The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research

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This article examines the legal status of "soft law" in the fields of medicine and medical research. Many areas of clinical practice and research involve complex and rapidly changing issues for which the law provides no guidance. Instead, guidance for physicians and researchers comes from what has often been called "soft law"—non-legislative, non-regulatory sources, such as ethics policy statements, codes, and guidelines from professional or quasi-governmental bodies.

This article traces the evolution of these "soft law" instruments: how they are created, how they are adopted within the professional community, and how they become accepted by the courts. It studies the relationship between soft law instruments and the courts. It includes an examination of the approaches to judicial analysis used by the courts in theory and in practice. The authors then examine the jurisprudence to see how courts will adopt professional norms as the legal standard of care in some circumstances and not others. They consider the legal concerns and ethical issues surrounding the weight attached to professional practices and norms in law. The authors demonstrate how practices and policies that guide professional conduct may ultimately bear weight as norms recognizable and enforceable within the legal sphere.

Cet article étudie le statut juridique du *soft law* en médecine et en recherche médicale. Plusieurs domaines de pratique clinique et de recherche subissent des changements rapides et complexes auxquels le droit n'est pas toujours en mesure de donner une réponse adéquate. Les médecins et les chercheurs se réfèrent donc à ce qu'on appelle communément *soft law*, c'est-à-dire des sources non législatives et non réglementaires telles que les déclarations de politique en matière d'éthique, les communiqués, les codes et les lignes directrices des organismes professionnels ou para-gouvernementaux.

Cet article étudie l'évolution des ces instruments de *soft law* en analysant leur mode de création et la façon dont ils sont acceptés par la communauté professionnelle puis par les tribunaux. Les auteures étudient la relation qu'ont les tribunaux avec les instruments de *soft law* et les approches d'analyse judiciaire qu'ils utilisent. Elles examinent également la jurisprudence pour étudier la façon dont les tribunaux adoptent des normes professionnelles afin d'évaluer l'étendue du devoir de prudence dans certaines situations. L'article aborde les questions juridiques et éthiques soulevées par l'importance accordée par le droit aux normes et pratiques professionnelles, et montre comment les pratiques et les politiques qui dirigent la conduite professionnelle peuvent devenir des normes reconnues par le droit.

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Revue de droit de McGill 2001
To be cited as: (2001) 46 McGill L.J. 473
Mode de référence : (2001) 46 R.D. McGill 473

Introduction

The law affects and regulates much of clinical medicine and research in a number of ways. A significant body of legislation and case law deals with issues such as privacy, confidentiality, liberty and security of the person, discrimination, competence to make choices, and disclosure of information for purposes of consent. Yet there are many situations faced by practitioners, investigators, patients, and research subjects that go beyond the scope of current law. Much of the guidance in dealing with complex issues comes from sources such as clinical and ethics policy statements, codes, and guidelines, which are meant to affect positively the conduct of medical practitioners and clinical investigators. Every medical professional is familiar with some of these, not the least of which is a code of ethics created by a professional organization, directing the behaviour of doctors, nurses, and other health care professionals. Other documents come from specialty societies and national and international organizations. A number of guidelines, codes, and policies trace their roots to governments, and are drafted by commissions or government-created agencies. They may deal in a general way with such issues as confidentiality of an individual's medical record, or they may refer to specific issues, such as the creation of human embryos for research.

I. Policies, Codes, and Guidelines as "Soft Law"

Ethics rests primarily on the voluntary actions of individuals, guided by their own consciences, whereas law is a collectively articulated set of rules backed by the state's power to coerce and sanction. In the areas of clinical practice and research, the law provides only the most general kinds of instruction or prohibition, and is only infrequently brought to bear to correct behaviour.[1] The role of ethics policies, codes, and guidelines in legal culture is ambiguous. When they overlap with existing law or are adopted by legislators in statutes or regulations, it is clear that they represent "legal standards" or "legal norms" and are binding in judicial decision making. Standards that are not enacted in law or regulation, however, do not have a definitive legal status, even though they may affect the behaviour of health care professionals.

This body of policies, codes, and guidelines has been referred to as "soft law" because of its uncertain legal status. When the "soft law" at issue deals with professional, rather than social, standards of conduct, the question of how it should be applied by a court becomes even more complex. Because the policies, codes, and guidelines have not been accepted in law or regulations, it may be argued that they are not binding on a court. Judges may therefore disregard "soft law" if the standards set by it are inadequate for ensuring that reasonable care and diligence are exercised in the

[1] See A.M. Capron, "Research Ethics and the Law" (1983) 128 Prog. Clinical & Biological Res. 13.

execution of professional responsibilities. The counter-argument is that professional "soft law" should be shown deference by a court, given that judges do not usually have sufficient expertise in the field from which the standard emanates and thus are not fit to substitute their own views for professional opinion.

This article provides an analysis of the legal status of "soft law" in medicine and medical research. Many areas of clinical practice and research involve complex and rapidly changing issues for which the law provides no guidance. In this context, guidance for physicians and researchers often comes from non-legislative, non-regulatory sources, such as ethics policy statements, codes, and guidelines from professional or quasi-governmental bodies. Clarification of their legal status is thus an important issue. As such, our work is devoted to tracing the evolution of these "soft law" instruments: how they are created, how they are adopted within the professional community, and how they become accepted by the courts. This analysis aims to demonstrate how practices and policies that guide professional conduct may ultimately bear weight as norms recognizable and enforceable within the legal sphere.

II. Creation of Policies, Codes of Conduct, and Guidelines

The role of policies and guidelines is intimately connected to the history of professional self-regulation. For certain professions, most notably law and medicine, self-regulation dates back to the medieval period, when no central government existed to dictate codes of conduct for professional groups. Instead, norms concerning acceptable practice were established by members of the professions themselves.[2] In the medical context, individual physicians functioned as "professionals" and as "entrepreneurs" before health care systems were financed by the state. Their decisions, both clinically and economically based, were subject to scrutiny only from the medical profession, and in the nineteenth century, from peer review and licensing bodies.[3]

In modern times the state has become the central authority for the regulation of professional groups. Nevertheless, a key characteristic of professionalism, even by today's standards, is the power to control professional conduct privately. That is, although the collective authority of the professional group is now granted and delimited by the state, the autonomy of the individual practitioner within this group is regulated by the profession itself.[4] In this way, it is clear that self-regulation remains an important reality for many professional groups, including those in the medical community.

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[2] See J.K. Lieberman, "Some Reflections on Self-Regulation" in P. Slayton & M.J. Trebilcock, eds., *The Professions and Public Policy* (Toronto: University of Toronto Press, 1978) 89 at 91.

[3] C. Tuohy & P. O'Reilly, "Professionalism in the Welfare State" (1992) 27 J. Can. Stud. 73.

[4] See *ibid.* at 75, 84.

One of the primary ways that self-regulation is achieved today is through the development of practice guidelines that establish normative standards of conduct for members of a professional community. It is therefore not surprising that most of these guidelines have traditionally been developed by associations of particular professional groups. In addition, licensing bodies, accreditation bodies, specialty societies, governments, and private sector insurers have also engaged in the formulation of professional guidelines, although to a lesser extent.[5] According to LeBlang, practice guidelines in the field of medicine aim to establish the legal standard of care. It is believed that, by adhering to this standard, health care workers will be able to defend themselves against malpractice claims.[6]

Medical practice guidelines may, however, serve purposes other than simply providing legal protection to practitioners in the field. For example, they may also exist to serve the interests of patients, research subjects, or both. Guidelines and codes inform patients and subjects of the conduct that the professional must follow in his or her practice. This empowers those who may otherwise be unaware of their rights regarding treatment or participation in research. According to Brook, access to guidelines that contain appropriateness ratings of particular treatment procedures would allow physicians to ensure quality health care for their patients. He maintains that medical literature must become more specific and directive, and that this can be achieved through the dissemination of medical practice guidelines.[7]

Improving the quality of health care may be another incentive for the development of guidelines. A 1992 report of the U.S. National Academy of Science's Institute of Medicine identified six aspects with which practice guidelines should be concerned.[8] Each of these is related to the goal of providing better health care. These include cost control, quality assurance, access to health care, patient empowerment, professional autonomy, medical liability, and management and rationalization issues.

Once issued, a guideline will be ineffective in fulfilling any of the objectives listed here until it gains normative status, that is, until it is perceived as establishing how professional practice must be executed. The following discussion examines how a guideline becomes normative within the profession, and how it may subsequently become binding in the legal community.

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[5] See R.N. Battista, "Clinical Practice Guidelines: Between Science and Art" (1993) 148 Can. Med. Ass'n J. 385 at 386.

[6] See T.R. LeBlang, "Medical Malpractice and Physician Accountability: Trends in the Courts and Legislative Responses" (1994) 3 Ann. Health L. 105 at 118-20.

[7] See R.H. Brook, "Practice Guidelines and Practicing Medicine: Are They Compatible?" (1989) 262 J.A.M.A. 2037.

[8] Institute of Medicine (U.S.), Committee on Clinical Practice Guidelines, *Guidelines for Clinical Practice: From Development to Use* (Washington, D.C.: National Academy Press, 1992) at 1-22, as cited in Battista, *supra* note 5.

III. Development as a Professional Norm

Guidelines are created to produce an "authoritative reference point" codifying conduct recognized as good practice, as well as accepted changes in an evolving area of a profession.[9] It is only when professionals in the field agree that a standard is a "scientific principle" governing the proper performance of their duties that they will perceive the standard as imperative.[10] Thus, the guideline becomes normative when it endorses accepted and followed professional practice.

This theory is supported by research conducted by Smith and Herbert that aimed to determine the impact of the recommendations issued by the Canadian Task Force on Periodic Health Examination upon the current practice of preventive medicine in British Columbia.[11] The study revealed that only those recommendations which complied with traditional and recommended practice were followed. Recommendations prescribing new manoeuvres were not adhered to, as physicians elected to continue to perform traditional practices known to be accepted in the professional community.

Professional custom and behaviour might seem to be more persuasive than a written guideline in establishing professional norms. Rather than directing customary practice, effective guidelines could be a consequence of professional custom and behaviour, developed only after a practice or particular change to it has been accepted and adhered to by the professional community. For instance, Brook advocates the creation of an institution specifically geared towards the development and testing of practice guidelines. Although this independent organization would formulate the guidelines, Brook states that, before being used, the guidelines must be "either strongly considered by the profession or supported by the literature as resulting in better health."[12] This analysis implies that physicians and researchers will meet the professional standard of care if their conduct satisfies accepted professional conduct.

Yet if practice guidelines merely codify customary professional practice, one may question whether they ever result in changing professional norms.[13] Where guidelines deal with a practice new to the profession or a practice accepted by some members of the profession but rejected by another school, they may effect some change to the practice. In these circumstances, however, the creation of the guideline must be accom-

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[9] See J. Chalmers, "Guidelines and Consensus Statements: Their Use and Impact" (1995) 9 J. Hum. Hypertension 37 at 38.

[10] A. Lajoie, "La normativité professionnelle dans le droit: trajets et spécificité formelle" (1995) 16 Droit & Société 159 at 170-71.

[11] H.E. Smith & C.P. Herbert, "Preventive Practice among Primary Care Physicians in British Columbia: Relation to Recommendations of the Canadian Task Force on the Periodic Health Examination" (1993) 149 Can. Med. Ass'n J. 1795.

[12] Brook, *supra* note 7 at 3030.

[13] Lajoie, *supra* note 10 at 187.

panied by other factors for it to acquire normative status. For instance, guidelines must be widely disseminated to bring them to the attention of professionals in the field and to allow for a discourse on whether they should affect current professional practice.[14]

More important to the status of guidelines, however, are the social and economic incentives and disincentives that may affect medical practice. Such factors determine whether professionals accept practice guidelines or codes of conduct and to what degree they will modify their professional conduct according to them.[15] For example, in a study conducted by Lomas, physicians were often reluctant to modify their practice after a guideline had been issued. This was due, in large part, to a perceived threat of malpractice suits against them for following a practice that had not yet been accepted within the profession. Other disincentives to implementing a guideline included patient pressure as well as explicit hospital policies that conflicted with the practice recommended in the guideline. These socio-economic factors usually act as deterrents to the acceptance of guidelines that prescribe practices yet to be employed by a professional community. In such circumstances, they rarely succeed in altering professional practice and thus do not become normative, even at the professional level.[16]

A study completed by Browman *et al.* identified an eight-step process through which guidelines are developed and implemented. This research revealed a widespread enthusiasm for guidelines, but only a minimal impact on actual clinical practices. The authors suggested that this may have resulted from a perception among physicians that guidelines challenge their autonomy in clinical decision making or that guidelines fail to consider the specific elements of daily practice.[17] Other disincentives to the implementation of some guidelines may pertain to the practicability of the prescribed procedures. For instance, where a practice recommended by the guideline has not been proven to be of any definite benefit to the patient, physicians may be reluctant to perform this manoeuvre.[18]

Therefore, generally speaking, members of a profession will accept a policy, guideline, or code of conduct as establishing the standard of care only when it endorses conduct that is already widely accepted and practiced. The guideline is then

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[14] J. Lomas, "Words without Action? The Production, Dissemination and Impact of Consensus Recommendations" (1991) 12 Ann. Rev. Pub. Health 41 at 55ff. See also Smith & Herbert, *supra* note 11 at 1799.

[15] J. Lomas, "Do Practice Guidelines Guide Practice? The Effect of a Consensus Statement on the Practice of Physicians" (1989) 321 New England J. Med. 1306 [hereinafter "Do Practice Guidelines Guide Practice?"]. See also Lajoie, *supra* note 10.

[16] "Do Practice Guidelines Guide Practice?", *ibid.*

[17] See G.P. Browman *et al.*, "The Practice Guideline's Development Cycle: A Conceptual Tool for Practice Guidelines Development and Implementation" (1995) 13 J. Clinical Oncology 502 at 509.

[18] Smith & Herbert, *supra* note 11 at 1978.

ascribed normative status, as members of the profession recognize it as the standard of care to which they must adhere in the exercise of their professional responsibilities.

IV. Development as a Legal Norm

A. Judicial Analysis of Professional Norms

Once a guideline is established as a professional norm, does it have normative status in the legal context? Could a policy adopted by the American or Canadian College of Medical Genetics ever have the normative force of law? Do clinical guidelines, the opinions of expert witnesses called to testify about the accepted standard of care within the professional community, or both bind the court? If so, professional norms or codes of conduct, as presented in written guidelines or through expert testimony, would automatically represent the legal standard of care.

Judicial analysis of professional responsibility, however, involves more than merely invoking and following current professional opinion about what is acceptable practice. Rather, courts will scrutinize and challenge these professional standards to ensure that they are commensurate with the obligations exacted by law. Policies and guidelines may assist courts in setting the accepted standard by which an individual or institution will be judged in any particular case. Yet as Pelly *et al.* describe, courts remain the final arbiters of the legal standard of care, and are thus free to base their judgments on considerations that reach beyond professional norms and guidelines.[19] In cases where a court finds that policies or guidelines prescribe inadequate standards, it must formulate more refined norms that meet the legal criteria of reasonableness and diligence.

This part of our discussion considers Canadian and American case law that reveals the impact that professional norms may exert on a court's assessment of the legal standard of care imposed upon medical professionals. Yet embodied within this jurisprudence are concerns related to ethical issues that arise within the context of medical practice and research. In the same way that clinical practice guidelines help courts discern whether professional conduct was reasonable and consistent with accepted practices, so may ethics codes guide their assessment of the moral underpinnings of professional choices and behaviour. More specifically, they illuminate the principles that are valued in a community and a society, and thereby help courts decide whether medical decisions and conduct uphold and promote these moral underpinnings. Given the importance that ethical guidelines may have for judicial decision making, the analysis undertaken in this article regarding the development of "soft

[19] J.E. Pelly *et al.*, "Clinical Practice Guidelines before the Law: Sword or Shield?" (1998) 169 Med. J. Aus. 330 at 332.

law" into legal norms will include instruments premised on ethics, as well as principles not premised on ethics.

Canadian law recognizes that the court, as the ultimate decision maker, is not bound by the profession's existing norms. Where the court finds that current professional practice does not meet the legal standard of reasonableness, no defence can be made by arguing that all professionals in the field follow similar practice. In these circumstances, the court may dismiss the professional norm and impose a higher standard on the profession.[20] The court's discretion to refuse to be bound by norms established by the medical community has also been recognized in American and Australian jurisprudence.[21]

Yet how does a court determine whether a professional policy, code, or guideline prescribes conduct consistent with a reasonable standard of care? There are two ways in which this task can be accomplished in the context of ethics.[22] First, the court may ask whether the instrument in question reflects international standards and ethical codes of conduct. If so, this indicates that the guideline, code, or policy prescribes legally and ethically acceptable conduct. A second point of reference for the court is domestic law. If the policy, code, or guideline deviates from any statement in locally applicable statutes, regulations, or jurisprudence concerning the requisite skill required for the relevant professional group, a court may set it aside. Moreover, if the instrument is markedly inconsistent with international or domestic standards, the court may find that the practices advocated by it amount to a breach of the requisite standard of care.[23] This implies a risk of liability for those groups overseeing the formulation of policies, professional codes of conduct, and guidelines.[24]

This discussion suggests that courts are not obliged to follow professional norms and guidelines, and are free to impose a separate standard of care acceptable in law. In reality, however, courts are often left without any choice but to accept professional practice standards. Although domestic and international legislation, regulations, and jurisprudence provide a body of juridical norms or "official rules" from which courts may formulate legal conclusions, these norms are often incomplete or imprecise.[25]

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[20] See *Hopp* v. *Lepp*, [1980] 2 S.C.R. 192, 112 D.L.R. (3d) 67. Regarding professional standards more generally outside the medical context, see *e.g. Roberge* v. *Bolduc*, [1991] 1 S.C.R. 374, (*sub nom. Dorion* v. *Roberge et al.*) 78 D.L.R. (4th) 666.

[21] In the U.S. see *Canterbury* v. *Spence*, 464 F.2d 772 (D.C. Cir. 1972); in Australia see *F.* v. *R.* (1983), 33 S.A.S.R. 189.

[22] See Medical Research Council of Canada, *Report of the Working Group on Liability* (Ottawa: MRC, 1990) at 44.

[23] *Ibid.* at 44-45.

[24] Pelly *et al.*, *supra* note 19.

[25] Lajoie, *supra* note 10 at 162-67.

Therefore, to interpret or complete the law, judges must borrow from extra-juridical norms, such as professional standards and guidelines.[26]

A court's inclusion of a professional standard or guideline in its analysis may result in the professional norm's becoming the legally accepted standard of care. For example, where experts testify that a guideline or policy establishes customary practice, courts will be reluctant to set this aside and impose another standard of care.[27] Thus, while in theory courts are not bound to follow professional standards and norms, they are unlikely to disregard them when they are supported and endorsed within the professional community. Once accepted and applied by a judge, the professional norm becomes legally normative as well.

B. Circumstances in Which Professional Norms May Be Adopted as the Legal Standard of Care

The transformation of a "soft law", professional norm into a legal norm frequently occurs in litigation concerning medical practice or research. Where the law regarding professional responsibility is unclear or incomplete the court will often refer to non-legal professional instruments to make legal findings. In these cases, the judge will usually invoke a policy, code, or guideline with expert testimony to determine whether it represents customary practice. For example, in *Institut Philippe Pinel de Montréal* v. *A.G.*,[28] the Quebec Court of Appeal was faced with the issue of whether a patient in a psychiatric hospital had the capacity to refuse treatment. The majority decision was based primarily on a test established in the *Hospitals Act* of Nova Scotia.[29] Its decision was also heavily influenced by the test expressed at the 1989 annual congress of L'Association des médecins psychiatres du Québec. Two norms were at play in this decision: the first was legal in nature, having been adopted in the statute of another province, and the second had normative status within the profession, having been recognized and followed by the psychiatric community. The court maintained that these two tests were complete enough to allow for its assessment of an individual's capacity to give or refuse consent to treatment. The court also heard expert testimony from three psychiatrists during proceedings that seemed to affect the majority's finding that the patient was incapable of refusing treatment.

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[26] P. Jestaz, "Rapport de synthèse (Les Standards)" (1988) 4 R.R.J. 1182.

[27] See D. Jutras, "Clinical Practice Guidelines as Legal Norms" (1993) 148 Can. Med. Ass'n J. 905; see also T.A. Caulfield, "Health Care Reform: Can Tort Law Meet the Challenge?" (1994) 32 Alta. L. Rev. 685.

[28] [1994] R.J.Q. 2523, [1994] R.D.F. 641 (C.A.).

[29] R.S.N.S. 1989, c. 208, s. 52(2).

Similarly, in *Dodds* v. *Schierz*[30] the Quebec Court of Appeal applied both expert testimony and practice guidelines to assess the question of professional responsibility. The trial judge had considered only the opinion of medical experts who testified and those published in medical literature. The Court of Appeal, however, made additional reference to a report from the Health Protection Branch ("HPB") of the Department of Health and Welfare Canada, ruling that the defendant should have been aware of this report, which warned against the practice he followed. This judgment indicates that where a policy establishes the level of skill and care required of a reasonable medical practitioner, such as the policy espoused in the HPB report, it may be applied as a legal norm. In *Dodds* the court found that the physician committed a professional fault. The defendant's practice was not consistent with that advocated in the code of conduct established by the HPB and it was a clinical practice that was not supported by the experts who testified at trial.

In the United States courts have used a similar approach in assessing the validity and weight of professional norms in litigation related to medical malpractice. For example, in *Frakes* v. *Cardiology Consultants*[31] the Tennessee Court of Appeal held that parameters set by the American College of Cardiology and the American Heart Association for interpreting exercise treadmill tests administered to patients were admissible as evidence for assessing the liability of a physician accused of negligence. In particular, the court held that these guidelines represent the standard of care for the profession. All three experts who testified at trial reported that these guidelines embodied the consensus standard among cardiologists.

This case demonstrates that practice guidelines, when supported by expert testimony, can wield a large impact on a court's finding that a health care provider is conforming with the standard of care. Even when an accepted guideline prohibits or merely warns against the defendant's particular behaviour, a court may use that as the primary basis for its decision. This principle is illustrated in the ruling in *DeJong (Litigation Guardian of)* v. *Owen Sound General and Marine Hospital*.[32] In its decision, the court referred to a hospital planning manual issued by the Institutorial Planning Branch of the Ministry of Health (Ontario) to determine whether a psychiatric hospital had acted negligently by placing a suicidal patient in a room with windows that lacked bars or reinforced safety glass. Hoilett J. ruled that, while the manual did not set out mandatory principles, it established "relevant considerations" for the court.[33] The hospital's failure to follow the safety measures recommended in the manual thus appeared to contribute to the court's finding of negligence in the hospital's

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[30] [1986] R.J.Q. 2623, 4 Q.A.C. 20 (C.A.) [hereinafter *Dodds*].

[31] (29 August 1997), Nashville 01-A-01-9702-CV-0069 (Tenn. C.A.), [1997] Tenn. App. LEXIS 597, online: LEXIS (Tennessee, APP) [hereinafter *Frakes*].

[32] [1996] O.J. No. 809 (Gen. Div.), online: QL (OJRE) [hereinafter *DeJong*].

[33] *Ibid.* at para. 95.

decisions regarding the patient's room and the level of observation under which he was placed.

Policies and guidelines do not always, however, determine the standard of care that a court will impose on medical professionals. In *DeJong* the court also made reference to the *Practice Guideline for Major Depressive Disorder in Adults*, a publication of the American Psychiatric Association, to assess whether the hospital administered proper doses of anti-depressant medication to the plaintiff. Although the prescription fell within the parameters set by the guideline, the court ruled that the patient in this case required higher doses of medication. Its finding was based primarily on the opinions of experts who testified that, while the practice guidelines were generally accepted and respected, they were not intended to be construed or to serve as a medical standard of care.[34] This view was adopted in the concurring opinion of Koch J. in *Frakes*, who held that, although practice guidelines are relevant for assessing the proper standard of medical care, they should not necessarily be interpreted as "conclusive evidence" of this standard.[35]

Where applicable, the court may look beyond local and national policies and invoke guidelines created by international organizations and committees. For instance, the *Helsinki Declaration*,[36] which outlines the ethical obligations of physicians and researchers who engage in biomedical research, was applied and followed in *Weiss* v. *Solomon*.[37] In this decision the court was required to determine whether a physician had satisfied his duty to disclose the risks of an experimental procedure to a volunteer subject. The court evaluated the subject's consent in light of legal provisions in the *Civil Code of Québec* and the *Code de déontologie des médecins*. Yet it also elaborated on the principles set out in domestic legislation by referring to the ethical tenets established in the *Helsinki Declaration*. Applying this international instrument, the court concluded that the physician had failed to disclose adequately the risks involved in participating as a research subject.

This discussion illustrates how a court may invoke non-legal instruments such as policies, codes, or guidelines to determine questions of professional liability. Where no legal norm exists in a statute or regulation or in case law, the guideline, professional norm, or both will have a significant, perhaps even decisive, impact on a

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[34] *Ibid.* at paras. 110ff.

[35] *Supra* note 31 at para. 45.

[36] *Declaration of Helsinki, Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects*, adopted by the 18th World Medical Assembly, Helsinki, 1964, rev. Tokyo (1975), Venice (1983), Hong Kong (1989), reprinted in (1997) 277 J.A.M.A. 925 [hereinafter *Helsinki Declaration*].

[37] [1989] R.J.Q. 731, 48 C.C.L.T. 280 (Sup. Ct.).

judge's conclusion. This essentially results in the professional community, rather than the legislator or the court, determining the legal standard of care.

Although courts have assessed the weight and validity of policies and practice guidelines primarily in medical malpractice cases, this analysis may also be undertaken in other contexts. A recent case argued before the Appellate Division of the Superior Court of New Jersey illuminates the ways in which professional norms may influence the judicial review of regulations developed and enacted by a legislature.[38] In its decision, the court considered challenges to regulations adopted by the New Jersey Department of Banking and Insurance ("DOBI") pursuant to the *Automobile Insurance Cost Reduction Act*.[39] These regulations purported to maintain the quality of medical care administered to those injured in automobile accidents, while at the same time discouraging medically unnecessary treatments and diagnostic tests for certain back and neck injuries. The regulations set out protocols that developed "care paths" designed to guide the treatment of such injuries, and thus avoid what was perceived as unnecessary treatment and overuse of benefits. In reviewing the viability of the protocols in question, the court examined the steps undertaken by the DOBI in devising them. The evidence revealed that Price Waterhouse Coopers ("PWC"), a health benefits consultant that had been enlisted by the DOBI to develop the "care paths", had conducted a literature search of standards set by national organizations. PWC also relied on an extensive bibliography of research that cited nationally accepted health care management and clinical practice guidelines, as well as guidelines formulated by the medical community and professional boards to determine commonly accepted professional standards considered beneficial for the treatment of automobile-related neck and back injuries. In light of this evidence, the court held that "reliable medical literature" and "credible medical evidence" had been considered in establishing standard treatment protocols for the DOBI. This finding contributed to the court's ultimate decision to uphold the legislative validity of the "care paths" developed by the DOBI.

In Europe professional guidelines have also exerted an impact on the drafting of legislation related to medical issues. Where complex matters are involved, legislators often turn to independent specialist bodies to prepare the technical information underlying law and policy. Where legislation explicitly incorporates a professional norm and refers to it as the standard of care, guidelines will carry the force of law. Otherwise, they will bear no definite legal authority and will not be considered as legally binding. Yet even in such cases, professional norms may be legally significant, given

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[38] See *New Jersey Coalition of Health Care Professionals* v. *New Jersey Department of Banking and Insurance, Division of Insurance*, 732 A.2d 1063, 323 N.J. Super. 207 (Sup. Ct. 1999).

[39] N.J. Stat. § 39:6A-1.1 (2000).

that they represent the "state-of-the-art", and thus may provide guidance for those charged with devising law and policy related to intricate medical and ethical issues.[40]

This analysis reveals the significant impact that professional norms and practices may wield on judicial decision making. Yet even before a court considers the relevance of professional standards for determining the legal standard of care, it must decide whether expert opinion is admissible evidence for the determination of a professional norm. In *Daubert* v. *Merrell Dow Pharmaceuticals*[41] the U.S. Supreme Court established a list of questions, commonly referred to as the "*Daubert* factors", that can be used to test the admissibility of the opinion of an expert scientific witness. Included among these "*Daubert* factors" is "[w]idespread acceptance" of the opinion within a relevant scientific community.[42]

The *Daubert* factors were subsequently applied in *Moore* v. *Ashland Chemicals*.[43] In this decision the majority held that, in assessing the admissibility of expert testimony, a trial judge must first determine whether the witness is qualified as an "expert". To do so, the court must consider whether the opinion he or she proffers is "grounded in the methodology of his discipline, i.e., the body of principles, methods, rules and postulates of his field of expertise; and whether his opinion is relevant to the case."[44]

This suggests that, in addition to the requirements set by fundamental evidentiary rules, the admissibility of expert testimony will be contingent on whether it is consistent with the body of professional "soft law" that currently serves to guide those practising in a given area of expertise. Courts will rely on professional norms not only to decide whether the conduct in question meets the legal standard of care, but also to decide whether it will hear and consider testimony of other professionals regarding that conduct. In light of *Daubert* and *Ashland*, it seems that if the expert opinion proffered does not reflect current accepted practices in a given profession, the court will not consider that testimony as relevant or reliable, and thus it will not be admitted.

C. Concerns about the Weight Attached to Professional Practices and Norms in Law

The significant degree to which courts rely on professional norms to discern what constitutes juridically acceptable professional conduct has been the subject of aca-

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[40] See *e.g.* P.J. Schwartz *et al.*, "The Legal Implications of Medical Guidelines—A Task Force of the European Society of Cardiology" (1999) 20 Euro. Heart J. 1152.

[41] 509 U.S. 579, 113 S. Ct. 2786 (1993) [hereinafter *Daubert* cited to U.S.].

[42] *Ibid.* at 594.

[43] 126 F.3d 679 (5th Cir. 1997) [hereinafter *Ashland*].

[44] *Ibid.* at 691.

demic criticism in the legal community. According to Arnold and Sprumont, professional norms should never be presumed by a court to represent the legal standard of care. Allowing the guidelines or any professional norm to be the sole source for establishing the standard of care may result in the self-regulation of professional bodies. This would insulate professionals from legal scrutiny of their practice, and would diminish their accountability to the recipients of their services.[45] They therefore advocate that legislative action be taken to establish the legal standard of care for the medical profession. This legislation may encompass current medical custom or may impose a more rigorous standard. In either case, it would eliminate the danger of allowing the practice and the profession to be completely self-governing. Similarly, Jutras maintains the view that, while practice guidelines and professional norms may influence a court's decision, they should not be regarded as legal norms. It is ouly once the "key legal players", that is, legislators and judges, have accepted that a professional norm has met the legal standard of care that it should be binding in judicial decision making.[46]

In addition to legal concerns, ethical issues of self-regulation in the medical profession have also been considered. Because medical professionals do not have an expertise in ethics, standards set by this community may not be consistent with ideas inherent in ordinary social morality and ethics.[47] For this reason, there must be a constant dialogue between the medical profession and ethicists about acceptable professional conduct. As such, to be ethical from a community or social standpoint, guidelines must reflect not only professional standards, but also the norms of the society in which professionals function. Thus, just as guidelines cannot be accepted as establishing the legal standard of care, so they cannot be held to represent the ethical norms of conduct for professionals in the medical community.

Although concerns regarding professional self-regulation may be well founded in theory, an approach that advocates fixing all professional norms into the letter of the law has certain practical difficulties, particularly within the framework of newly developing areas of medicine and research. The ethical issues that surface in such contexts are not static; they arise as new knowledge is gained and new technologies are developed. A legislative approach does not have regard to the evolving nature of practice in these fields, and would be workable for only some, but not all, of the ethical issues that may arise.

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[45] P. Arnold & D. Sprumont, "The 'Nuremberg Code': Rules of Public International Law" in U. Tröhler & S. Reiter-Theil, eds., *Ethics Codes in Medicine: Foundations and Achievements of Codification Since 1947* (Brookfield, Vt.: Ashgate, 1998) 84.

[46] Jutras, *supra* note 27.

[47] A. Lynch, "Medical Professionalism: Toward a Contemporary Canadian Model" (1992) 27 J. Can. Stud. 107.

Conclusion

While policies, codes, and guidelines concerning ethical professional conduct may exhort certain behaviour, they do not enforce it. What society demands for enforcement purposes falls short of what it may promote as ethical conduct. The law's collectively articulated provisions, backed by the power of sanction, are representative of society's interests. Nevertheless, statutory provisions are cumbersome as instruments, and frequently not flexible or nuanced enough to provide the detailed guidance required in complex and rapidly developing fields of medicine and research. In some cases, the standard of care required by the law is less rigorous than the norms established in a guideline, policy, or code.

The "soft law" of professional communities has been important in assisting courts with questions of professional responsibility. In the absence of a legal norm on a particular issue, "soft law" may be the determinative factor in the outcome of a case. Legislators may also adopt, or courts may follow, clinical and ethics policies, codes, or guidelines if they meet the requirements of the legal standard of care. The cases discussed above demonstrate that a court's acceptance of these instruments as the legal standard of care involves hearing expert testimony which corroborates the practice recommended by them. At this last stage of the evolution of policies, codes, or guidelines, they become transformed into legal norms, and for the common law, become binding for future judicial decisions.

This evolution of "soft law" into legal norms may take place within various areas of medicine and research, and is particularly likely to occur in fields characterized by rapid and ongoing developments. In this context it is often impossible for the law to match the pace of change, leaving many aspects of professional conduct unregulated by legislation or jurisprudence. Continued technological advancements in genetic science provide one example of this, and reveal the importance of "soft law" for guiding clinical practice and research. Physicians and investigators working in genetics are confronted with novel and complex ethical issues, many of which have yet to be addressed by the courts or legislatures. As a result, many policies, codes, and guidelines have been developed for the ethical conduct of clinical genetics and genetic research.

The formulation of "soft law" for guiding genetic medicine and research has been undertaken by bodies at the international[48] and national[49] levels, as well as by profes-

[48] See *e.g.* UNESCO, *Universal Declaration on the Human Genome and Human Rights* (Paris: UNESCO, 1997), reprinted in *Records of the General Conference*, UNESCO, 29th Sess., 29 C/Res. 19 (1997) at 41, online: UNESCO <http://www.unesco.org/ibc/uk/genome/project/index.html> (date accessed: 11 November 2000); *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, Eur. T.S. 164, online: Council of Europe <http://www.coe.fr/eng/legaltxt/164e.htm> (date accessed: 11 November 2000); Council of International Organizations of Medical

sional agencies committed to promoting ethical conduct in clinical genetics and genetic research.[50] These codes, policies, and guidelines provide an ethical framework for the professional endeavours undertaken within this domain. Yet given the relatively short time since its creation, this body of "soft law" has yet to be the subject of extensive judicial or legislative attention and interpretation. Nevertheless, in fields as new and as quickly burgeoning as genetics, the presence of codes, policies, and guidelines is essential for setting the initial parameters of acceptable clinical and research practices. Moreover, these instruments provide a benchmark for legal institutions seeking to define protocols of professional conduct mandated by law. As the discussion here reveals, however, whether such professional standards will also bear normative force at law depends upon either the will of legislators or the judgment of the courts.

Sciences (CIOMS), "International Guidelines for Biomedical Research Involving Human Subjects" in Z. Bankowski & R.J. Levine, eds., *Ethics and Research on Human Subjects: International Guidelines: Proceedings of the XXVIth CIOMS Conference, Geneva, Switzerland, 5-7 February 1992* (CIOMS: Geneva, 1992) Annex 1.

[49] In Canada see *e.g.* Medical Research Council of Canada, National Sciences and Engineering Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement. Ethical Conduct for Research Involving Humans* (Ottawa: MRC, 1998).

In the U.K. see *e.g.* Advisory Committee on Genetic Testing, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public* (London: Health Departments of the United Kingdom, 1997), online: Department of Health (U.K.) <http://www.doh.gov.uk/genetics/hgts.htm> (date accessed: 11 November 2000); Advisory Committee on Genetic Testing, *Report on Genetic Testing for Late Onset Disorders* (London: Health Departments of the United Kingdom, 1997), online: Department of Health (U.K.) <http://www.doh.gov.uk/genetics/lodrep.htm> (date accessed: 11 November 2000).

In the U.S. see *e.g.* National Advisory Council for Human Genome Research, "Statement on Use of DNA Testing for Presymptomatic Identification of Cancer Risk" (1994) 271 J.A.M.A. 785; E. Marshall, "Policy on DNA Research Troubles Tissue Bankers" *Science* 271:5248 (26 January 1996) 440.

[50] See *e.g.* American Society of Human Genetics Ad Hoc Committee on DNA Technology, *DNA Banking and DNA Analysis: Points to Consider* (1987), online: Federation of American Societies for Experimental Biology <http://www.faseb.org/genetics/ashg/policy/pol-02.htm> (date accessed: 11 November 2000); American Society of Human Genetics, "Statement on Informed Consent for Genetic Research" (1996) 59 Am. J. Hum. Genetics 471; American Society of Human Genetics, "Statement of the American Society of Human Genetics on Genetic Testing for Breast and Ovarian Cancer Predisposition" (1994) 55 Am. J. Hum. Genetics; American Society of Human Genetics, *Professional Disclosure of Familial Genetic Information* (1998), online: Federation of American Societies for Experimental Biology <http://www.faseb.org/genetics/ashg/policy/pol-29.htm> (date accessed: 11 November 2000); American College of Medical Genetics Storage of Genetics Materials Committee, *Statement on Storage and Use of Genetic Materials* (1995), online: Federation of American Societies for Experimental Biology <http://www.faseb.org/genetics/acmg/pol-17.htm> (date accessed: 11 November 2000).