance to different patients. A high incidence and a low magnitude or risk (high risk of a minor but ugly skin rash, for example) may be a less acceptable risk to some patients than a low incidence and high magnitude of risk (remote risk of stroke or fatal reaction). Moreover, both alternatives might be rejected by some patients in favor of no treatment and its attendant risks. Courts, however, tend to look only to the incidence of risk. See, e.g., Watkins v. United States, 482 F. Supp. 1006, 1013 (M.D. Tenn. 1980) (court stated that physicians are not required to warn of rare side effects, no matter what their magnitude); Hamish v. Children's Hosp. Medical Center, 387 Mass. 152, 439 N.E.2d 240, 243 (1982); see also 2 President's Commission, supra note 5, at 105 table 3.1; Andrews, supra note 55, at 197. The Canadian Supreme Court has declared that material risks include those that are mere possibilities but of high magnitude. Reibl v. Hughes, 1980 S.C.R. 880.

Material risks include: (1) minor risks with high incidence, (2) major risks with low incidence, and (3) major risks with high incidence. See Koury v. Follo, 272 N.C. 366, 158 S.E.2d 548, 555 (1968) (court held that parents must be given the opportunity of an informed election between exposing their child to the risk of prolonged bronchitis and possible pneumonia on the one hand and incurring the risk of total and permanent deafness of their child on the other).

141. Koch-Weser, supra note 96, at 303 (arguing that it is naive to think that drugs capable of helping patients will not hurt somebody and that a completely safe drug is a pharmacological absurdity); see Marsh v. Arnold, 446 S.W.2d 949, 952 (Tex. Civ. App. 1969) (any administration of drugs by a physician involves risks); R. Mendelsohn, supra note 5, at 72; R. Mendelsohn, supra note 99, at 39 (there is no such thing as a safe drug; Eli Lilly himself once said that a drug without toxic effects is no drug at all).

142. Hearings, supra note 98, at 2107; R. Mendelsohn, supra note 5, at 7, 105; R. Mendelsohn,
have the beneficial effect intended.\textsuperscript{143} Even if this estimate is overstated, it is clear that a large percentage of prescriptions are not effective.\textsuperscript{144} In these situations, the user has nonetheless been exposed to the drug's side effects.

Prescription drug therapy is less predictable than surgery, and the risk of side effects is greater and more complex, than those usually associated with surgery.\textsuperscript{145} Taking several prescription drugs in combination enhances the risk of side effects.\textsuperscript{146} Risks are also enhanced when physicians, as they often do, treat side effects from one drug by prescribing another drug.\textsuperscript{147} Rarely can the physician or the patient feel comfortable about the efficacy and safety of a drug because of the lack of adequate data about the particular drug and the possibility of adverse reactions.\textsuperscript{148} This "uncertainty," although indigenous to all of medical practice,\textsuperscript{149} pervades the practice of prescribing drugs far more than it does surgical therapy.\textsuperscript{150}

An often overlooked aspect of prescription drug therapy is that the drug affects not just the user but has a direct, physiological impact on other persons. For example, a pregnant woman might want to weigh for herself the benefits from her use of a particular drug against the risks the drug presents to the fetus.\textsuperscript{151}

\textsuperscript{143} R. MENDELSOHN, supra note 5, at 58, 64.
\textsuperscript{144} S. Klaw, supra note 102, at 23–25; H. Lennard, supra note 96, at 32.
\textsuperscript{145} 1 President's Commission, supra note 96, at 85–89; see also H. Lennard, supra note 96, at 81; R. MENDELSOHN, supra note 5, at 70–71, 74, 75; L. Tushnet, supra note 103, at 196 n.203.
\textsuperscript{146} See R. MENDELSOHN, supra note 99, at 41; S. Sagov, supra note 47, at 103–04; L. Tushnet, supra note 103, at 204.
\textsuperscript{147} H. Lennard, supra note 96, at 81; R. Mendelssohn, supra note 99, at 31. In one case, for example, the side effects from Thorazine are treated with artene, which in turn can cause a Thorazine syndrome. R. Mendelssohn, supra note 5, at 58; L. Tushnet, supra note 103, at 209–10.
\textsuperscript{148} Hearings, supra note 98, at 2140; see Marsh v. Arnold, 446 S.W.2d 949, 952 (1969) (physician testified that the benefits received from drugs outweigh the bad effects, but that any administration of drugs is a precarious procedure and that the real dangers from the use of drugs are unknown); Koch-Weser, supra note 96, at 303 (demand for completely safe drug is both naive and absurd).
\textsuperscript{149} Physicians would be more cautious about claims to have found the answer to the treatment of any disease if they developed an appreciation of medicine's vast ignorance. J. Katz, supra note 5, at 182. Although certain drugs, such as anticoagulants, antibiotics, hypotensive agents, insulin, and steroids have been available for 15 to 40 years, many of their true effects on patients and diseases are unknown. Id. at 166; see also Watkins v. United States, 482 F. Supp. 1006, 1012 (M.D. Tenn. 1980) (medicine is not an exact science).
\textsuperscript{150} J. Katz, supra note 5, at xvii–xviii, 26, 46, 166. See generally 1 President's Commission, supra note 96, at 30 n.48. For an interesting discussion of the uncertainty which physicians feel but won't reveal to patients, see J. Katz, supra note 5, at 170–71. For a discussion of the notion of "certainty" as a goal of medical training, and the detrimental impact it has on the therapy and the choice of patients, see id. at 183–87. See also S. Klaw, supra note 103, at 25–26; T. Preston, supra note 49, at 83–87.
\textsuperscript{151} See R. MENDELSOHN, supra note 99, at 39; R. Mendelssohn, supra note 5, at 70–73, 167–68; L. Tushnet, supra note 103, at 195. For another example of drugs exposing nonusers to risks, see
The risk-benefits factor also requires the participation of the individual patient in a manner that courts rarely recognize. The side effects from a drug may be serious (a stroke) or minor (a skin rash). Thus, patients may regard the magnitude of the possible side effects as very important to their therapeutic choice. Similarly, a side effect may have a low (1 in 1,000,000, for example) or high (1 in 100) chance of occurring. Consequently, patients may also regard the incidence of the risk as important to their choice of therapy. Courts tend to focus only on the incidence of the risks, assuming that patients are concerned with serious side effects only when they have a high probability of occurring. In so doing, courts fail to consider all of the variables in this incidence-magnitude rubric. A particular patient's concerns about the risk of side effects are likely to be more complex than courts have recognized. A particular patient may be very concerned about a serious side effect, even if the incidence is only 1 in 1000, if the benefits from the drug are slight, such as relief from minor pain. Of course, the greater the illness or pain, the more likely the patient may be to assume a greater risk in order to obtain relief. The choice, however, belongs to the patient, not to the physician. By failing to recognize all the variables and combinations of the incidence-magnitude rubric, courts deprive patients of the opportunity to make informed choices.152

If courts examined closely the special factors that dominate prescription drug therapy, they would not defer so readily to medical practice as the standard for determining the existence and scope of the physician's duty to inform in the prescription drug context. These same considerations would cause courts to begin shaping an informed consent model that recognizes the individual, idiosyncratic (not merely "reasonable") patient's need to participate in prescription drug therapy. By moving to a subjective-patient standard for determining proximate cause, courts would, for the first time in the informed consent context, give full force and effect to the patient's rights of self-determination and bodily integrity.

III. INFORMED CONSENT IN THE PRESCRIPTION DRUG CONTEXT: PRESENT STATE OF THE LAW

Extreme deference to the medical profession is the most obvious aspect of the judicial attitude toward informed consent in the prescription drug context. While this deferential attitude pervades the entire field of informed consent, the medical profession's role is most pronounced in the prescription drug context.153


152. See supra note 140.
consent,\textsuperscript{153} it is striking against the background of the special factors permeating prescription drug therapy.\textsuperscript{154} According to several commentators, courts seem to have little concern for preserving the rights of patients and protecting them from drug abuses caused by the medical profession and the drug industry.\textsuperscript{155} Indeed, an analysis of the informed consent standard applied in prescription drug cases indicates that courts almost unanimously adopt a medical profession viewpoint rather than a patient perspective.\textsuperscript{156}

Even though courts have generally refrained from asking the difficult and essential questions about the scope of physicians' duty to communicate,\textsuperscript{157} the courts have not been injudicious or insensitive. Rather, the case law demonstrates that deference to the medical profession, in conjunction with the failure to recognize the special factors inherent in the prescription of drugs, has caused courts to rely completely on the professional standard to determine the presence of informed consent in the prescription drug context.\textsuperscript{158}

In most prescription drug cases courts adopt and apply the medical-community standard of disclosure with little or no stated rationale and with rarely more than a reference to some unarticulated necessity to defer to the judgment of the medical profession.\textsuperscript{159} Although in adopting the objective-patient model courts articulate more clearly the rationale for deferring to the medical profession,\textsuperscript{160} the abrogation of patients' rights is essentially the same. Both models ignore the needs and preferences of the particular patient, although the reasonable-patient model may inadvertently protect

\textsuperscript{153} See supra notes 47-64 and accompanying text; infra note 160 and accompanying text.
\textsuperscript{154} See supra notes 91-132 and accompanying text.
\textsuperscript{155} J. Katz, supra note 5, at 58; R. Mendelsohn, supra note 5, at 36, 119, 125-36; T. Preston, supra note 49, at 112; S. Sago, supra note 47, at 125.
\textsuperscript{156} See supra note 8.
\textsuperscript{157} See supra notes 51, 67-68, and accompanying text.
\textsuperscript{158} See supra note 8 and text accompanying note 156.
\textsuperscript{159} See, e.g., Watkins v. United States, 482 F. Supp. 1006, 1012 (M.D. Tenn. 1980) (court observed that the law will not hold a physician guilty of negligence even if the physician's judgment proved incorrect, unless it can be shown that the course chosen was clearly against the course recognized as correct by the medical profession); Finley v. United States, 314 F. Supp. 909, 916 (N.D. Ohio 1970) (court held that it could not formulate an independent judgment as to whether proper medical standards require the giving of a cautionary instruction whenever a physician prescribes a common medication with some known side effect); Carmichael v. Reitz, 17 Cal. App. 3d 977, 95 Cal. Rptr. 381, 391-92 (1971) (existence and scope of physician's duty to inform should be established by expert testimony of other physicians); Oakes v. Gilday, 351 A.2d 85, 89 (Del. Super. Ct. 1976) (court required a showing of the applicable standard of the medical community in that locality or similar localities); Pederson v. Dumouchel, 72 Wn. 2d 73, 79, 431 P.2d 973, 978 (1967) (physicians are responsible in damages when they fail to exercise the degree of skill and care that is usually possessed by the average member of the profession acting in the same or similar circumstances).
\textsuperscript{160} See supra notes 33-36 and accompanying text.
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the particular patient's needs and preferences if the information material to
the particular patient's choice happens to coincide with the information
material to the choice of the hypothetical "reasonable" patient.161

A. Pennsylvania: A Case Study

One of the most expansive explanations for deferring to the medical
profession in the prescription drug context came in a recent Pennsylvania
trial court opinion, Boyer v. Smith.162 Pennsylvania bases its informed
consent doctrine on a battery theory,163 which the Boyer trial court believed
inapplicable in the prescription drug context. Nevertheless, the trial court's
opinion provides one of the clearest illustrations of both unwarranted
deferece to the medical profession and a failure to consider any of the
factors unique to prescription drug therapy.

In Boyer, the jury found for defendant physician, who allegedly had
failed to advise plaintiff of the serious side effects associated with the use of

161. See supra note 32 and accompanying text.
162. Boyer v. Smith, No. 80-12190-6, slip op. (C.P. Bucks County, Pa., Jan. 28, 1985), aff'd, 497
163. The Pennsylvania Supreme Court adopted the doctrine of informed consent in 1966, basing its
theory on the fact that an operation without the patient's consent is a technical assault. Gray v.
Grunnagle, 423 Pa. 144, 223 A.2d 663, 668-69 (1966). Gray involved a surgical procedure, which the
jury found was performed without the patient's consent. Gray, 223 A.2d at 664-65. In reversing the
trial court's judgment for defendant notwithstanding the verdict, the Pennsylvania Supreme Court failed
to set forth an express standard establishing the physician's duty to the patient. In a battery context, with
no issue of alternative treatment presented, the court apparently felt that the only standard needed was
one that ensures that the surgeon give the patient "a true understanding of the nature of the operation to
be performed." Gray, 223 A.2d at 674. The jury's only task in such a case is to determine whether
the plaintiff consented to the operation, or essentially to the operation, performed by the defendant. 223
A.2d at 674. Five years later the Superior Court of Pennsylvania, an intermediate appellate court, was
presented with a similar appeal involving the question whether defendant physician had informed
260, 286 A.2d 647 (1971). The narrow factual issue raised by plaintiff was whether defendant had
informed plaintiff of the collateral risks, including perforation of her stomach, associated with the
procedure. Cooper, 286 A.2d at 648. Because Gray had recognized an individual's right to bodily
integrity, the superior court rejected use of the medical-community standard to determine whether
defendant had adequately informed plaintiff of collateral risks of the examination. Id. at 650. Without
other relevant precedent in Pennsylvania, the court looked to other jurisdictions and adopted a
reasonable patient standard. Id. However, because the gastroscopic examination in Cooper involved a
physical touching, the court in Cooper followed Gray by expressly recognizing that an operation
performed without an informed consent is a technical assault. Id. at 649. Later informed consent
decisions in Pennsylvania, including one prescription drug case, have refused to extend the doctrine of
informed consent to situations where no touching is involved. See Malloy v. Shanahan, 280 Pa. Super.
440, 421 A.2d 803, 805 (1980); Boyer v. Smith, No. 80-12190-6, slip op. at 5 (C.P. Bucks County, Pa.,
the potent pain killer Butazolidin. Plaintiff had accompanied her husband to his appointment with defendant, to whom she incidentally complained about pain in her lower back and leg. Defendant diagnosed the condition as nerve root compression and prescribed both a ten-day supply of Butazolidin and bed rest. Defendant also advised her that Butazolidin could cause oral and gastrointestinal ulcers. However, he did not inform her of other potential side effects, their probability of occurring, or of alternative treatments, even though he was aware of Butazolidin's life-threatening potential and of the existence of alternative less potent drugs. Seven days after beginning the use of the drug, plaintiff suffered a severe adverse reaction from which she almost died.

The trial court, apparently following Pennsylvania precedent, refused to charge the jury on informed consent as a separate and distinct basis of liability. Nevertheless, the trial court went on to give an expansive explanation for the court's deferential attitude to the medical profession in the prescription drug context:

Unless the risk of serious side effects is substantial, drug treatment is not ordinarily regarded as radical. It also differs significantly from surgical procedures in its incidence and variety of applications. Regardless of the degree of testing and governmental approval, it is well known that no drug is entirely safe. . . . To require a physician to advise a patient of the warnings and disclaimers of drug manufacturers would not serve the same beneficial purpose as that of informed consent in a surgical situation. Confronted with the dire consequences such as are enumerated in the *Physicians' Desk Reference*, it would often be extremely difficult for a patient to make an intelligent decision. A patient's ultimate reliance would still have to be placed in a clinician's judgment to a far greater extent than in cases of surgery.

The trial court used the traditional malpractice standard to charge the jury, asking the jury to determine whether the defendant physician failed to act as a reasonable physician in the same circumstances. On the basis of

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165. *Id.*
166. *Id.*
167. *Id.* at 2.
168. *Id.*
169. *Id.*
170. *Id.* at 4; see supra note 163.
172. *Id.* at 7. But see *Cooper v. Roberts*, 220 Pa. Super. 260, 286 A.2d 647, 650 (1971) (the court refused to apply the reasonable physician standard to informed consent cases because the main issue was whether the patient made an effective assent to treatment and not whether the physician conformed to the accepted medical practice).
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this charge, the judge limited the plaintiff's argument to the jury, allowing her to contend "that a reasonable practitioner would have disclosed the remote possibility of a grave reaction to the taking of butazolidin." In refusing to charge the jury on informed consent as a separate theory of liability, the trial court exhibited almost complete deference to the medical profession. The court's refusal to acknowledge any validity or significance to a patient-oriented standard demonstrated a lack of recognition of the patient's need to participate in the drug prescribing process. Had the trial court recognized the unique factors inherent in the prescription drug context, many of which were directly involved in the case, it would not have drawn the erroneous and unfounded conclusion that prescription drug therapy requires less patient participation than do bodily invasive procedures, such as surgery.

The trial court either ignored or misapplied many of the special factors inherent in prescription drug therapy. One factor implicated in Boyer was the pervasive use of prescription drugs that is often caused by the need of physicians to create certainty in the treatment setting. If defendant physician had not unilaterally decided to give plaintiff a particular quick cure, and had he been more concerned with her participation in the process, he would likely have considered other alternatives, including a more conservative therapy (bed rest) without any medication.

The factor of overprescribing also played an important role in the case. Defendant did not consider either a safer drug alternative or a nondrug alternative. In fact, defendant, like other physicians in the local medical community, prescribed Butazolidin as a drug of first choice despite strong warnings in the PDR to the contrary and despite the fact that plaintiff's condition was not included in the list of indicated uses for Butazolidin when defendant prescribed it.

174. Id. at 2.
175. Id. at 6.
176. For a discussion of the need for certainty, see supra notes 101, 150 and accompanying text. For a discussion of the tendency to overprescribe in general, see supra notes 102–15 and accompanying text.
177. See Reproduced Record at 355a–58a, Boyer. For a discussion of patient idiosyncrasies in general, see supra notes 138–40 and accompanying text.
178. See Reproduced Record at 148a–49a, Boyer.
179. For a discussion of overprescribing in general, see supra notes 102–15 and accompanying text.
180. Reproduced Record at 145a–46a, 242a, Boyer.
181. Id. at 155a–56a, 246a–47a, 358a–59a. Defendant testified that he was aware that the PDR stated that Butazolidin should not be considered as a drug of "first choice." Id. at 152a.
182. Id. at 151a–52a. For an explanation of the role the PDR plays in the prescription process, see supra note 127.
183. Reproduced Record at 196a, Boyer.
Overprescribing also relates to, and is in fact manifested in, another important factor present in Boyer. At the time defendant prescribed Butazolidin for plaintiff, numerous drugs were available as alternatives,\textsuperscript{184} all of which were less potent and therefore less likely to cause dangerous side effects.\textsuperscript{185} The defendant did not mention to the plaintiff any of the alternatives to Butazolidin, drug or nondrug.\textsuperscript{186} The trial court failed to mention alternatives in its opinion, despite the fact that defendant admitted that he had known at the time that eight to ten alternative drugs were available, and despite the fact that expert testimony established that bed rest, without drug therapy, was a viable alternative in plaintiff’s case.\textsuperscript{187}

The trial court barely acknowledged the risk-benefit factor by recognizing that all drugs have some danger inherent in their use.\textsuperscript{188} The court implicitly recognized the risk-benefit factor in allowing the plaintiff to argue to the jury that a reasonable physician would have disclosed to plaintiff the “remote possibility”\textsuperscript{189} of a grave risk inherent in the use of Butazolidin. Nevertheless, by emphasizing the low incidence of the risk, the court effectively played down the seriousness of the side effects; the failure to disclose the seriousness of the side effects denied the plaintiff the opportunity to make an informed choice.\textsuperscript{190} Additionally, by not charging the jury on informed consent as a separate theory of recovery, and by applying the professional standard of the reasonable medical practitioner, the court forced the jury to ignore the preference plaintiff might have had as a result of the incidence of the risk and the magnitude of the side effect.

\textsuperscript{184} For a discussion of alternatives generally see supra 133–37 and accompanying text.

\textsuperscript{185} Reproduced Record at 242a, Boyer. Bed rest was also a viable alternative therapy for plaintiff. \textit{Id.} at 197a. Of all the alternatives for treatment for plaintiff at that time, Butazolidin was the most potent and the most likely to cause life-threatening side effects. \textit{Id.} at 242a. Butazolidin is the trademark of Geigy Pharmaceuticals, a Division of the Ciba Geigy Corporation, for phenylbutazone, a nonsteroidal, antiarthritic, anti-inflammatory agent. PHYSICIANS DESK REFERENCE 878 (32d ed. 1978) [hereinafter cited as PDR]. The PDR warns that Butazolidin should never be administered casually and in bold print instructs the physician to thoroughly read information provided before prescribing the drug. \textit{Id.} Among the adverse reactions listed in the PDR are liver dysfunction, fatal blood dyscrasias, including aplastic anemia, peptic ulceration, and gastrointestinal bleeding. \textit{Id.} Further, the PDR warns that in individuals forty and over there is an increase in the possibility of adverse reactions. \textit{Id.} at 879.


\textsuperscript{187} Reproduced Record at 148a, Boyer.


\textsuperscript{189} \textit{Id.} at 7. The court interpreted the jury’s verdict as establishing that the reasonable orthopedist in the same circumstances as the defendant physician would not have made known the drug’s extremely toxic, but unusual side effects. \textit{Id.}

\textsuperscript{190} \textit{Id.} at 6. For a discussion of the risk factor in general, see supra notes 140–53 and accompanying text.
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Plaintiff’s condition was not life-threatening and did not demand immediate, high-powered therapy. Under the circumstances, she might well have chosen a less potent pain killer, with less risk of serious side effects, despite the fact that the incidence of grave risk from Butazolidin was low.

In its memorandum opinion, the trial court did not indicate whether plaintiff’s idiosyncrasies played any role in its decision. It appears, however, that the court failed to consider this factor in formulating the disclosure standard. Defendant physician admitted that he did not take the plaintiff’s medical history, other than a brief history of the origin of the pain. Yet the PDR indicates that no prescription of Butazolidin should be written without first taking a detailed history of the patient. The court made no mention of the physician’s failure to follow this procedure. Moreover, both the court and the defendant failed to consider whether plaintiff, if given information about an alternative treatment, might have had some personal, or idiosyncratic, preferences about what risks of side effects she was willing to accept in order to relieve her pain. Plaintiff, however, was not given a choice.

Although prescription drug use requires constant monitoring, the court apparently ignored the role monitoring played in the patient’s situation. The then-current edition of the PDR stated that any patient under treatment with Butazolidin “should remain constantly under the close supervision of the physician.” The PDR also recommended that any prescription of the drug should be for a one-week period. Yet defendant gave plaintiff a ten-day prescription, with no instructions to report back to him sooner than seven to ten days. These instructions did not reflect the fact that plaintiff, at fifty-five years-of-age, was in the higher risk category of users, to whom the PDR suggests that physicians give careful instructions.

191. Plaintiff was suffering from sciatica, which caused leg and back pains. Boyer v. Smith, No. 80-12190-6, slip op. at 1 (C.P. Bucks County, Pa., Jan. 28, 1985), aff’d, 497 A.2d 646 (Pa. Super. 1985). Plaintiff was not working; taking care of Mr. Boyer was her sole responsibility. Record On Appeal at 357a, Boyer. Defendant prescribed Butazolidin because he assumed she was working and he considered her condition acute. Id. at 107a. Nevertheless, defendant had over 15 drugs to choose from, many of which had less risk of side effects. Id.
192. Reproduced Record at 155a, Boyer.
193. See supra note 127.
194. Reproduced Record at 98a, 147a–48a, Boyer; PDR, supra note 185, at 878.
195. See supra notes 138–53 and accompanying text.
196. For a discussion of the need for monitoring in general, see supra notes 116–21 and accompanying text.
197. Reproduced Record at 147a, 151a, Boyer; PDR, supra note 185, at 878.
198. Reproduced Record at 148a, Boyer; PDR supra note 185, at 878.
199. Reproduced Record at 159a–60a, 377a, Boyer.
200. Id. at 150a–51a, 196a–97a, 377a; PDR, supra note 185, at 879. Patients over 40 years-of-age presented increased risks, with special attention required when patients were 60 or older. Id.
One last aspect of the uniqueness of prescription drug therapy that the court apparently overlooked is the limited pharmacological knowledge of prescribing physicians.\textsuperscript{201} The defendant testified that he understood the pharmacology of Butazolidin, which presumably resulted in his failure to consult the \textit{PDR} before prescribing the drug for plaintiff.\textsuperscript{202} At that time, however, defendant did not even have a copy of the \textit{PDR} in his office.\textsuperscript{203} Despite defendant's professed knowledge of the pharmacology of Butazolidin, he prescribed it as a drug of first choice against a strong warning to the contrary in the \textit{PDR};\textsuperscript{204} he gave it to plaintiff, who at the time was fifty-five, well above the age at which the \textit{PDR} indicated that the drug, already dangerous, becomes much more toxic;\textsuperscript{205} he prescribed the drug with virtually no instructions, whereas the \textit{PDR} warns that to avoid life-threatening adverse reactions, it is essential that the physician give careful instructions to the individual patient;\textsuperscript{206} and he prescribed the drug, as apparently did many of his local peers in his locality, for a condition for which the \textit{PDR} indicates the drug is not intended.\textsuperscript{207}

Before adopting a medical-community perspective over a patient-oriented disclosure standard, courts should consider the type of facts and circumstances present in \textit{Boyer}: (1) technical information concerning the prescribed drug was available in the \textit{PDR}, the content of which is regulated by the FDA (although provided to the \textit{PDR}'s publisher by the drug manufacturers);\textsuperscript{208} (2) the technical information contained a warning in clear language about the possibility of serious side effects under certain circumstances;\textsuperscript{209} (3) the patient appeared to fall within those circumstances; and (4) the medical condition was neither an emergency nor life-threatening.\textsuperscript{210}

These facts and circumstances dictate that the court should have seriously questioned the appropriateness of a deferential standard of disclosure.\textsuperscript{211} Unless courts require physicians to consider such facts and

\textsuperscript{201} For a discussion of physicians' lack of pharmacological knowledge in general, see supra notes 122–32 and accompanying text.

\textsuperscript{202} Reproduced Record at 152a, \textit{Boyer}.

\textsuperscript{203} \textit{Id.} at 147a.

\textsuperscript{204} \textit{Id.} at 152a; see \textit{PDR}, supra note 185, at 878.

\textsuperscript{205} Reproduced Record at 150a–51a, 196a–97a, \textit{Boyer}.

\textsuperscript{206} \textit{Id.} at 151a; \textit{PDR}, supra note 185, at 878.

\textsuperscript{207} Reproduced Record at 196a, \textit{Boyer}; \textit{PDR}, supra note 185, at 878.

\textsuperscript{208} See supra notes 129–32 and accompanying text.

\textsuperscript{209} Reproduced Record at 98a, 103a–04a, \textit{Boyer}.

\textsuperscript{211} The \textit{Boyer} court explained its decision as follows:

To require a physician to advise a patient of the warnings and disclaimers of drug manufacturers would not serve the same beneficial purpose as that of informed consent in a surgical situation. Confronted with the dire consequences such as are enumerated in the \textit{Physicians' Desk Reference} it would often be extremely difficult for a patient to make an intelligent decision. A patient's
circumstances and to communicate them to the patient, the patient's rights of self-determination and bodily integrity have no force and effect.

B. Other Jurisdictions

Boyer graphically demonstrates judicial deference to the medical profession and disregard for the special factors pertaining to prescription drug therapy. Other jurisdictions have adopted similar attitudes. Some jurisdictions, for example, have demonstrated a desire to maintain the medical-community standard by overlooking, and even rationalizing, physicians' failure to use the PDR to maintain their knowledge of the risks associated with drug therapy. Wisconsin courts seem to exhibit a similar attitude. For example, in Trogun v. Fruchtman, plaintiff contracted hepatitis from the use of the drug isoniazid hydrazate ("INH"), which had been prescribed for an inactive case of tuberculosis. Plaintiff's condition fell into the least serious category of inactive cases. The court held that because physicians in plaintiff's locality were not aware of the risk of contracting hepatitis from the INH treatment, defendant was not negligent in failing to warn plaintiff of this risk. Yet the PDR published one year before defendant prescribed the drug for plaintiff indicated that hepatitis was a risk inherent in the use of the drug.

In obvious deference to the medical-community standard, the Trogun court minimized the PDR information about the risk of hepatitis in two ways. It played down the risk of hepatitis identified in the PDR by overemphasizing PDR language identifying hepatitis as one of the risks that had ultimate reliance would still have to be placed in a clinician's judgment to a far greater extent than in cases of surgery.


There is no basis for the assertion that warnings of drug reactions do not serve the same purpose as do warnings of adverse consequences of surgery. That it would be difficult for a patient to make an intelligent decision in a particular case is not a valid reason to deprive patients of all choice, either in that case or in all cases. In light of the particular, but probably not unique, circumstances of her situation, one suspects that had the plaintiff in Boyer been given some choice, she probably would have chosen an alternative treatment. Whether she ultimately would have relied on the defendant's judgment and consented to use of Butazolidin cannot be known with any assurance because her doctor never discussed risks or alternatives with her.

212. For a discussion of PDR use in general, see supra notes 122–32 and accompanying text.
213. 58 Wis. 2d 596, 207 N.W.2d 297 (1973).
214. Trogun, 207 N.W.2d at 299.
215. Id. at 304. Plaintiff had a "primary" case, the least serious of the four categories of inactive tuberculosis. Id.
216. This finding, reached on appeal, was based on the testimony of medical experts at trial. Trogun, 207 N.W.2d at 310.
217. Id. at 315.
218. Id. at 304 (quoting PDR, supra note 185 (1967 ed.)).
“occasionally been reported.” Nowhere in the opinion does the court state what probability of risk it interprets “occasionally” to mean. The court, however, does make clear that it focused only on what it saw as a low incidence of risk and ignored any consideration of the magnitude of the side effect. The court continued to overemphasize the PDR language by quoting in italics a sentence from the PDR not italicized therein: “Side effects are infrequently encountered and are rarely serious.” Contrary to the court’s implied finding, hepatitis is very serious; even if hepatitis occurs infrequently, the PDR gives adequate notice of the severe risks of hepatitis. By minimizing the effect of the PDR language, the court gave decisive weight to the testimony of physicians that they were not aware of the risk of hepatitis as a side effect of the drug INH.

Courts have routinely failed to take into consideration the interrelationship between the incidence and the magnitude of the side effect, as they relate to the patient’s underlying condition. In this respect, courts tend to overlook or ignore particular concerns and preferences, even idiosyncrasies, that patients may have regarding the risks they are willing to accept. A New Jersey case, Calabrese v. Trenton State College, illustrates the point. Plaintiff argued, unsuccessfully, that the court should have considered that his risk of contracting rabies was slight under the circumstances, but the risk of side effects from the rabies treatment was substantial, especially considering the seriousness of the side effects. In fact, plaintiff suffered brain damage as a result of the treatment. The Calabrese court, relying on standard medical judgment, held that plaintiff need not have been informed of the risks. According to the court, the adequacy of disclosure to the patient must be measured by the medical-

219. See id.
220. Id.
221. For a discussion of the relationship of the incidence and magnitude of the risks of all alternatives, including that of no treatment, in conjunction with the risks associated with the patient’s underlying condition, see supra notes 140–52 and accompanying text.
222. Trogun, 207 N.W.2d at 304, 310. Another example of a court engaging in similar rationalizing came in Niblack v. United States, 438 F. Supp. 383 (D. Colo. 1977). In Niblack, the court lumped together the risk of aseptic necrosis, a relatively serious condition, with every other side effect, including minor ones, without considering the incidence and magnitude relationships and the impact disclosure of these relationships would have had on plaintiff’s decision. Id. at 384 n.2, 388–89.
223. See supra notes 140–52 and accompanying text.
224. See supra notes 138–40 and accompanying text.
226. Plaintiff had presented the argument that “the remoteness of the danger of rabies, when considered in the light of the possible adverse side effects associated with the anti-rabies vaccine, makes the prevention of rabies a greater hazard than the hazard presented by an untreated dog bite victim.” Calabrese, 392 A.2d at 604.
227. Plaintiff suffered “chronic severe organic brain damage secondary to [the] rabies vaccine.” Id. at 603.
community standard because no lay jury can be expected to reach a conclusion on such a technical matter unaided by such testimony. For example, it may well be that medical practice regards the risk material to the case as being so statistically remote that, when measured by the gravity of harm to be expected from lack of such treatment, disclosure thereof is normally not made.\textsuperscript{228}

Reliance on professional medical judgment focused the \textit{Calabrese} court’s attention solely on probability ("statistically remote"),\textsuperscript{229} causing the court to ignore the severity of the side effect. \textit{Calabrese} demonstrates two aspects of a court’s attitude about the patient’s role in the decisionmaking process. First, the court was unwilling to consider any particular concerns or preferences the patient may have had about accepting the risks.\textsuperscript{230} The court’s failure to recognize the key role played by the factors inherent in prescription drug therapy, such as the incidence-magnitude rubric,\textsuperscript{231} led the court to endorse standard medical judgment. This reliance on medical judgment compounded the problem because physicians reach such judgments by failing to recognize the same special factors and their importance to particular patients. Thus, courts and physicians deprive patients of the right to make fundamental choices concerning their own bodies.\textsuperscript{232}

Second, the \textit{Calabrese} court relied on the argument that a lay jury cannot understand technical matters without the aid of expert medical testimony.\textsuperscript{233} This argument demonstrates confusion of the need for expert medical testimony regarding the existence of particular risks (not all cases require such testimony) with the relatively easy question of whether the patient received and understood information pertinent to that patient’s decision. By combining the two issues under the guise of technicalities requiring expert medical opinion, the court is again led to the adoption of the medical-community standard.

The nearly universal application of the medical-community model in prescription drug cases deprives patients of the opportunity to make fundamental choices concerning their own bodies. For the judiciary to give full force and effect to the patient’s rights of self-determination and bodily integrity, courts must fashion a new informed consent model that focuses on the patient’s individual decisionmaking process.

\textsuperscript{228} \textit{Calabrese}, 392 A.2d at 606.
\textsuperscript{229} \textit{Id.}
\textsuperscript{230} \textit{Id.} at 604.
\textsuperscript{231} \textit{See supra} notes 140–52 and accompanying text.
\textsuperscript{232} \textit{See supra} notes 15–21 and accompanying text.
\textsuperscript{233} \textit{Calabrese}, 392 A.2d at 606.
IV. PROTECTING THE PATIENT'S RIGHT TO CHOOSE: A PROPOSED DUTY/DISCLOSURE SCHEME

A. The Foundation

In determining the scope of the disclosure duty in prescription drug cases, courts must recognize that there are special factors that bear directly and indirectly upon the needs and concerns of all the parties. Without recognizing the importance of these factors, courts cannot give protection to the basic right of self-determination and bodily integrity of patients undergoing drug therapy.  

Courts must also examine their willingness to accept entrenched medical attitudes as the basis for all rights and liabilities inherent in the doctrine of informed consent. Physicians prescribe drugs without adequately considering the special factors pertaining to patients' circumstances and concerns. In addition, physicians are unwilling to trust patients to know their own needs.  

Given the attitude of most physicians, the doctrine of informed consent will be, at best, merely one canon in a code of professional conduct, with no effective legal basis, unless courts are willing to intervene. Courts must recognize that they, better than the medical profession, can formulate legal standards for professional medical conduct.  

Finally, courts must focus on the essential purpose of the doctrine of informed consent. The doctrine is based on the fundamental notion of individual autonomy. Implicit in the language of individual autonomy is the protection of the individual's dignitary interest. In prescription drug

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235. See J. Katz, supra note 5, at 85–86.


237. The root premise is the concept, fundamental in American jurisprudence, that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body.” Schloendorff v. Society of N.Y. Hosp., 211 N.Y. 125, 105 N.E. 92, 93 (1914). True consent requires that the patient make an informed choice, which includes the opportunity to evaluate knowledgeably the options available and their risks. Canterbury v. Spence, 464 F.2d 772, 780 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972); see supra notes 15–21 and accompanying text.

238. See supra note 46. Courts also should consider that patients have certain contractual rights. The surgical context is an area basically governed by contractual concepts, under which the surgeon must operate in accordance with the agreement made between the parties. Cooper v. Roberts, 220 Pa. Super. 260, 286 A.2d 647, 651 (1971). Consent for the operation or treatment arises from the contract between the surgeon and the patient, with consent limited to what the parties understood was to be done. Cooper, 286 A.2d at 651. A patient’s agreement to a procedure, including prescription drugs, cannot be considered informed consent unless the patient understands all reasonable alternatives and risks. To understand the extent of the contract between the parties, the patient must have this knowledge. Apparently, courts find that patients waive their right to be informed in prescription drug therapy about
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cases, courts have upheld the autonomy of physicians by adopting the medical-community standard and in the process have overlooked the dignity and autonomy of the individual patient. Even if those courts applied the alternative objective-patient model, they would still fall short of protecting the rights of particular patients. Through closer scrutiny in the prescription drug context of the duty, scope of duty, and proximate cause considerations that underlie the doctrine of informed consent, courts would recognize the need to set standards that reflect the particular patient's perspective.

B. A Patient-Oriented Standard: The Need for Subjectivity

An objective-patient model cannot be applied successfully to prescription drug cases. Courts reject the subjective-patient model in favor of an objective-patient model because they fear that a subjective standard would impose an unrealistic burden on physicians. Requiring physicians to communicate with their patients is neither unrealistic nor unfair. The "objective" standard, however, does not depend on meaningful communication between physician and patient, but on a nondescript process that ultimately relies completely on medical opinion in lieu of patient participation.

As the court in Canterbury v. Spence noted, the objective approach calls for physicians, based on their medical training and experience, to "sense how the average, reasonable patient expectably would react." This standard does not impose any legal obligation on the physician to communicate with the patient. Rather, the physician need only reach a unilateral decision by "sensing" how the patient feels. Furthermore, the physician’s preferred drug will prevail because medical training and experience teach the physician not to communicate with a fully participating patient. Relying on a physician’s ability to sense what the particular patient wants often leads to miscommunication. In Boyer v. Smith, the physician

239. See supra notes 8, 15–21 and accompanying text.
240. See, e.g., Canterbury v. Spence, 464 F.2d 772, 787 (D.C. Cir.) (the physician can never know exactly what the patient would consider important to his decision), cert. denied, 409 U.S. 1064 (1972); Cooper v. Roberts, 220 Pa. Super. 260, 286 A.2d 647, 650–51 (1971) (reasonable patient standard gives maximum effect to the patient’s right to be the arbiter of the medical treatment he will undergo without requiring the physician to be a mindreader).
241. See supra notes 82–85 and accompanying text.
243. Id. at 787.
244. J. Katz, supra note 5, at 39–40.

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developed his inaccurate impressions because of inadequate communication with the patient. The court should not have held that such impressions created an adequate basis for prescribing Butazolidin for the patient.

C. Disclosure Scheme

1. Affirmative Duty to Communicate

Any reasonable standard of disclosure must be based on an affirmative duty to communicate fully. In order to delineate the requirements of adequate communication, it is important to recognize that a nondescript sensing of how “the average, reasonable patient expectably would react” cannot substitute for thorough and meaningful communication between physician and patient. Reading the mind of the patient in order to determine the information pertinent to the patient’s decision is not an adequate standard for the burden of communication. What is needed is a straightforward articulation of a standard of meaningful communication that incorporates the full disclosure that the objective model optimally would require.

246. See supra notes 164–69, 192–95 and accompanying text.

247. This approach presupposes that courts do not indulge in any presumptions, as some courts have, that the medical practitioners have properly discharged their duty. See Watkins v. United States, 482 F. Supp. 1006 (M.D. Tenn. 1980); Finley v. United States, 314 F. Supp. 905 (N.D. Ohio 1970). Such an approach represents unwarranted deference to the medical profession. See supra notes 47–95 and accompanying text. There is no articulated or obvious reason for this deference. See Watkins, 482 F. Supp. at 1012; Finley, 314 F. Supp. at 911. See generally J. Katz, supra note 5, at 1–29. This presumption adds to plaintiff’s burden of persuasion, if not burden of production, and eases defendant physician’s corresponding burdens. The presumption is ultimately another example of the failure of the courts to recognize the basic and fundamental right of self-determination of each individual. For discussion of physicians’ affirmative duty to invite their patients to think with them and to work collaboratively toward a decision, see J. Katz, supra note 5, at 59, 133, 144–47, 211.

248. See Canterbury, 464 F.2d at 787.

249. In fairness to Judge Robinson, author of the court’s opinion in Canterbury, it appears that he did have in mind some notion of communication, for he recognized that a physician could learn enough about the particular patient to determine what information would be material to that patient’s decision. 464 F.2d at 787. Canterbury, however, sets forth a narrowly limited duty to communicate. The physician must communicate, in effect, only with the average, reasonable patient, and not in any meaningful sense with the particular patient. Id. at 787. Further, the physician need make little effort to ensure that the patient understands the communication, and in fact fulfills the duty merely by conveying information without engaging the patient in any meaningful dialogue. Id. at 780 n. 15. Sensing what information would be material to the average patient’s decision is a poor substitute for asking the particular patient what information is important to his or her decision. See Scott v. Bradford, 606 P.2d 554, 559 (Okla. 1979).

250. See supra note 76.

251. See Canterbury, 464 F.2d at 787 (most optimal standard from patient perspective is to require disclosure of potential risk whenever the particular patient would deem it significant in giving an informed consent). Under the duty that objective-patient courts settle upon, the physician is bound to disclose what information reasonable persons would consider material to their decision whether to undergo drug therapy. This does not require the physician to be a mindreader or require disclosure of every risk. Cooper v. Roberts, 220 Pa. Super. 260, 286 A.2d 647, 650 (1971). The Cooper duty is to
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communication must be based on the right of self-determination and bodily integrity of particular patients without undermining those rights by falling back onto a reasonable-patient standard.\(^{252}\)

Thorough, two-way communication benefits both physician and patient. The physician is assured of fair treatment and the communication protects patients’ rights of self-determination and bodily integrity. Moreover, thorough communication almost certainly results in less patient resentment\(^{253}\) and better healing.\(^{254}\)

disclose “all those facts, risks, and alternatives that a reasonable man in the situation which the physician knows or should have known to be the plaintiff’s would deem significant in making a decision to undergo the recommended treatment.” Cooper, 286 A.2d at 650. Nevertheless, the Cooper communication requirement poses as much difficulty as the Canterbury requirement. See supra notes 34, 249. Many, or perhaps even most, physicians do not as a rule make this full disclosure before prescribing drugs, and most patients accept the physician’s judgment that a prescription drug is the appropriate therapy. See supra notes 5–6 and accompanying text. Consequently, the physician most likely perceives the reasonable patient as passive and unquestioning. By adopting the objective standard, a court reinforces the practice of limited, noncommunicative disclosure by an autonomous physician to a passive patient. See, e.g., Boyer v. Smith, No. 80-12109-6, slip op. at 6 (C.P. Bucks County, Pa., Jan. 28, 1985), aff’d, 497 A.2d 646 (Pa. Super. 1985). Just as physicians have a need to take action, and writing a prescription satisfies this need, patients also have a need to have action taken by the physician because they want something in return for the fee being paid. Receiving a prescription satisfies this need. Consequently, not only must physicians learn to ask questions, but they must be persuaded to use that skill and to communicate more readily. Of course, a plaintiff’s verdict in a malpractice lawsuit might begin to educate the physician about the reasonable person concept. But courts have a responsibility to articulate the physician’s duty in easily understandable language before the risk materializes. Communicating with a particular patient is easier for, and fairer to, the physician than having to make a legal determination of what constitutes the reasonable person in a particular medical context.

Although both Canterbury and Cooper recognized the need for physicians to communicate fully with the particular patient, both courts settled for a communication and disclosure standard that defers to professional medical judgment.

\(^{252}\) See J. Katz, supra note 5, at 75–76. As Professor Katz stated:

The whole point of the inquiry [is] to safeguard the right of individual choice, even where it may appear idiosyncratic. Although law generally does not protect a person’s right to be unreasonable and requires reasonably prudent conduct where injury to another may occur, it remains ambiguous about the extent to which prudence can be legally enforced where the potential injury is largely confined to the individual decision maker. For example, courts have split on the question of whether . . . an adult patient may be compelled to undergo unwanted blood transfusions. Id. at 76 (footnotes omitted).

In Canterbury, Judge Robinson recognized the need to move toward a subjective standard, yet chose not to do so for fear of unduly burdening the physician. 464 F.2d at 785. Further, he reintroduced the community-medical standard by declaring that when medical judgment enters the picture, prevailing medical practice must be given its just due. Id. However, he failed to set out the meaning or limits of “just due.” “[I]f the grand rhetoric of self-determination is to have meaning, framing the question in terms of the reasonable person grossly and unnecessarily substitutes judicial paternalism at a critically wrong point.” J. Katz, supra note 5, at 77; see also Scott v. Bradford, 606 P.2d 554 (Okla. 1979).

\(^{253}\) It appears that less patient resentment would reduce, perhaps significantly, the number of medical malpractice suits filed. N. Cousins, supra note 139, at 162–63; J. Katz, supra note 5, at 209–10; E. Mischler, supra note 120, at 106, 117; T. Preston, supra note 49, at 190–91; S. Sagov, supra note 47, at 125; J. Stein, supra note 99, at 98–99; see also J. Katz, supra note 5, at 114

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2. The Communication Process

In any case where the physician determines that a prescription drug is a possible, recommended, or preferred mode of treatment, the legal standard should require the physician to determine the spectrum of prescription drugs that could be used. In many cases, numerous drugs could be employed within a range going from barely effective (but safe) to extremely effective (but relatively dangerous). The physician must also identify, where possible, the least potent and least dangerous as well as the most potent and most dangerous of the available drugs, and determine the risks and hazards of each by consulting the PDR or other reliable and readily available source of such information.

In addition to considering alternative drugs, any meaningful consent to prescription drug therapy presupposes that the patient understands the alternatives to drug therapy, including diet, surgery, or even no treatment. Thus, the physician must determine alternative treatment (and nontreatment) methods as well as the significant risks associated with those alternatives.

(subsequent disagreements between physician and patient will be less disturbing).

Even if informed consent liability makes a physician act only for self-preservation, the final result will be the same as if the physician's actions were motivated by a concern for patient welfare. The patient benefits, through better health care, realistic expectations of the treatment, and increased confidence and trust in the physician; the physician benefits through fewer lawsuits. See generally Comment, Informed Consent in Medical Malpractice, 55 CAL. L. REV. 1396 (1967); Meisel, The Expansion of Liability For Medical Accidents: From Negligence to Strict Liability by Way of Informed Consent, 56 Neb. L. REV. 51 (1977). "Defensive medicine," however, does have its drawbacks, and is not an acceptable substitute for open, meaningful communication. Defensive medicine results in overtreating and overtesting, both at considerable cost to the patient. "Since doctors who are sued tend to have had poor relationships with their patients from the beginning, it seems that . . . a close, personal, and friendly doctor-patient relationship is the best preventive measure." S. Sagov, supra note 47, at 124-25.

Patients who are not adequately informed prior to a procedure or a treatment tend to do poorly afterwards when compared to patients who received adequate information. See generally McHugh, Christman & Johnson, Preparatory Information: What Helps and Why, 1982 AM. J. NURSING 780.

Patients who are better informed have a realistic idea of what to expect and are not surprised or confused by an unexpected reaction to the drug. See 1 President's Commission, supra note 96, at 153f; M. Belsky & L. Gross, supra note 116, at 139; E. Mischler, supra note 120, at 128 n.81; T. Preston, supra note 49, at 24; S. Sagov, supra note 47, at xx.

See supra notes 133-37 and accompanying text.

See supra notes 122-32 and accompanying text. For example, in Boyer, the prescribing physician did identify the most potent drug, but failed to go further and share that information with the patient. Boyer v. Smith, No. 80-12190-6, slip op. at 5 (C.P. Bucks County, Pa., Jan. 28, 1985), aff'd, 497 A.2d 646 (Pa. Super. 1985). Although the defendant physician in Boyer did not consult the PDR prior to prescribing Butazolidin for plaintiff, id. at 6, it is likely there are cases where the physician knows a particular drug, as well as its alternatives and the side effects of each, thoroughly enough to be able to proceed without consulting the PDR. Such a situation is probably more rare, however, than most physicians would admit.

See supra notes 122-32, 140-52 and accompanying text.
Before communicating medical and nonmedical choices to patients, physicians have a duty to consider both the standard medical history and medical idiosyncrasies (for example allergies, age, and sex) and to consider the nonmedical history, background, and idiosyncrasies of each patient (for example the patient’s personal health habits including whether the patient is a smoker, drinker, or drug user). Nonmedical idiosyncrasies have an important bearing on the individual’s treatment preferences. Some patients have a high level of curiosity and special concern about health. This concern often prompts these patients to stop smoking, to avoid or reduce the consumption of alcohol, and to monitor diet very carefully as to salt, sugar, fat, chemical additives, and caffeine. Such patients might well have some thoughts and feelings about prescription drug therapy that the physician ought to take into consideration during any discussion of alternatives and risks.

Having considered both the prescription drug and nondrug therapeutic alternatives, including no present treatment, and having become familiar with the particular patient’s idiosyncrasies, both medical and nonmedical, the physician is in a position to disclose all the treatment alternatives and the risks associated with them that might be significant to the particular patient. Based on the patient’s medical history and particular concerns, habits, and idiosyncrasies, the physician should enumerate all of the

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258. See supra notes 138–40 and accompanying text; President’s Commission, supra note 96, at 38–39, 71, 154; J. Katz, supra note 5, at 78, 82–83.

259. The study of nutrition seems to be of little importance in the medical school curriculum. See N. Cousins, supra note 103, at 114–15, 117. However, enough is known about the relationship between diet and health that physicians have dietary choices available as alternatives to drug therapy in a variety of situations, id. at 114, including diet and exercise as an alternative treatment for diabetes and handling stress.


261. See supra notes 249–51 and accompanying text. The test for whether the physician has disclosed all the necessary facts, risks, and alternatives necessary to the reasonable plaintiff's decision, the so-called “materiality" test, is sometimes stated in terms of what information the plaintiff would deem to be “significant” in making the consent. See Cooper v. Roberts, 220 Pa. Super. 260, 286 A.2d 647, 650 (1971). In Canterbury, Judge Robinson seems to prefer the word “material." 464 F.2d 772, 787 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972). However, the courts in Cooper and Canterbury have in mind the same test. The materiality test, which they apply to the reasonable patient, can apply more readily to a particular patient, but with additional emphasis on “alternatives," including no treatment. See supra notes 237–38; see also Cooper, 286 A.2d at 651. If there is a significant difference between the Cooper and Canterbury application of the materiality test it is that Canterbury seems to focus more on “risks" with little or no reference to additional "facts" and "alternatives." Canterbury, 464 F.2d at 779. On the other hand, Cooper focuses more on additional facts and alternatives. 286 A.2d at 650.
alternatives that would likely affect the patient's choice of therapy. There are, of course, exceptional circumstances in which the physician would be justified in withholding certain information from particular patients. These exceptions, or "privileges," have been clearly defined in numerous court decisions. Finally, the physician must determine whether the patient is able to make an informed choice. To meet this responsibility, the physician need only inquire, by means of a brief dialogue, whether the patient sufficiently understands each alternative and its attendant risks.

3. Elements of a Claim

To claim lack of informed consent in a prescription drug case, a plaintiff should have to establish the same elements required for other claims of lack of informed consent—duty, breach, causation (both in fact and proximate), and damages. In a prescription drug case, however, particular elements ought to be given special emphasis because of the unique nature of prescription drug therapy.

The obligation of the physician is to communicate and not merely to disclose risks. The duty to communicate in a meaningful fashion, taking into consideration the unique aspects of prescription drug therapy, 262 The most commonly used exceptions to disclosure include: (1) nondisclosure of a risk which was not reasonably foreseeable and not inherent in the procedure; (2) the therapeutic privilege (full disclosure would be detrimental to the patient's best interests); (3) nondisclosure of commonly known risks that the patient will be presumed to already know; (4) no disclosure is required where the patient explicitly requests to be told no information; and (5) a physician need not disclose the various alternatives and risks in an emergency situation. E.g., Holt v. Nelson, 11 Wn. App. 230, 240-41, 523 P.2d 211, 218-19 (1974).

Physicians sometimes argue that an "active practice" precludes meaningful dialogue with patients, and courts sometimes seem to accept that argument. See Kaiser v. Suburban Transp. Sys., 65 Wn.2d 461, 469, 398 P.2d 14, 19 (1965). But see Katz, supra note 22, at 159-60 (physicians do not have to "sense" or "second guess" how the patient will react; instead physicians should explore what questions need further explanation); Trichter & Lewis, supra note 54, at 165-66 (enhanced informational flow substantially increases the physician's opportunities to learn a patient's history, physical condition, and mental state).

See supra notes 94-152 and accompanying text.

5. Katz, supra note 5, at 23 (only the individual knows).

When patients have a relationship based upon confidence and honesty with their physicians, and when, through this increased communication, patients have a better understanding of the treatment, studies have shown patients do better. See generally McHugh, supra note 254; Meisel, supra note 253. The patient has realistic expectations of the treatment's effects and won't be shocked by an unknown side effect. Further, by increasing the quality of communication the number of malpractice suits brought should decline. See supra notes 253-54. At a decreased risk of being sued, physicians would be encouraged to treat high-risk patients and to practice less defensive medicine. Lack of information is often a precipitating factor in treatment refusals by patients. Patients who discover that certain procedures are potentially very risky refuse treatment until reasonable justification and more information is provided. President's Commission, supra note 96, at 80.

See supra notes 94-152 and accompanying text.
ultimately rests on the rights of bodily integrity and self-determination of the patient as an individual, not as a reasonable or average person.267

A breach of the prescribing physician’s duty consists of any failure to communicate with the patient in a meaningful fashion.268 Meaningful communication requires the physician to discuss with the patient each of the following considerations: all prescription drug alternatives; all other alternative therapies, including no treatment; the risks of each alternative; and the particular patient’s idiosyncratic needs, desires, and preferences, both medical and nonmedical. A failure to communicate regarding any one of the required considerations would constitute a breach of the prescribing physician’s duty.

The causation element of a plaintiff’s claim has two parts: causation in fact and proximate causation. Causation in fact is in reality medical causation, established by proof that the drug in fact caused the plaintiff’s injury.269

267. See supra notes 15–21 and accompanying text.

268. See supra notes 34, 64–69, 72–74, 85–86 and accompanying text.

On the other hand, the community-medical standard requires the use of expert testimony to establish what would constitute a breach of the duty to communicate. The physician is liable only for violating this medical-community standard. See, e.g., Watkins v. United States, 482 F. Supp. 1006 (M.D. Tenn. 1980) (community medical standard plus a presumption of due care on the part of the physician); Finley v. United States, 314 F. Supp. 905 (N.D. Ohio 1970) (diagnosis is technical and specialized subject matter on which expert testimony is necessary to establish standards of proper conduct, but expert testimony is not necessary when physician’s negligence has been so gross it requires only common knowledge to understand); Calabrese v. Trenton State College, 162 N.J. Super. 145, 392 A.2d 600 (1978) (adequacy of disclosure determined by expert testimony; the plaintiff also employs expert testimony); Koury v. Follo, 272 N.C. 366, 158 S.E.2d 548 (1968); Kaiser v. Suburban Transp. Sys., 65 Wn. 2d 461, 464, 398 P.2d 14, 16 (1965). With the introduction of the objective “reasonable” patient standard, expert testimony as to the prevailing community medical standard is no longer necessary or controlling. See, e.g., Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972); Cobbs v. Grant, 8 Cal. 3d 229, 104 Cal. Rptr. 505, 502 P.2d 1 (1972); Hamilton v. Hardy, 37 Colo. App. 375, 549 P.2d 1099 (1976); Wilkinson v. Vessy, 110 R.I. 606, 295 A.2d 676 (1972); Hunter v. Brown, 4 Wn. App. 899, 484 P.2d 162 (1971); Trogun v. Fruchtman, 58 Wis. 2d 396, 297 N.W.2d 297 (1973). However, expert testimony may be used to establish the prevailing community-medical standard, which the defendant physician may raise as a defense. See, e.g., Niblack v. United States, 438 F. Supp. 383 (D. Colo. 1977) (physician may raise community-medical standard and therapeutic privilege as a defense); Hunter v. Brown, 4 Wn. App. at 907, 484 P.2d at 1165–67 (the medical standard might be relevant and material in persuading the trier of facts that the surgeon disclosed all facts that his patient should know for purposes of informed consent, and such evidence should be weighed as any other evidence and be judged by “reasonable man” standards of conduct).


269. Typically, this proof requires expert medical testimony. See Finley v. United States, 314 F. Supp. 905, 910 (N.D. Ohio 1970) (diagnosis is a technical and specialized subject matter on which expert testimony is necessary to establish standards of proper conduct); Calabrese v. Trenton State College, 162 N.J. Super. 145, 392 A.2d 600 (1978) (the plaintiff must use expert testimony to establish that the treatment used had certain risks).
The proximate cause element of a plaintiff's claim relates directly to the validity of the consent. The question is whether plaintiff would have consented to the drug therapy had adequate disclosure and discussion been provided by the prescribing physician. Aside from the issue of whether it is the particular plaintiff or the reasonable person who would have consented, use of the subjective patient (particular plaintiff) standard raises the additional question of the admissibility of plaintiff's hindsight testimony. If courts exclude plaintiff's testimony on this point, little evidence would be available to the plaintiff for proving proximate cause.

270. See, e.g., Canterbury, 464 F.2d at 790 (court found a causal connection existed only when disclosure of significant risks incidental to treatment would have resulted in a decision against treatment by a prudent person in the patient's position); McPherson v. Ellis, 305 N.C. 266, 272, 287 S.E.2d 892, 896 (1982) (court stated that subjective standard required the jury to determine whether, if informed, this particular patient would have foregone treatment); Holt v. Nelson, 11 Wn. App. 230, 236, 523 P.2d 211, 216 (1974) (causal connection exists between physician's failure to inform the patient of risks involved and injury suffered by the plaintiff only when disclosure of significant risks incidental to treatment would have resulted in a decision against treatment, with the patient's testimony being relevant, but not controlling); see also Niblack v. United States, 438 F. Supp. 383, 389 (D. Colo. 1977) (physician's failure to warn patient of possible side effects of proposed treatment was not the proximate cause of injuries suffered by the patient because of these side effects, where even if the patient had been adequately informed of the risk of these side effects, he would not reasonably have rejected the treatment); Sharpe v. Pugh, 270 N.C. 598, 155 S.E.2d 108, 113 (1967) (subjective standard); Kaiser v. Suburban Transp. Sys., 65 Wn. 2d 461, 465, 398 P.2d 14, 16 (1965) (discussion of intervening acts); Trogun v. Fruchtman, 58 Wis. 2d 596, 207 N.W.2d 297, 315 (1973) (objective standard).

271. See supra notes 10, 22, 30-45, 67-76, and accompanying text.

272. It is obviously self-serving for plaintiff to state, after suffering an injury caused by a prescription drug, that had there been adequate communication by the physician, plaintiff would not have taken the drug. Canterbury v. Spence, 464 F.2d 772, 790 (D.C. Cir.) (plaintiff's testimony hardly represents more than a guess, perhaps tinged by the circumstances that the uncommunicated hazard had materialized), cert. denied, 409 U.S. 1064 (1972); Scaria v. St. Paul Fire & Marine Ins., 68 Wis. 2d 1, 227 N.W.2d 647, 654 (1975) (hindsight testimony places the physician in jeopardy of the patient's bitterness and places the fact finder in the position of deciding whether a speculative answer to a hypothetical question is to be credited); see also Niblack v. United States, 438 F. Supp. 383, 389 (D. Colo. 1977); Cobbs v. Grant, 8 Cal. 3d 229, 104 Cal. Rptr. 505, 502 P.2d 1, 11 (1972); Hamilton v. Hardy, 37 Colo. App. 375, 549 P.2d 1099, 1105 (1976) (self-serving, speculative, and subjective). Plaintiff's self-serving testimony would also seem to have no relevance in a case where an objective, reasonable patient standard was being used. Nonetheless, some courts do allow it in the prescription drug context, even where an objective standard is used. See, e.g., Canterbury, 464 F.2d at 791. Although the relevance objection is not present where the particular patient standard is used (see Scott v. Bradford, 606 P.2d 554, 558-59 (Okla. 1979)), the objection to the testimony as speculation and conjecture is still valid.

273. It is conceivable that objective testimony, either by plaintiff, or by persons who know plaintiff, concerning plaintiff's health habits and concerns, or about plaintiff's minor condition (e.g., mild pain) might constitute a sufficient basis upon which the jury could conclude that the particular patient would not have consented had adequate communication been made. This situation, however, would appear to be the exception. In most cases it seems likely that plaintiff could offer little or no admissible evidence on this point.
Courts could solve this evidentiary dilemma by creating a presumption that the particular plaintiff would not have consented had adequate communication been made.274 This presumption would protect plaintiff's dignitary interest,275 which is the essential component of plaintiff's rights of self-determination and bodily integrity. Courts should view the dignitary interest as the paramount interest to be protected.276 Creating the presumption that plaintiff would not have consented but for the physician's failure to communicate adequately appears, on its face, to prejudice the interest of the defendant physician. However, the courts must begin to focus not on the privileges of physicians, but on the rights of patients, which courts have recognized only by lip service277 and have, in fact, left unprotected.278 In fairness to physicians, the presumption ought to be rebuttable. Although

274. The presumption would arise only after plaintiff had introduced evidence from which a jury could reasonably find that the communication was so inadequate as to constitute a breach of the physician's duty. See supra notes 81–85 and accompanying text; infra note 281 and accompanying text. A similar presumption exists in the securities fraud context, where the plaintiff need not subjectively prove the causation element, but rather a "presumption" of reliance may be raised. See Blackie v. Barrack, 524 F.2d 891, 906 n.22 (9th Cir. 1975). The Blackie court concluded that causation is adequately established by proof of purchase and of the materiality of misrepresentations, without direct proof of reliance. 524 F.2d at 906. The misrepresentations are material in the sense that a reasonable investor might have considered them important in decisionmaking. Once causation has been established by this presumption, the burden shifts to the defendant to disprove the prima facie case of causation in one of two ways: (1) by disproving materiality or (2) by proving that an individual purchased despite knowledge of misrepresentation, or that the purchase still would have been made despite disclosure. Id.

An alternative solution to this evidentiary dilemma in the prescription drug context is the use of expert (psychiatrist or psychologist) testimony that given plaintiff's psychological makeup, plaintiff would not have consented to using the drug had adequate communication been made. Even assuming that expert opinion is admissible to predict future or hypothetical behavior, which seems a questionable assumption, the procedure would add a cumbersome and expensive element to plaintiff's claim without protecting plaintiff's rights of self-determination and bodily integrity. See supra notes 15–21, 46 and accompanying text.

275. Plaintiff's dignitary interest is clearly not protected if an objective, reasonable-patient standard is applied to the causation test. See Scott v. Bradford, 606 P.2d 554, 557–59 (Okla. 1979); see also supra note 46 and accompanying text. Moreover, the dignitary interest is also not protected even if a subjective standard is used since there appears to be an insurmountable evidentiary barrier to proving an element of plaintiff's claim. See supra note 273.

276. See supra notes 15–21, 46 and accompanying text.

277. J. Katz, supra note 5, at 77–80, 83, 84. There is in this society public policy designed to encourage doctors to render aid and assistance, and to protect them when doing so, as evidenced by the "Good Samaritan Statutes." A general policy to promote individual health, however, can hardly be the basis for overriding the traditional common law rights of self-determination and bodily integrity. See supra notes 15–21 and accompanying text. These individual rights, given essential protection by the doctrine of informed consent, do not compete with or contradict the policy of promoting individual health. Informed consent, and the accompanying physician-patient communication, may in fact promote rather than interfere with better individual health care. See supra note 254.

278. See supra notes 47–93, 151–233 and accompanying text. Use of the proximate cause presumption has the additional benefit of preserving the integrity of the rules of evidence. See supra notes 272–73 and accompanying text.
rebutting the presumption would not be easy, if the patient can prove every other element of the claim, a rebuttable presumption of proximate cause does not create a basic unfairness.

The patient ought to be required to prove physical or emotional injury in order to recover on an informed consent claim. Since courts can adequately protect the patient's dignitary interest by the rebuttable presumption of no consent, continuing to require plaintiffs to prove actual damages does not significantly prejudice any interest of the patient. Moreover, the actual damage requirement should protect physicians from patient harassment. Elimination of the plaintiffs' burden to prove actual damages might result in a dramatic increase in frivolous claims.

V. CONCLUSION

Undoubtedly, contemporary medical technology, and especially prescription drugs, provide extensive benefits to patients. However, these benefits are offset, both qualitatively and quantitatively, by the risk of dangerous side effects created by that same technology. One can understand why medical practitioners have a preference for the technological solution to medical problems. Prescribing a drug, for example, focuses the patient on a specific, medical concern and creates an expectation that as a matter of course the illness will be cured. The physician can thereby avoid having to interact with the patient as a person and as a consequence spend less time with each patient in the "active practice." This approach to medicine, and specifically to prescription drug therapy, does not ensure

279. See supra note 262.
280. If plaintiff's dignitary interest is to be given adequate protection, the presumption probably ought to be rebuttable in only the exceptional case. Defendants ought to be able to rebut the presumption where they can clearly prove that the patient would still have consented after being fully informed. See supra note 274. The patient could certainly waive any rights to be informed, for example, and presumably proof thereof would rebut the presumption. See supra note 262. In any event, any unfairness to the physician is far outweighed by the gross infringement of the patient's fundamental rights of self-determination and bodily integrity that now occurs under the present standards of informed consent. See supra notes 86–90 and accompanying text.
281. Arguably, to give full recognition to the patient's dignitary interest, the patient ought to be able to recover without proof of any physical or emotional injury. See J. Katz, supra note 5, at 79. A recovery in such a case, however, would be unfairly punitive.
282. See supra notes 102–05, 122–32, 141–52 and accompanying text.
283. See N. Cousins, supra note 103, at 134–35 (increasing technology pushing the physician further away from the patient); see also infra note 284 and accompanying text.
284. This expectation arises as a result of the patient's strong need for treatment. See Hearings, supra note 98, at 1303. In addition, writing a prescription is often an "easy-out" for a physician. See Wartman, supra note 96 (prescriptions often result from the assumption that it is a concrete, definable action that should be the natural outcome of a visit to a physician).
happier patients, better healing, better medicine in general, or adequate protection of a patient's rights of self-determination and bodily integrity. The counterpart to technological medicine lies essentially in better communication by physicians. Such communication will not take place, however, until courts adopt a subjective model of informed consent. It has been too easy for physicians to think of treatment solely in terms of the disease and selecting the best remedy based on incomplete medical criteria.

Courts have confused the question whether a patient or a jury can grasp technicalities of medical science with the separate question whether the treatment decision should be made by the physician and patient on the basis of factors that physicians must get from the patient, not from their medical training and background. This confusion results in protection for physicians and their expertise through the medical-community standard. Little incentive is left for physicians to change their practice in a manner that would give protection to patients' rights of self-determination and bodily integrity.

Only courts can recognize the rights of individual patients and give meaning to those rights by fashioning a clear, unequivocal, and fair duty of informed consent. Courts must set forth the physician's duty to obtain an informed consent in the prescription drug context by focusing on the particular patient with regard to both the scope of the duty and proximate cause. Until courts place physicians under a duty to inform, judicial opinions will continue to perpetuate medical autonomy at the expense of individual liberty. Without judicial intervention, patients' rights of self-determination and bodily integrity, as well as the intangible dignitary interest, will continue to be little more than empty promises.

285. See supra notes 15–21, 46, 96–115, 138–40 and accompanying text; see also 2 President's Commission, supra note 96, at 86 table 2-23 (only 35% of the public is very satisfied with their doctor); M. Belsky & L. Gross, supra note 116, at 139; J. Katz, supra note 5, at 209, 210, 212; E. Mischler, supra note 120, at 106, 128; S. Sagov, supra note 47, at 125; J. Stein, supra note 99, at 98–99.

286. J. Katz, supra note 5, at 82–84; R. Mendelsohn, supra note 5, at 78; T. Preston, supra note 49, at 155; R. Mendelsohn, supra note 99, at 173–83.

287. N. Cousins, supra note 103, at 111; J. Katz, supra note 5, at 28–29; R. Mendelsohn, supra note 99, at 173–83; see supra notes 15–21 and accompanying text.
