THE REASONABLE PATIENT-PLUS SOLUTION: RETHINKING MEDICAL INFORMED CONSENT IN PUERTO RICO

ARTICLE

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I. Introduction

At some point, every individual will be confronted with important decisions about their medical care or that of their family. It is ultimately the decision of the patient or legal guardian whether to consent to the risks and benefits that are inherent to every medical treatment, because "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body."[1] The right to decide whether to submit to a medical treatment is critical because the interest at play is generally none other than the patient's bodily integrity and it is the patient who will ultimately suffer the consequences if any risk associated with the treatment materializes.

The doctrine of informed consent is the legal tool that protects patient autonomy or "the right of every patient to self-determination that is, to freely decide what

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[1] *Schloendorff v. Soc'y of N.Y. Hospital*, 211 N.Y. 125, 129 (N.Y. 1914).

should be done with his/her body."[2] In order for individuals to freely decide about medical treatments, they must have enough information about their health condition, the treatment alternatives, and the potential risks and benefits of the treatments. Given the complexity of the medical field, patients generally depend on their physicians to provide the information necessary to appraise their situation and decide whether to grant or withhold consent to a treatment. Thus, it is critical that physicians exercise their legal obligation to obtain informed consent from their patients by providing this information.

Failure to protect patient autonomy and obtain valid informed consent is the norm in the medical practice.[3] Thus, an informed consent standard such as Puerto Rico's Physician-Centered Standard that requires doctors to follow the customary practice in the medical community simply perpetuates this failure. The current medical practice and legal standard not only fails to protect patients' ability to make informed decisions about their health care, but is also not conducive to reducing healthcare costs, improving health outcomes, or fostering doctor-patient relationships. Of course, one would be hard-pressed to find a physician who does not strive to act in the best interest of the patient. However, in the process, physicians often trample upon the patients' rights to make informed decisions about health care. A careful approach customized to Puerto Rico's medical regulatory system can promote valid informed consent practices that respect patient autonomy and improve patient safety while reducing medical malpractice liability risks.

Part I of this article discusses the bioethical foundations of the legal doctrine of informed consent and presents how physicians generally fail to meet their duty to obtain valid informed consent in decisions regarding their patients' medical care. **Part II** describes the first step of the Reasonable Patient-Plus Solution, which calls for an adoption of the Reasonable Patient informed consent standard of disclosure in Puerto Rico. This part describes the legal foundations of the doctrine of informed consent and compares the two major informed consent doctrines employed in courts across United States and Puerto Rico. The first, which has been adopted in Puerto Rico, is the professional practice or Physician-Centered Standard ("PCS"). The second is the Reasonable Patient Standard ("RPS"), which is more attuned to current notions of patient autonomy and should be adopted by Puerto Rico's courts or legislature. Finally, **Part III** describes the second step of the Reasonable Patient-Plus

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[2] *Sepúlveda de Arrieta v. Barreto Domínguez*, 137 D.P.R. 735, 742 (1994); Herminio M. Brau del Toro & Raúl A. Marcial Rojas, *La Doctrina del Consentimiento Ilustrado para Tratamiento Médico*, 54 Rev. Jur. U.P.R. 113, 140-48 (1985) (discussing the authority of a legal guardian to provide informed consent in different contexts).

[3] Clarence H. Braddock III, Kelly A. Edwards, Nicole M. Hasenberg, Tracy L. Laidley, & Wendy Levinson, *Informed Decision Making in Outpatient Practice Time to Get Back to Basics,* 282 J. of the American Medical Association, 2313, 2317 (1999); Clarence H. Braddock III, Pameal L. Hudak, Jacob J. Feldman, Sylvia Bereknyei, Richard M. Frankel, & Wendy Levinson, *"Surgery is Certainly one Good Option": Quality and Time-Efficiency of Informed Decision-Making in Surgery*, 90 J of Bone and Joint Surgery Am. 1830, 1833-4 (2008).

Solution, which calls for the two main regulatory bodies of Puerto Rico's medical practice, the Junta de Licenciamiento y Disciplina Médica de Puerto Rico ("Junta") and the Colegio de Médicos-Cirujanos de Puerto Rico ("Colegio"), to take effective steps towards promoting respect for patients' rights and compliance with the informed consent standard of disclosure. The Junta and the Colegio can achieve this by using their investigative and disciplinary authority to enforce the informed consent standard of disclosure, to amend the physicians' Code of Professional Ethics and to train physicians on bioethics and medico-legal doctrines relevant to their everyday practice.

II. Bioethical Underpinnings of Informed Consent

A. Defining Patient Autonomy and Informed Consent

The abhorrent acts of torture and unconsented medical experimentation by Nazi physicians during World War II gave rise to modern impetus for obtaining informed consent from patients in the medical context.[4] Undoubtedly the most resounding lesson from that experience is captured in the first principle of the Nuremberg Code: "The voluntary consent of the human subject is absolutely essential."[5] Of course, modern-day doctor-patient relationships in Puerto Rico and the United States are not to be compared with the acts of Nazi physicians. Yet, the need for honoring patient autonomy, which is at the heart of that first principle, is as present as ever in every-day medical practice.[6] In fact, in recent years in Puerto Rico, there has been a call for more attention to the importance of patient autonomy and bioethics in the medical context.

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[4] Evelyne Shuster *Fifty Years Later: The Significance of the Nuremberg Code*, 337 New England Journal of Medicine 1436 (1997).

[5] *Nuremberg Code* accessed on April 7, 2012 available at http://ohsr.od.nih.gov/guidelines/nuremberg.html (Reprinted in the National Institutes of Health, Office of Human Subjects Research website from *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council* Law No. 10, Vol. 2, pp. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949); *See also* Jonathan D. Moreno, *Reassessing the Influence of the Nuremberg Code on American Medical Ethics*, 13 J. of Contemporary Health Law and Policy 347 (1997) (discussing the influence of the Nuremberg Code in U.S. medical ethics and how the message of the importance of consent "proved hard to ignore").

[6] Interestingly, the Hippocratic Oath, or a modified version–which is commonly taken by medical students in White Coat Ceremonies in medical schools in Puerto Rico and the U.S.–has been harshly criticized because it makes no mention of patient autonomy nor does it seem to give the concept much prominence. A study carried out in the year 2000, examined the different oaths administered by the 122 accredited medical schools in the United States and Puerto Rico. Only 11 of these schools administered oaths that explicitly addressed respect for patient autonomy. *See* Evelyne Shuster, *The Nuremberg Code: Hippocratic Ethics and Human Rights*, 351 Lancet 974 (1998); Audiey C. Kao & Kayhan P. Parsi, *Content Analyses of Oaths Administered at U.S. Medical Schools in 2000*, 79 Academic Medicine 882, 884 (2004).

In 2005, a Commission formed by the Governor to evaluate the state of Puerto Rico's Health Care System recommended the creation of a Bioethics Commission to promote research and advise the Administración de Seguros de Salud ("ASES" or "Health Insurance Administration") and the branches of government about the ethical aspects of health care delivery.[7] Later, in 2007, the University of Puerto Rico School of Medicine recognized the increasing importance of bioethics in medicine by founding the Academy for the Humanities in Medicine to promote research and implementation of bioethics principles in the practice of medicine.[8] Finally, in 2008, Law No. 139 made it a legal obligation for medical schools in Puerto Rico to offer required courses in bioethics, and for physicians to complete continuing credit courses in bioethics to renew their license to practice medicine every 3 years.[9]

B. Elements of Informed Consent from a Bioethics Perspective

Bioethics has become a key component of modern medicine in part because the doctor-patient relationship is marked by a profound asymmetry of knowledge in favor of the physician and the stakes at play could not be any higher, the patient's bodily integrity. Thus, physicians must be held to a high ethical standard to prevent willful or involuntary abuses to patients' rights. Obtaining valid informed consent from patients is often one of the most overlooked and important ethical considerations in everyday medical practice. Physicians are faced with the challenge of honoring patient autonomy every time they take part in their patient's medical decision-making process. In order to honor patient autonomy, physicians must ensure that they obtain informed consent from patients before any kind of medical decision, even those regarding whether to undergo diagnostic tests, commence or modify a medication regimen and whether to undergo a surgical procedure just to name a few. Informed consent is a matter of degree, and the bioethics literature talks about a number of components generally agreed to be essential for evaluating the level of informed consent. These elements include: competence, voluntariness, disclosure, understanding, and consent.[10] This article focuses on the requirements for obtaining informed consent among patients or legal guardians considered to be competent and making voluntary decisions about medical care. However, the

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[7] Comisión para Evaluar el Sistema de Salud del Estado Libre Asociado de Puerto Rico, *Informe: Evaluación del Sistema de Salud de Puerto Rico; Hacia el Desarrollo Integral del Sistema de Salud de Puerto Rico*. p. 23 (2005).

[8] University of Puerto Rico School of Medicine, Academy for the Humanities in Medicine, *Declaration*, accessed on March 30, 2012, *available at* http://www.md.rcm.upr.edu/index.php?option=com_content&view=article&id=128:declaration.

[9] Public Law No. 139-2008, 20 L.P.R.A. § 135f (Law No. 139 of 2008 created the Junta de Licenciamiento y Displina Médica de Puerto Rico ("Junta") which is the medical board that has the responsibility of regulating the practice of medicine in Puerto Rico).

[10] Tom L. Beauchamp & James F. Childress, PRINCIPLES OF BIOMEDICAL ETHICS 79, 80 (Oxford Univ. Press, 5th ed. 2001).

elements of competence and voluntariness are *sine qua non* first steps for obtaining informed consent in the medical context. **Table 1** presents a brief description of these elements from a bioethics perspective.

TABLE 1: Elements of Informed Consent from a Bioethics Perspective

Competence	a patient is generally considered competent if he or she is "able to understand a therapeutic or research procedure, to deliberate regarding its major risks and benefits, and to make a decision in light of this deliberation" [11]
Voluntariness	"a person acts voluntarily to the degree that he or she wills the action without being under the control of another's influence" or a "debilitating disease, psychiatric disorder or drug addiction" among other conditions.[12]
Disclosure	this requirement is met in the degree that the physician or other health care provider informs the patient about: "(1) those facts or descriptions that patients . . . usually consider material in deciding whether to refuse or consent to the proposed intervention," . . . "(2) information the professional believes to be material, (3) the professional's recommendation, (4) the purpose of seeking consent, and (5) the nature and limits of consent as an act of authorization." [13]
Understanding	generally patients are said to understand "if they have acquired pertinent information and have justified, relevant beliefs about the nature and consequences of their actions."[14]
Consent	a patient provides consent when he or she makes a decision in favor or against a plan, and authorizes the chosen plan.[15]

The more a physician ensures that these elements are present in medical decision-making, the closer the physician gets to ethically valid informed consent. However, where societies draw the line to delimitate adequate informed consent in the medical context is a decision that depends on a multiplicity of factors including: the value given to patient autonomy, the legal precedents, and public policy considerations. Some of the public policy considerations include the level of resources available to the government, the possible costs in terms of physician time and training, the possible effects on medical liability and the perceived feasibility of achieving the goal of obtaining informed consent from every patient and for every medical decision.

The courts in different states and Puerto Rico have made varying determinations about these factors. As will be discussed in the following parts of the article,

[11] *Id.*
[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] *Id.*

approximately half of the states and Puerto Rico have adopted a Physician-Centered standard ("PCS") of informed consent, which places a premium on the element of disclosure, but gives much less importance to the element of patient understanding. Although the emphasis of the PCS is on disclosure, when compared to current notions of patient autonomy in Puerto Rico,[16] the PCS functions poorly to promote the disclosure of material information relevant to make informed decisions. The reason for this shortcoming is that the PCS only requires that physicians disclose those risks that are customary to disclose in the relevant medical practice.

The informed consent PCS is extremely problematic from a patient autonomy perspective because it can easily perpetuate inadequate informed consent practices. That is, if the custom is to provide an insufficient level of information about risks, alternative treatments or the prospects of success, then physicians can continue to follow that practice without repercussions. This perpetuation problem is exacerbated by the fact that patients have an asymmetrical relationship with physicians. Compared to their physicians, lay patients know little about the medical field and whether the doctor met the customary standard of disclosure.[17] Thus, the vast majority of breaches of the standard of care regarding informed consent are bound to go unreported because the patients are not aware that their rights have been violated.

C. Low Prevalence of Valid Informed Consent in the Medical Practice

In order to address the level at which physicians honor the elements of informed consent, a number of studies have examined medical decision-making between doctors and patients. Strikingly, many of these studies have found that in most doctor-patient medical decision-making instances, physicians do little to ensure that adequate levels of the elements of disclosure and understanding are attained. For example, a study in the United States recorded and analyzed 3,552 clinical decisions made between 124 physicians and their patients in community-based private offices.[18] The medical decisions ranged from ordering routine laboratory tests to prescribing and changing medications to prostate cancer screenings and counseling

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[16] Both the Colegio de Médicos-Cirujanos de Puerto Rico's Code of Medical Ethics and the Bill of Patients' Rights and Responsibilities of Puerto Rico recognize that respect for patient autonomy and obtaining ethically valid informed consent goes beyond simply disclosing the risks of medical treatments. Colegio de Médicos-Cirujanos de Puerto Rico, *Code of Professional Ethics No. 7044*, Preamble Pp. 7 (2005) accessed on April 7, 2012 available at http://www.colegiomedicopr.org/download.php?id=754; Carta de "Derechos y Responsabilidades del Paciente" Law No. 194 of August 25, 2000 art. 9(b) (2000).

[17] In fact, in most PCS states expert medical testimony is generally required to show whether the physician met the standard of care in terms of informed consent. *Culbertson v. Mernitz*, 602 N.E.2d 98, 104 (1992).

[18] Clarence H. Braddock III, Kelly A. Edwards, Nicole M. Hasenberg, Tracy L. Laidley, & Wendy Levinson, *Informed Decision Making in Outpatient Practice Time to Get Back to Basics,* 282 J. of the American Medical Association, 2313, 2317 (1999).

regarding surgery.[19] This study found that physicians discussed the clinical issue or the nature of the decision in 71% of cases.[20] Yet, alarmingly, physicians only discussed treatment alternatives in 11.3% of decisions and potential risks and benefits in 7.8% of decisions.[21] Even for complex decisions, which included decisions about prostate cancer screening, counseling for surgery, and type of anesthesia, physicians discussed the clinical issue or the nature of the decision in 89.5% of decisions, and only discussed alternative treatments in 29.5% of decisions and the potential risks and benefits in 26.3%. The patient's understanding of the physician's explanations was assessed by physicians with questions such as "Does that make sense to you?" in only 6.9% of these complex decisions and in 1.5% of all decisions examined.[22]

A similar study carried out in the United States and Canada examined medical decisions regarding orthopedic surgeries such as hip and knee replacements, and hip, knee, wrist and shoulder surgeries among others.[23] Researchers found that physicians discussed the nature of the decision in 92% of cases, but physicians addressed alternative treatments in only 62% of decisions and the potential risks and benefits of the treatment in 59%.[24] All of these decisions revolved around surgeries and yet, in approximately 40% of decisions, the physicians did not discuss alternative treatments or the potential risks and benefits. Finally, physicians attempted to assess patients' understanding in only 12% of cases.[25]

Together, these studies suggest that the customary practice in the medical community is in fact to disclose little or nothing at all about alternative treatments and the potential risks and benefits of treatments. These are essential pieces of information, which allow the patient to make an informed decision as to whether to consent to a medical course of action. Therefore, under a PCS, which simply requires physicians to follow the customary practice in the field, physicians can continue to dishonor patient autonomy and obtain invalid informed consent, within the parameters of the law.

D. Practices that Promote Patient Autonomy and Informed Consent Benefit the Health Care System

Not only is an inadequate level of disclosure and assessment of a patient's understanding problematic in that it does not allow a patient to provide informed

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[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] Clarence H. Braddock III, Pameal L. Hudak, Jacob J. Feldman, Sylvia Bereknyei, Richard M. Frankel, & Wendy Levinson, *"Surgery is Certainly one Good Option": Quality and Time-Efficiency of Informed Decision-Making in Surgery*, 90 J of Bone and Joint Surgery Am. 1830, 1834 (2008).
[24] *Id.*
[25] Clarence H. Braddock III, Pameal L. Hudak, Jacob J. Feldman, Sylvia Bereknyei, Richard M. Frankel, & Wendy Levinson, *"Surgery is Certainly one Good Option": Quality and Time-Efficiency of Informed Decision-Making in Surgery*, 90 J of Bone and Joint Surgery Am. 1830, 1833-4 (2008).

consent, but this largely unilateral approach to doctor-patient relationships does a disservice to the general health care system and the pursuit of the Triple Aim. The Triple Aim in health care is what Donald M. Berwick has described as the essential goals for achieving high-value health care in the United States.[26] The theory is that the United States will not achieve high-value health care unless it develops effective initiatives aimed at: "improving the individual experience of care; improving the health of populations; and reducing the per capita costs of care for populations."[27]

Studies suggest that the Triple Aim is promoted when physicians engage in patient-centered behaviors,[28] which allow patients to participate as partners in healthcare decision-making and management.[29] For example, a recent study showed that while physicians who engage in more patient-centered communication behaviors take more time per patient visit, these physicians have significantly lower diagnostic testing expenditures and overall expenditures per patient.[30] Furthermore, another study showed that physicians who engage in more patient-centered communication behaviors are more likely to be perceived as competent and trustworthy by patients, which is generally associated with patient satisfaction. In addition, these patients expressed that under the care of a patient-centered physician, they were more likely to undergo an evidenced-based recommended treatment, which is associated with better health outcomes.[31]

One of the essential aspects of patient-centered communication is to treat patients as partners in healthcare decision-making, which includes sharing power and responsibility.[32] When physicians forgo discussing treatment alternatives and the potential risks and benefits of a course of action or assessing a patient's understand-

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[26] Donald M. Berwick, Thomas W. Nolan and John Whittington *The Triple Aim: Care, Health, And Cost*, 27 Health Affairs 759, 760 (2008).

[27] *Id.*

[28] Patient-centered communication is defined as "the set of skills and behaviors used by physicians to promote a relationship in which patients actively participate as partners in healthcare decision making and management" Somnath Saha & Mary C. Beach, *The impact of patient-centered communication on patients' decision making and evaluations of physicians: A randomized study using video vignettes*, 84 Patient Education and Counseling 386 (2011).

[29] Somnath Saha & Mary C. Beach, *The impact of patient-centered communication on patients' decision making and evaluations of physicians: A randomized study using video vignettes*, 84 Patient Education and Counseling 386, 388-9 (2011).

[30] Ronald M. Epstein, Peter Franks, Cleveland G. Shields, Sean C. Meldrum, Katherine N. Miller, Thomas L. Campbell, & Kevin Fiscella, *Patient-Centered Communication and Diagnostic Testing*, 3 Annals of Family Medicine 415, 418 (2005); *But see* Clarence H. Braddock III, Pameal L. Hudak, Jacob J. Feldman, Sylvia Bereknyei, Richard M. Frankel, & Wendy Levinson, *"Surgery is Certainly one Good Option": Quality and Time-Efficiency of Informed Decision-Making in Surgery*, 90 J of Bone and Joint Surgery Am. 1830, 1836 (2008) (concluding that surgeons can obtain ethically valid informed consent while not engaging in substantially longer visits with each patient).

[31] Somnath Saha & Mary C. Beach, *supra* n. 30.

[32] Nicola Mead & Peter Bower, *Patient-Centredness: A Conceptual Framework and Review of the Empirical Literature*, 51 Social Science & Medicine 1087, 1089 (2000).

ing of a medical decision, they are doing a disservice to the efforts to improve patient experience, obtain better health outcomes and reduce costs. The PCS foments this disservice by encouraging or at least acquiescing to an informed consent practice that does not protect patient autonomy nor promotes patient-centered behaviors.

III. Legal Underpinnings of Informed Consent

State courts have historically established the informed consent standard of care required in the medical practice by adopting one of two approaches. Approximately half of the states and Puerto Rico have adopted a professional practice or Physician-Centered Standard (PCS) and the rest of the states and Washington D.C. have adopted a more patient-centered standard generally referred to as the Reasonable Patient Standard (RPS).[33] These doctrines are purportedly aimed at protecting patient autonomy, although neither of them is optimally equipped for it. Both doctrines define informed consent in a one-dimensional way by focusing on the element of disclosure.[34] On the one hand, the PCS does not require the physician to disclose information that a patient would generally consider material in deciding whether to refuse or consent to a medical course of action. On the other hand, while the RPS has the great advantage that it requires that physicians disclose those risks that would be considered material by a reasonable patient, this standard still does not require physicians to assess whether patients understand the information before they make a medical decision.

In the remainder of the article, I will argue that the optimal solution ("Reasonable Patient-Plus Solution") for improving informed consent practices in Puerto Rico is to shift to a RPS because it is substantially more protective of patient autonomy than the PCS and invite the Colegio de Médicos-Cirujanos de Puerto Rico ("Colegio") and the Junta de Licenciamiento y Disciplina Médica de Puerto Rico ("Junta") to amend the physicians' Code of Professional Ethics to make the informed consent requirements more conducive to protecting patient autonomy and ensuring patient understanding. In addition, I will argue that these medical practice regulatory bodies should prioritize compliance with the informed consent standard by using their investigative and disciplining authority. Finally, the Junta and the Colegio should ensure that medical students and physicians learn about bioethics

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[33] David M. Studdert, Michelle M. Mello, Marin K. Levy, Russell L. Gruen, Edward J. Dunn, E. John Orav, & Troyen A. Brennan, *Geographic Variation in Informed Consent Law: Two Standards for Disclosure of Treatment Risks*, 4 Journal of Empirical Legal Studies 103, 105-109 (2007); The legislature of the State of Texas adopted a reasonable patient standard in its Medical Liability and Tort Reform Act of 2003, but also created the "Texas Medical Disclosure Panel" to determine the risks related to medical care that physicians should disclose to their patients. Tex. Civ. Prac. & Rem. Code Ann. § 74.101 - § 74.102 (2003) accessed on April 8, 2012 http://www.statutes.legis.state.tx.us/Docs/CP/htm/CP.74.htm.

[34] Tom L. Beauchamp & James F. Childress, PRINCIPLES OF BIOMEDICAL ETHICS 79 (Oxford Univ. Press, 5th ed. 2001).

and the law surrounding the medical practice in order to promote compliance with the patients' right to grant or withhold informed consent and decrease the risk of medical malpractice liability.

A. Physician-Centered Standard of Informed Consent

The PCS was adopted by the Supreme Court of Puerto Rico in the 1994 case of *Sepúlveda de Arrieta v. Barreto Domínguez*.[35] Interestingly, there was an initial attempt by the Supreme Court of Puerto Rico to adopt the RPS in the 1988 case of *Rodríguez Crespo v. Hernández*.[36] However, the Court explicitly rejected the RPS in *Sepúlveda de Arrieta* and the PCS has been the standard applied in Puerto Rico ever since. In *Sepúlveda de Arrieta*, the Court held that the standard of disclosure in informed consent cases is that "the physician has the duty to inform the patient of those risks that are customarily disclosed in the prevailing practice of medicine."[37] Specifically, the physician has the duty to inform the patient about: "the nature of the treatment alternatives", "the probabilities of success of the treatment, the risks and benefits of these and the prognosis in case the diagnosed condition was not treated."[38]

i. Elements of the Physician-Centered Standard

In the legal framework of the PCS, a physician may clearly have breached the duty to disclose risks to the patient; yet, this is not sufficient to hold a physician legally accountable. The PCS requires that the patient presents enough evidence to prove that the risk, which was undisclosed by the physician, actually materialized.[39] In addition to these two requirements, the patient must show that there is a causal connection between the physician's negligence (i.e. breach of the duty to disclose) and the patient's injury.[40] Courts in the U.S. generally follow a different approach to causality than in Puerto Rico. U.S. jurisdictions follow two principal approaches.

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[35] Sepúlveda de Arrieta v. Barreto Domínguez, 137 D.P.R. at 752-53 (1994).

[36] Rodríguez Crespo v. Hernández, 121 D.P.R. 639 (1988).

[37] Sepúlveda de Arrieta, 137 D.P.R. at 753 (Author's translation of "el medico [tiene] el deber de informar aquellos riesgos, conforme lo establecido por la práctica prevaleciente de la medicina.").

[38] Sepúlveda de Arrieta, 137 D.P.R. at 752 (Author's translation). See also Ríos Ruiz v. Mark, 119 D.P.R. 816, (1987); Rodríguez Crespo v. Hernández, 121 D.P.R. 639 (1988); However, no consent is required when there is an emergency in which "it is not practical or it is impossible to obtain consent." Montes v. Fondo del Seguro del Estado de P.R., 87 D.P.R. 199 (1963); Furthermore, consent is not required "where an explanation of every risk attendant upon a treatment procedure may well result in alarming a patient who is already apprehensive and who may, as a result, refuse to undertake surgery or a treatment in which there is a minimal risk or where such disclosure may result in actually increasing the risk by reason of the psychological results of the apprehension itself." Torres Pérez v. Hospital Dr. Susoni, Inc., 95 D.P.R. 867 (1968) (quoting Woods v. Brumlop, 71 N.M. 221, 228 (N.M. 1962)).

[39] Sepúlveda de Arrieta, 137 D.P.R. at 756-57.

[40] Sepúlveda de Arri*eta,* 137 D.P.R. at 755.

The majority of states follow an objective patient standard of causality which requires that the patient shows that a reasonable patient in the plaintiff-patient's position would not have consented to the treatment had the materialized risk been disclosed.[41] A small minority of U.S. jurisdictions follow a subjective patient standard of causality, in which the court does not examine what a reasonable patient would have done, but whether the particular plaintiff-patient who alleges the violation would have consented to the treatment had the materialized risk been disclosed.[42]

Founded in civil law tradition, when examining causality, the Puerto Rican courts place the spotlight on the alleged tortfeasor, instead of examining if the patient subjectively or objectively would have assumed the risk had the patient been informed.[43] That is, the plaintiff-patient "must present evidence that allows the court to evaluate how the patient's decision would have been affected had the patient known the risk that was undisclosed *and if such effect was foreseeable from the point of view of the [physician]*."[44] Thus, the patient has to prove that the alleged tortfeasor-physician should have been able to foresee that had the materialized risk been disclosed, the patient would not have consented to the treatment and thus no harm would have occurred.

Together, the elements of an informed consent cause of action (i.e. negligence, injury, and causality) make it very difficult for a patient to prove such violation and recover damages. On top of that, the PCS requires that a plaintiff present medical expert testimony in order to prove that the standard of care in the medical practice required the physician to disclose the materialized risk. The costs of expert testimony places the prospects of bringing an informed consent legal claim out of the economic reach of many, if not most, individuals. In addition, the difficulty of proving informed consent cases, together with the costs involved, also make the prospects of finding a lawyer to take an informed consent tort case for a contingent fee even more remote. In sum, these obstacles amount to a PCS that by itself provides little incentive for physicians to be attentive to protecting patient autonomy and empowering patients.[45] Notwithstanding these shortcomings, and the fact that there seems to be a general consensus among courts that the RPS is more protective of patient autonomy, the Supreme Court of Puerto Rico in *Sepúlveda de Arrieta* adopted the PCS.

The RPS is equipped to be a more protective standard than the PCS because the RPS sets a minimum standard of disclosure that is not dependent on whatever the customary practice of physicians may be. This is a critical advantage of the RPS be-

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[41] *Canterbury v. Spence*, 464 F.2d 772, 790-91 (D.C. Cir. 1972) (discussing the subjective and objective patient standard of causality and adopting the objective standard).

[42] *Scott v. Bradford*, 606 P.2d 554, 559 (Okla. 1979).

[43] *Sepúlveda de Arrieta,* 137 D.P.R. at 758.

[44] Demetrio Fernández Quiñones, *Responsabilidad Civil Extracontractual*, 68 Rev. Jur. U.P.R. 441, 445 (1999) (Author's translation and emphasis).

[45] *See* Peter H. Schuck, *Rethinking Informed Consent*, 103 Yale L.J. 899, 935-37 (1994) (discussing the difficulty of succeeding in an informed consent cause of action).

cause many argue, and numerous studies suggest, that a readily ascertainable standard of care in the medical practice is more of a court-created myth than a reliable guiding force for physicians.[46] This customary practice-independent standard of disclosure helps make the RPS more in tune with current notions of the importance of patient autonomy and should ideally be adopted by the courts in Puerto Rico. However, the RPS suffers from some of the same practical obstacles as the PCS regarding a plaintiff's ability to bring a successful informed consent legal claim. Therefore, it is necessary that not only Puerto Rico's courts or the legislature adopt the RPS, but as will be discussed later in this article, it is necessary that Puerto Rico's medical regulatory bodies also become part of the solution to amend, educate and promote compliance with the legal duty to obtain informed consent.

B. Reasonable Patient Standard of Informed Consent

The RPS was originally adopted by the Court of Appeals for the District of Columbia in *Canterbury v. Spence*.[47] In *Canterbury*, the Court expressed doubts that it was the physicians' custom to disclose the relevant risks to their patients[48] and reasoned that respect for a patient's right for self-determination is so important that it "demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves."[49] The *Canterbury* court's concern about the level of disclosure that takes place in the medical practice is still a legitimate concern today, particularly in light of studies that confirm how prevalent it is for physicians to omit disclosing many of the risks inherent to their proposed treatments.[50] The *Canterbury* court held that "the test for determining whether a particular peril must be divulged is its materiality to the patient's decision."[51] A risk is considered material "when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy."[52]

In contrast to the PCS, the RPS brings the patient into the picture. Under Puerto Rico's current PCS, physicians simply need to follow the actions of other physicians

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[46] Philip G. Peters, Jr. *The Role of the Jury in Modern Malpractice Law*, 87 Iowa L. Rev. 909, 946 (2002).

[47] *Canterbury*, 464 F.2d at 787.

[48] *Id.* at 784.

[49] *Id.*

[50] Clarence H. Braddock III, Kelly A. Edwards, Nicole M. Hasenberg, Tracy L. Laidley, & Wendy Levinson, *Informed Decision Making in Outpatient Practice Time to Get Back to Basics,* 282 J. of the American Medical Association, 2313, 2317 (1999); Clarence H. Braddock III, Pameal L. Hudak, Jacob J. Feldman, Sylvia Bereknyei, Richard M. Frankel, & Wendy Levinson, *"Surgery is Certainly one Good Option": Quality and Time-Efficiency of Informed Decision-Making in Surgery*, 90 J of Bone and Joint Surgery Am. 1830, 1833-4 (2008).

[51] *Canterbury*, 464 F.2d at 786-87.

[52] *Id.* at 787 (quoting Waltz & Scheuneman, *Informed Consent to Therapy*, 64 N.W.U.L.Rev. 628, 639-40 (1970)).

in the practice, without much regard to the patients' informational needs. Under an RPS doctrine, physicians would need to take into account what a reasonable patient would consider material to making a medical decision. The physician does not have to disclose those risks of which "persons of average sophistication are aware" nor those which "the patient has already discovered, or those having no apparent materiality to the patient's decision."[53] Probably the two factors that contribute the most to the materiality of a risk are the frequency of injury and the magnitude of the possible harm.[54] "A very small chance of death or serious disablement may well be significant; a potential disability which dramatically outweighs the potential benefit of the therapy or the detriments of the existing malady may summons discussion with the patient."[55] Of course, there is no bright-line rule about what needs to be disclosed in an RPS doctrine. Neither is there a bright-line rule for the PCS. Nonetheless, physicians generally treat patients on a daily basis and come to know their common fears and concerns. At some points, physicians even find themselves in the patient's seat. Therefore, determining what a reasonable patient would consider a material risk is not a demanding standard in terms of the physicians' ability to discern what must be disclosed.

In fact, determining the materiality of a risk is so accessible that under the RPS the courts generally do not require medical expert testimony to establish the materiality of a risk.[56] This helps make the RPS a less costly standard in which to pursue claims, because there are fewer aspects of the litigation that require expert testimony. However, this does not mean that the RPS makes it easy for patients to get a verdict in their favor. Just as in the case with the PCS, in order to collect damages under a RPS, the patient needs to prove more than just a breach of the standard of disclosure. The patient also needs to prove that the undisclosed risk materialized and that the physician's negligence was the legal cause of the patient's injury. In order to prove causality, the *Canterbury* court adopted the objective patient standard of causality,[57] but other courts have adopted the subjective standard.[58] In keeping with Puerto Rico's civil law tradition, if Puerto Rico's courts or the legislature were to adopt a RPS, they could simply retain the same standard of causality currently used under the PCS and focus on the alleged tortfeasor.[59] **Table 2** summarizes what the elements for the tort of informed consent could be if Puerto Rico adopted a RPS.

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[53] *Canterbury*, 464 F.2d at 788.
[54] *Id.*
[55] *Id.*
[56] *Canterbury*, 464 F.2d at 792.
[57] *Canterbury*, 464 F.2d at 791.
[58] *Scott v. Bradford*, 606 P.2d 554, 559 (Okla. 1979).
[59] *Sepúlveda de Arrieta*.137 D.P.R. at 758.

TABLE 2: Proposed Elements for Establishing the Tort of Lack of Informed Consent in Puerto Rico under a Reasonable Patient Standard

Negligence	a physician fails to disclose a risk that a reasonable patient would consider material when determining whether to consent to a medical treatment or course of action; AND
Injury	the previously undisclosed risk by the physician materializes;[60] AND
Causality	the alleged tortfeasor/physician should have been able to foresee that had the materialized risk been disclosed, the patient would not have consented to the treatment.[61]

C. Weighing Vital Practical Considerations of Adopting the Reasonable Patient Standard

i. Growth of Managed Care Techniques in Puerto Rico's Health Care System

In 1994, when the Supreme Court of Puerto Rico adopted the PCS, managed care techniques such as capitation agreements were only starting to become the norm in Puerto Rico. With the passage of Puerto Rico's Health Reform Act in 1994, and to this day, most patients in Puerto Rico receive treatment by physicians working under capitation agreements.[62] In a capitation agreement, the physician is generally paid a fixed amount per patient regardless of the kind or amount of treatment that a patient requires; therefore the physician has the incentive to ration care and prescribe less expensive treatments.[63] Furthermore, private and public health insurance systems often employ managed care techniques that implicitly incentivize physicians to prescribe and patients to opt for certain types of treatments that may be considered sufficiently effective, but involve greater risks than more expensive alternatives.[64] Managed care techniques make the adoption of a RPS even more

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[60] *Id*. at 756-57.

[61] *Id*. at 758; Demetrio Fernández Quiñone*s,* Responsabilidad Civil Extracontractual, 68 Rev. Jur. U.P.R. 441, 445 (1999).

[62] Pan American Health Organization, *Health Systems Profile Puerto Rico: Monitoring and Analysis Health Systems Change/Reform*, 42 (2007) *available at* http://new.paho.org/hq/dmdocuments/2010/Health_System_Profile-Puerto_Rico_2007.pdf.

[63] Government reports in Puerto Rico have cautioned about this ethical dilemma: Comisión para Evaluar el Sistema de Salud del Estado Libre Asociado de Puerto Rico, *Informe: Evaluación del Sistema de Salud de Puerto Rico; Hacia el Desarrollo Integral del Sistema de Salud de Puerto Rico*, p. 28, 60 (2005).

[64] See Joan H. Krause The Brief Life of the Gag Clause: Why Antigag Clause Legislation Isn't Enough 67 Tenn. L. Rev. 1, 13 (1999) (discussing implicit incentives generated by managed care techniques to

necessary because the economic motives to reduce health care cost also create the perverse incentive for physicians to limit the disclosure of risks and treatment alternatives. This helps drive the customary standard of risk disclosure down because it is not in the physicians' or the insurance companies' economic interest to disclose more risks. This is not to suggest that physicians are purposefully acting against the best interests of their patients by not disclosing risks, but that these conflicting interests are part of the reality of everyday medical practice in Puerto Rico and the RPS can help curtail this collateral effect of managed care techniques.

While there are clearly strong reasons why a RPS should be adopted in Puerto Rico, the RPS also presents some possible hazards in terms of its impact on the health care field. Nevertheless, the overall benefits of a RPS seem to outweigh the risks. The two major concerns that must be taken into account when considering a shift to a RPS are the allocation of limited medical resources, and its effects on malpractice liability.

ii. Limited Medical Resources

In the last decade, the number of adult primary care visits to physicians in the United States has increased over 10% and the time spent per patient visit has also significantly increased.[65] Physicians often worry that they do not have enough time to spend with each patient.[66] One common concern voiced by physicians and courts, such as the Supreme Court of Puerto Rico, is that the RPS may require that physicians spend an excessive amount of time with each patient in order to obtain valid informed consent, which would delay services and consume excessive medical resources.[67]

This concern often arises due to a misunderstanding of what is required to meet the RPS. Some mistakenly believe that the RPS amounts to giving the patient a medical education or that it requires discussing every possible risk inherent to a medical course of action. As described before, discussing the material risks simply involves disclosing those risks that a reasonable patient would consider relevant for making an informed decision about their medical treatment. In addition, the physician does not need to disclose those risks that are obvious to a person of average

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withhold information about treatment alternatives); *See also* Jennifer Arlen & W. Bentley MacLeod, Malpractice Liability for Physicians and Managed Care Organizations 78 N.Y.U.L. Rev. 1929, 1932 (2003) (discussing how managed care organizations create incentives for physicians to opt for less expensive treatment options).

[65] Lena M. Chen, Wildon R. Farwell & Ashish K. Jha, *Does Good Care Take Longer?* 169 Archives of Internal Medicine 1866, 1868 (2009).

[66] Clarence H. Braddock III & Lois Snyder, *The Doctor Will See You Shortly: The Ethical Significance of Time for the Patient-Physician Relationship*. 20 Journal of General Internal Medicine 1057, 1057 (2005).

[67] *Sepúlveda de Arrieta*.137 D.P.R. at 750.

sophistication or those that the patient has already discovered.[68] In contrast to the concern voiced by some physicians and courts, studies suggest that physicians can obtain ethically valid informed consent, which is even more complete than simply disclosing the material risks, without engaging in substantially longer visits.[69]

Furthermore, other studies suggest that even if physicians who engage in more patient-centered communication behaviors spend more time with patients, these physicians have significantly lower expenditures per patient and thus conserve medical resources.[70] This suggests that perception may not be reality when it comes to the expenditure of medical resources under a RPS, and that there are ways of fostering patient autonomy while conserving medical resources. Furthermore, approximately half of the states and Washington D.C. have successfully adopted a RPS. These could serve as models for implementing RPS practices that strike a balance between respect for patient rights and autonomy and the conservation of medical resources.

D. Medical Malpractice Crisis

i. Medical Malpractice Liability Crisis

One important concern about adopting a RPS is that it may increase medical liability exposure. Studies show that verdicts for plaintiffs are more common in United States jurisdictions with RPS compared to those with PCS.[71] Nevertheless, the RPS promotes a number of benefits for physicians and patients, including reduced health care costs, improved health outcomes, reduced incidence of medical errors and reduced risk of malpractice lawsuits, which can clearly outweigh the slight increase in medical liability exposure.

Physicians in the United States and Puerto Rico are immersed in a malpractice liability crisis. A study from the American Medical Association reveals that 61% of physicians have been sued for malpractice at least once by the time the time they are 55 years old.[72] Furthermore, 50% of pediatricians have been sued by the time

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[68] *Canterbury*, 464 F.2d at 788.

[69] Clarence H. Braddock III, Pameal L. Hudak, Jacob J. Feldman, Sylvia Bereknyei, Richard M. Frankel, & Wendy Levinson, *"Surgery is Certainly one Good Option": Quality and Time-Efficiency of Informed Decision-Making in Surgery*, 90 J of Bone and Joint Surgery Am. 1830, 1836 (2008).

[70] Ronald M. Epstein, Peter Franks, Cleveland G. Shields, Sean C. Meldrum, Katherine N. Miller, Thomas L. Campbell, & Kevin Fiscella, *Patient-Centered Communication and Diagnostic Testing*, 3 Annals of Family Medicine 415, 418 (2005).

[71] David M. Studdert, Michelle M. Mello, Marin K. Levy, Russell L. Gruen, Edward J. Dunn, E. John Orav, & Troyen A. Brennan, *Geographic Variation in Informed Consent Law: Two Standards for Disclosure of Treatment Risks*, 4 Journal of Empirical Legal Studies 103, 116-17 (2007).

[72] Carole K. Kane, *Medical Liability Claim Frequency: A 2007-2008 Snapshot of Physicians*, American Medical Association, p. 5 (2010) accessed on: April 8, 2012, *available at* http://www.ama-assn.org/ama1/pub/upload/mm/363/prp-201001-claim-freq.pdf.

they are 55 years old, 50% of obstetricians/gynecologists have been sued before they are 40 years old and 90% of surgeons 55 or older have been sued. [73] Sixty-five percent of claims are eventually dropped, dismissed or withdrawn, but the average defense cost per claim is $40,649.[74] To make matters worse, Puerto Rico has more than twice the rate of malpractice award payments (5.6 per 100,000) than the average across the United States (2.4 per 100,000), although Puerto Rico's average malpractice award payment of $66,761 is lower than that across the United States ($285,218).[75]

The medical malpractice liability crisis affects every citizen in terms of the types of services offered and the availability of services. For example, a recent study in Puerto Rico examined how the medical liability environment has impacted physician practices in San Juan. This study showed that out of 951 physicians who participated in the study, 40% have been the subject of malpractice claims.[76] This is consistent with the American Medical Association's findings that 42.2% of all physicians have been sued.[77] Among all participants in the Puerto Rico study, 70% of physicians reported that they have considered making changes to their practices in order to decrease medical liability risks.[78] These changes include not offering emergency services (48%), not accepting high-risk patients (50%), not performing surgery (16%), closing office (16%), relocating (19%) and retiring early (22%).[79] Consistent with this study, a commission established by the Governor of Puerto Rico in 2005 concluded that although 70% of medical malpractice suits in Puerto Rico are dropped because they are frivolous or lack merit, they still encourage physicians to close their practice, retire, perform less risky procedures or relocate outside of Puerto Rico.[80]

ii. Patient Safety Crisis

It is clear that the medical liability environment is in dire need of reform in Puerto Rico and the United States. Any reform must include measures that improve

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[73] *Id.*

[74] *Id.*

[75] American College of Emergency Physicians, *The National Report Card on the State of Emergency Medicine 2009: Evaluating the Emergency Care Environment State by State*, p. 59, 120 (2009) accessed on: March 24, 2012 *available at* http://www.emreportcard.org./uploadedFiles/ACEP-Report-Card-10-22-08.pdf.pdf.

[76] Norma I. Cruz, *The Medical Liability Environment in San Juan: Results of a Survey*, 29 Puerto Rico Health Sciences J. 66, 68 (2010).

[77] Carole K. Kane, *supra* n. 73.

[78] Norma I. Cruz, *The Medical Liability Environment in San Juan: Results of a Survey*, 29 Puerto Rico Health Sciences J. 66, 68 (2010).

[79] *Id.*

[80] Comisión para Evaluar el Sistema de Salud del Estado Libre Asociado de Puerto Rico, *Informe: Evaluación del Sistema de Salud de Puerto Rico; Hacia el Desarrollo Integral del Sistema de Salud de Puerto Rico*. p. 260 (2005).

the malpractice liability exposure of physicians; however, any reform must also include measures that attempt to improve patient safety by decreasing the incidence of malpractice. There is a consensus that not only is there a medical malpractice liability crisis, but there is also a patient safety crisis that needs to be addressed.[81] A seminal report on medical errors by the Institute of Medicine estimated that up to 98,000 patients die every year in the United States due to preventable medical mistakes.[82] Furthermore, another study estimated that 535,772 severe medical injuries occur every year in hospitals in the United States.[83] Of these severe medical injuries, about 180,528 (33%) are due to medical negligence.[84] Nevertheless, only approximately 2 out of 10 severe medical injuries due to medical negligence are ever claimed.[85]

iii. Recent Attempts to Alleviate the Medical Liability Crisis in Puerto Rico

There have been a variety of attempts in Puerto Rico to address the medical malpractice liability crisis. For example, since last year, Puerto Rico's legislature has considered a bill that would set a cap on non-economic medical malpractice damages (P. del S. 2195 and P. de la C. 3453)[86] similar to that of the State of Texas' Medical Liability and Tort Reform Act of 2003.[87] An analysis of the merits of this bill for improving the medical liability environment in Puerto Rico is beyond the scope of this article.[88] However, a measure such as this clearly requires a more comprehensive approach because it focuses on the problem of medical malpractice liability exposure, but does little to promote patient safety by curtailing the incidence of medical errors.

Notably, a cap on medical malpractice damages along with the current PCS in Puerto Rico would put patients in a hazardous situation. That is, studies show that

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[81] *See* Lucian L. Leape & Donald M. Berwick, Five Years After to Err is Human: What Have We Learned? 293 J. of the American Medical Association 2384, 2384 (2005); *See also* Lucian L. Leape, *Errors in Medicine*, 404 Clinica Chimica Acta 2, 2 (2009).

[82] Linda T. Kohn, Janet M. Corrigan, & Molla S. Donaldson eds., *To Err Is Human: Building a Safer Health System*, Institute of Medicine, Washington, DC: National Academy Press (1999).

[83] David M. Studdert, Michelle M. Mello, Atul A. Gawande, Troyen A. Brennan, and Y. Claire Wang, *Disclosure of Medical Injury to Patients: An Improbable Risk Management Strategy*, 26 Health Affairs 215, 216 (2007).

[84] *Id.*

[85] *Id.*

[86] P. del S. 2195**,** 16ta. Asamblea Legislativa , 5ta. Sesión Ordinaria 26 de mayo de 2011, accessed on: April 8, 2012 *available at* http://senadopr.us/Proyectos%20del%20Senado/ps2195-11%20(LF-173).pdf; P. de la C. 3453, 16ta. Asamblea Legislativa, 5ta. Sesión Ordinaria 23 de mayo de 2011, accessed on: April 8, 2012 *available at* http://www.oslpr.org/.

[87] Tex. Civ. Prac. & Rem. Code Ann. § 74.301 (2003), accessed March 24, 2012 *available at* http://www.statutes.legis.state.tx.us/Docs/CP/htm/CP.74.htm.

[88] For further analysis of P. del S. 2195 and P de la C. 3453 *See* María Eugenia Torralbas Halais, *Análisis Constitucional: Topes de Impericia Médica*, __ Rev. Jurídica U. Inter. P.R. __ (2012).

physicians generally do not adequately inform patients about the risks assumed when patients undergo medical treatments.[89] Thus, if a medical malpractice cap went into effect without addressing the pervasive lack of informed consent in the medical field, patients would find themselves in a situation in which they will generally not be adequately informed about the risks of medical treatments, and then if the undisclosed risk materializes a jury or judge may not be able to make the patient whole as they see fit. At a minimum, such course of action would be ethically suspect, especially when there are means available for improving the informed consent culture.

When the State of Texas adopted a cap on non-economic medical malpractice damages, they also created the Texas Medical Disclosure Panel "to determine which risks and hazards related to medical care and surgical procedures must be disclosed by health care providers or physicians to their patients or persons authorized to consent for their patients and to establish the general form and substance of such disclosure."[90] Furthermore, that same bill established that the "the only theory on which recovery may be obtained [for failing to obtain informed consent] is that of negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent."[91] Therefore, the Texas legislature adopted a RPS along with the cap on non-economic medical malpractice damages. The government of Puerto Rico should, by all means, search for ways to improve the medical malpractice liability environment, but these measures must be accompanied with measures to improve the medical informed consent culture and decrease the incidence of medical errors.

iv. Adopting the Reasonable Patient Standard as a Measure to Alleviate the Medical Malpractice Crisis in Puerto Rico and Promote Patient Safety

Adopting a RPS to promote ethically valid informed consent is a solid step towards decreasing malpractice incidence and the risk of malpractice lawsuits, while at the same time protecting the patients' right to self-determination. The RPS would protect patient autonomy by requiring a minimum level of risk disclosure that is not dependent on the medical custom. In addition, the RPS will help to address both the problem of malpractice liability risks and malpractice incidence, because the pro-

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[89] Clarence H. Braddock III, Kelly A. Edwards, Nicole M. Hasenberg, Tracy L. Laidley, & Wendy Levinson, *Informed Decision Making in Outpatient Practice Time to Get Back to Basics,* 282 J. of the American Medical Association, 2313, 2317 (1999); Clarence H. Braddock III, Pameal L. Hudak, Jacob J. Feldman, Sylvia Bereknyei, Richard M. Frankel, & Wendy Levinson, *"Surgery is Certainly one Good Option": Quality and Time-Efficiency of Informed Decision-Making in Surgery*, 90 J of Bone and Joint Surgery Am. 1830, 1833-4 (2008).

[90] Tex. Civ. Prac. & Rem. Code Ann. § 74.102 (2003) accessed on March 24, 2012 *available at* http://www.statutes.legis.state.tx.us/Docs/CP/htm/CP.74.htm.

[91] Tex. Civ. Prac. & Rem. Code Ann. § 74.101 (2003) accessed on March 24, 2012 *available at* http://www.statutes.legis.state.tx.us/Docs/CP/htm/CP.74.htm.

cess of obtaining ethically valid informed consent by meeting the reasonable patient standard promotes better doctor-patient communication, which studies suggest significantly lowers the risk of malpractice suits and medical errors.[92] Consistent with this conclusion, a recent report on medication errors from the Institute of Medicine recently concluded that:

> The first step [to decrease errors] is to allow and encourage patients to take a more active role in their own medical care. In the past the nation's health care system has generally been paternalistic and provider-centric, and patients have not been expected to be involved in the process. But one of the most effective ways to reduce medication errors . . . . is to move toward a model of health care where there is more of a partnership between the patients and the health care providers.[93]

Grounded on the above discussion, the Puerto Rican courts and the legislature are invited to adopt a RPS of informed consent. However, a RPS will only serve as a first step towards promoting a culture of ethically valid informed consent and better doctor-patient communication. In order to reap the economic and health benefits that come from promoting a culture of respect for patient autonomy, it is necessary that the change occurs from within. That is, physicians must be actively involved in promoting patient autonomy and more egalitarian doctor-patient relationships. In the final part of this article, I will discuss how the Colegio de Médicos-Cirujanos de Puerto Rico ("Colegio") and the Junta de Licenciamiento y Disciplina Médica de Puerto Rico ("Junta") can play a crucial role in this process.

IV. Central Role of Physicians in Improving Informed Consent Practices in Puerto Rico

A comprehensive approach to improving the informed consent culture in Puerto Rico's medical practice requires that physicians take a leading role in promoting patient autonomy. This is mainly for three reasons. First, although the RPS is more

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[92] Wendy Levinson, Debra L. Roter, John P. Mullooly, Valerie T. Dull, & Richard M. Frankel, *Physician-Patient Communication: The Relationship with Malpractice Claims among Primary Care Physicians and Surgeons*, 277 J. of the American Medical Association 553, 557 (1997); Philip J. Moore, Nancy E. Adler, & Patricia A. Robertson, *Medical Malpractice: The Effect of Doctor-Patient Relations on Medical Patient Perceptions and Malpractice Intentions*, 173 Western J. of Medicine 244, 248 (2000); Institute of Medicine of the National Academies, *Preventing Medication Errors: Quality Chasm Series, Report Brief*, p. 2 (2006) accessed on: March 25, 2012, *available at* http://www.iom.edu/~/media/Files/Report%20Files/2006/Preventing-Medication-Errors-Quality-Chasm-Series/medicationerrorsnew.pdf.

[93] Institute of Medicine of the National Academies, *Preventing Medication Errors: Quality Chasm Series, Report Brief*, p. 2 (2006) accessed on: March 25, 2012, *available at* http://www.iom.edu/~/media/Files/Report%20Files/2006/Preventing-Medication-Errors-Quality-Chasm-Series/medicationerrorsnew.pdf.

protective of patient autonomy than the PCS, both of these legal standards place particular focus on the element of disclosure. However, there are other components, such as patient understanding, that the RPS and PCS do not reach. In order to promote an ethically valid informed consent culture, physicians must take self-regulatory measures aimed at ensuring patient understanding and participation in medical decision-making.

Second, the RPS and PCS are legal standards that are difficult to prove in courts of law; thus they provide little incentive for physicians to comply with the informed consent standard of disclosure. Therefore, self-regulatory measures for incentivizing compliance with the standard of disclosure must be enacted. Third and finally, a cultural shift in the physicians' approach to treating the doctor-patient relationship as a partnership and protecting patient autonomy involves a modification in their complex day-to-day practices which are better understood by physicians, thus optimally such shift requires a bottom-up strategy in which physicians self-regulate. Two key players in Puerto Rico's medical regulatory system that can promote patient understanding and compliance with the standard of disclosure are the Junta de Licenciamiento y Disciplina Médica de Puerto Rico ("Junta") and the Colegio de Médicos-Cirujanos de Puerto Rico ("Colegio").

A. Regulatory Authority of the Junta de Licenciamiento y Disciplina Médica in Puerto Rico

i. Structure of the Junta

The Junta and the Colegio have the authority and flexibility to promote, investigate and enforce initiatives for improving the medical practice in Puerto Rico. The Junta, as it is currently structured, was created in 2008 by Law No. 139.[94] The Junta is a board composed of 9 physicians appointed by the Governor; five of these physicians are appointed to 5-year terms and the rest have 4-year terms.[95] Each appointee can serve a maximum of 2 terms and must not be "a shareholder or belong to the Board of Trustees or Directors, or be an executive officer of a health care services company, insurance company, pharmaceutical company, managed care company, university or school of medicine."[96] Each appointee must also sign a sworn statement stating that they will not enter into any conflict of interest associated with their work in the Junta.[97] The Governor has the authority to remove any member of the Junta if there is just cause.[98]

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[94] Ley de la Junta y Licenciamiento y Disciplina Médica, Ley Núm. 139 del 1 de agosto de 2008, 20 L.P.R.A. §§ 131 et. seq.
[95] 20 L.P.R.A. § 132 (2008).
[96] *Id.*
[97] *Id.*
[98] *Id.*

ii. Responsibilities of the Junta

The Junta is responsible for establishing the requirements for admission into the practice of medicine in Puerto Rico and administering the licensing exams.[99] The Junta also has the authority and responsibility of issuing or denying licenses to practice medicine.[100] Furthermore, physicians in Puerto Rico must renew their license to practice medicine every 3 years, and the Junta has the authority to approve or deny the renewal of these licenses.[101] To renew a license, physicians must disclose information related to claims or actions raised against them associated with their practice.[102] In addition, the Junta requires that physicians meet a number of continuing education credits, which include courses in bioethics.[103]

iii. Investigative and Disciplining Authority of the Junta

Law No. 139 grants the Junta the authority to initiate investigations and disciplinary proceedings against physicians following the filing of a well-founded complaint or accusation raised by any individual or legal person, or motu propio.[104] These investigations must comply with the Law of Uniform Administrative Proceedings of Puerto Rico.[105] In addition, these investigations must be confidential and are carried out by an investigative officer hired by the Junta or named by the Secretary of Justice when the accusation involves medical malpractice.[106] The investigative officer has the power and authority that the law provides for prosecutors of the Justice Department of Puerto Rico.[107] In these disciplinary proceedings, the Junta must ensure the due process of law which includes: notifying the accused physician of the charges, giving the physician the opportunity to be represented by counsel, a fair and impartial hearing in front of the Junta or examining committee, and allowing the physician to present evidence, argue and to bring forth and question witnesses.[108]

The Junta may impose sanctions against the physician if a preponderance of the evidence shows that the physician incurred in the alleged violations.[109] In cases that involve medical malpractice, these sanctions include: censuring the physician, a period of probation in the practice of medicine, a requirement that the physician

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[99] 20 L.P.R.A. § 132e (2008).
[100] *Id.* (at art. 8(g)).
[101] 20 L.P.R.A. §§ 132e, 135e. (2008).
[102] 20 L.P.R.A. § 135f (2008).
[103] *Id.*; Reglamento General de La Junta de Licenciamiento y Disciplina Médica art. 9.2(C) (2010).
[104] 20 L.P.R.A. § 134 (2008).
[105] 20 L.P.R.A. § 134b (2008); Public Law No. 170-1988, 3 L.P.R.A. §§ 2101 *et. seq.*
[106] 20 L.P.R.A. § 134a. (2008).
[107] *Id.* (at art. 27(i)).
[108] 20 L.P.R.A. § 134b (2008).
[109] *Id*. (at art. 28(d))

submits to periodic peer reviews of the physician's medical practice, additional training or education, suspension or revocation of the physician's license to practice medicine, or a suitable restriction or limitation in the practice of medicine.[110]

iv. Exercising the Junta's Authority to Promote Compliance with the Informed Consent Standard of Disclosure

The Junta has ample authority to regulate the medical practice in Puerto Rico. Failure to obtain legally valid informed consent constitutes medical malpractice. The Junta cannot demand the payment of damages to victims of malpractice, but it has enough regulatory authority to serve as a powerful mechanism to promote the protection of patient autonomy. If the Junta makes it a priority to use its investigative and disciplinary authority to enforce compliance with the informed consent standard of disclosure it could have a potent effect in promoting a culture of ethically valid informed consent in Puerto Rico. Of course, one concern is the degree to which a regulatory body composed of members of the medical profession would be willing to step up enforcement of the informed consent standard against its colleagues. However, this is the Junta's legal responsibility and it can make a profound difference in promoting respect for patient rights and autonomy if it choses to do so.

Ideally, one would not need a "carrot and stick" approach and the prospect of promoting patient safety, respecting patients' rights and autonomy, empowering patients, promoting better doctor-patient relationships, improving health outcomes and decreasing the risk of malpractice liability would be enough to entice physicians to obtain ethically valid informed consent. However, studies show that the customary practice is that physicians do not often disclose risks and alternatives of treatment to their patients.[111] Therefore, using the Junta's disciplining authority as a "stick" to promote physician compliance with the standard of disclosure under the threat of possible sanctions is necessary.

v. Bioethics and Medico-Legal Training for Physicians to Promote Compliance with the Informed Consent Standard of Disclosure

The threat of sanctions should certainly not be the only approach to promote patient rights and autonomy. Ideally, the Junta should also make it a priority to educate physicians about the importance of obtaining ethically valid informed consent. The Junta has the means to do this, because it already requires physicians to take at least 6 credit hours of continuing education courses in bioethics to renew their license to practice every 3 years.[112] Therefore, all it would take for the Junta to help educate

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[110] 20 L.P.R.A. § 134a. (2008).

[111] Clarence H. Braddock III, Kelly A. Edwards, Nicole M. Hasenberg, Tracy L. Laidley, & Wendy Levinson, *supra* n. 90.

[112] 20 L.P.R.A. § 135f (2008); Reglamento General de La Junta de Licenciamiento y Disciplina Médica, art. 9.2(C) (2010).

physicians about the importance of patient autonomy and the benefits of compliance with the informed consent standard is to require that some portion of these credits are used to train physicians on how to comply with the standard of disclosure and the bioethical underpinnings of it. The Colegio could play an important role in this effort by designing and offering continuing education courses that address these issues through the Instituto de Educación Médica Continua ("IEMC" or Institute for Continuing Medical Education), which was created by law as part of the Colegio to provide continuing education courses for physicians.[113]

In these courses physicians should be trained to understand their legal obligations by using court opinions that are relevant to their practice and by introducing the bioethics that serve as the foundation for these legal obligations. Discussing how current bioethical notions apply to the legal obligations and court opinions relevant to the medical practice will allow physicians to learn not only about the ethics of medical practice, but also how to prevent medical malpractice suits. This article specifically proposes that medical students and physicians receive training in the legal and ethical underpinnings of informed consent in order to promote patient autonomy and compliance with the physicians' duty to disclose risks related to medical treatments. Yet, the same strategy can be proposed with regards to other relevant medico-legal doctrines, such as the legal parameters for establishing a doctor-patient relationship, the duty to treat and the duty to provide care that conforms to the standard of care, to name a few.

While at the moment, the legal standard of disclosure is the PCS, these courses should ideally train physicians on the legal requirements of both the PCS and RPS so that they can compare and contrast the merits of the two major doctrines, understand what is required to comply with them and appreciate their bioethical underpinnings. Finally, the Junta should also require that these topics be covered as part of the bioethics curriculum requirement in medical schools across Puerto Rico.[114] This will help ensure that future generations of physicians will learn how to pursue the best interest of their patients while protecting their patients' autonomy and legal rights.

B. Regulatory Authority of the Colegio de Médicos-Cirujanos de Puerto Rico

Every licensed physician must be a member of the Colegio de Médicos-Cirujanos de Puerto Rico ("Colegio") in order to practice medicine in Puerto Rico.[115] The Colegio was created by law in 1994 with the purpose of monitoring and promoting the quality of the medical practice and collaborating with the Junta in disciplinary proceedings for violations of law and ethical norms.[116]

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[113] Public Law No. 77-1994, 20 L.P.R.A. § 73(c); P. del S. 286, 12ma Asamblea Legislativa, 1ma Sesión Ordinaria (30 de abril de 1993).

[114] 20 L.P.R.A. § 135f (2008).

[115] 20 L.P.R.A. § 73g (2001).

[116] Exposición de Motivos Law No. 77 of August 13, 1994 20 L.P.R.A. § 73.

The Colegio plays an important regulatory function in Puerto Rico's medical practice because it can receive and investigate claims submitted by any citizen about the professional conduct of the Colegio's members.[117] Upon giving the interested parties an opportunity to be heard, if the Colegio's Committee for Ethics and Disciplinary Proceedings ("CEDP") finds just cause for a possible unethical or illegal conduct, it must refer the case to the Junta.[118] When the Colegio refers a case to the Junta it must "include a detailed report of the investigation, the procedures that were followed and the legal conclusions and recommendations." [119] The Colegio's authority to investigate possible ethical and legal violations of its members supplements, but does not preclude, the Junta's authority to carry out investigations.[120]

Although only the Junta is authorized to impose disciplinary sanctions, the Colegio's investigative authority may serve as an ideal tool for promoting patient autonomy and compliance with the informed consent standard of disclosure. The Colegio is an organization composed of physicians and therefore close to those who engage in daily doctor-patient relationships. Similar to the Junta, the Colegio's willingness to prioritize the investigation of breaches to the informed consent standard of disclosure can have a major impact in changing physicians' practices. Neither the Colegio nor the Junta can force a physician to pay out damages to patients; thus, from a patient's perspective there is less of an incentive to use the Colegio's or Junta's claims process. However, the Colegio can initiate investigations on its members motu propio and makes it relatively accessible for individuals to submit a claim. The claim form can be downloaded on the Colegio's website and submitted to the Colegio's CEDP, describing the allegations against the physician along with a sworn statement.[121] This makes the process of enforcing the standard of disclosure more accessible to patients than proceeding through the courts and incurring the costs associated with a lawsuit.

i. Physicians' Code of Professional Ethics

As part of the Colegio's responsibility to cooperate with the Junta in disciplinary proceedings, in 1994 it was given the authority to create a Código de Cánones de Ética Profesional ("Code of Professional Ethics") that would govern the professional conduct of its members.[122] The Colegio has the authority to investigate physicians for violations to this Code and to refer these cases to the Junta for further

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117 20 L.P.R.A. § 73e (2001).
118 20 L.P.R.A. § 73e (2001).
119 Reglamento General de La Junta de Licenciamiento y Disciplina Médica, art. 10.3 (2010).
120 20 L.P.R.A. § 73e (2001).
121 Committee for Ethics and Disciplinary Processes of the Colegio de Médicos-Cirujanos de Puerto Rico, *Claim Form*, accessed on: March 31, 2012 available at: http://www.colegiomedicopr.org/download.php?id=131.
122 20 L.P.R.A. § 73(g).

investigation and imposition of disciplinary sanctions.[123] Additionally, the Colegio has the authority to propose amendments to the Code of Professional Ethics in order to "promote the health and well-being of the people, and excellence in the practice of medicine."[124] The Colegio's CEDP is the committee within the Colegio that has been designated to prepare proposals for amendments to the Code of Professional Ethics.[125] After the Colegio's CEDP evaluates and prepares a proposal for amending the Code of Professional Ethics, it must submit this proposal to the Colegio's Medical Senate and Government Board.[126] If these bodies approve the amendments, they are then submitted to the Junta for approval, modification or rejection of the amendments.[127]

ii. Patient Autonomy and Informed Consent in the Code of Professional Ethics

The Colegio's Code of Professional Ethics has four pertinent parts that deal with patient autonomy and informed consent. As a reflection of the changing ethical considerations in medicine and the growing recognition of the importance of patient autonomy, the Code's preamble states in relevant part:

> The ethical dimension of medicine as formulated by Hippocrates, has been revised and expanded by the reflections of clinical bioethics. The Hippocratic Oath, only refers to the principles of beneficence and non-malfeasance. That is, the physician would swear commitment to acting in the patient's best interest and to abstain from hurting the patient (primum non nocere). As citizens in the more educated and developed societies demand explanations about diagnoses and treatment plans, they demand the right to participate in the decision-making process related to their health care. In recognition of this fact, contemporary clinical bioethics has been compelled to expand the ethical parameters. Now, in addition to beneficence and non-malfeasance, the bioethics discourse has incorporated the **principles of autonomy**, distributive justice, compassion, and human solidarity, among others.[128]

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[123] Reglamento del Comité de Ética y Procedimientos Disciplinarios del Colegio de Médicos-Cirujanos de Puerto Rico art. 2.1 (H) (2005) accessed on: April 1, 2012, *available at* http://www.colegiomedicopr.org/download.php?id=775.124 Law No. 56 of July 13, 20 L.P.R.A. § 73c, Art. 4(f) (Author's translation).

[125] Reglamento del Comité de Ética y Procedimientos Disciplinarios del Colegio de Médicos-Cirujanos de Puerto Rico art. 2.1 (H) (2005) accessed on: April 1, 2012, *available at* http://www.colegiomedicopr.org/download.php?id=775.

[126] Reglamento del Comité de Ética y Procedimientos Disciplinarios del Colegio de Médicos-Cirujanos de Puerto Rico art. 2.1 (H) (2005) accessed on: April 1, 2012, *available at* http://www.colegiomedicopr.org/download.php?id=775.

[127] Law No. 56 of July 13, 2001 art. 4(F), P. del S. 227, 20 L.P.R.A. § 73c.

[128] Colegio de Médicos-Cirujanos de Puerto Rico, *Code of Professional Ethics No. 7044*, Preamble p. 7 (2005) accessed on: April 8, 2012, *available at* http://www.colegiomedicopr.org/download.php?id=754 (Author's translation and emphasis).

Consistent with the importance of patient autonomy expressed in this preamble, the Code's first canon states in relevant part "the physician's primary loyalty is to the person of the patient" and this "loyalty implies . . . respect for the right to self-determination of the patient (*principle of autonomy*)."[129] Canon 1 ends by stating that "the patient will participate with the physician in the decision-making process regarding the care and treatments of the condition."[130]

Notably, Canon 4 states that "the physician has the ethical obligation to advise the patient about the possible courses of action (the advantages and disadvantages of each course of action) in such a way that the patient can exercise his/her right to give an informed consent."[131] Canon 4 goes on to specify that "what is important is not the mere consent but the informed character of the consent provided" and that if a "patient is not in a position to understand the explanation regarding the case" the physician must take measures to identify someone who can serve as a representative for the patient.[132]

This acknowledgement of the element of patient understanding for obtaining informed consent is commendable because, as discussed previously, it is not captured in Puerto Rico's PCS legal approach to informed consent and studies suggest that physicians generally do not attempt to assess patients' understanding of the medical decisions.[133] Overall, the Code of Professional Ethics reflects an acknowledgement by physicians in Puerto Rico that informed consent requires considerably more than what is contemplated by Puerto Rico's PCS or even what would be required by a RPS. While this is a vital recognition, the Colegio could take additional steps to effectively promote a culture of ethically valid informed consent in the day-to-day practice of medicine in Puerto Rico.

iii. Exercising the Colegio's Authority for Promoting Patient Autonomy and Compliance with the Informed Consent Standard of Disclosure

Grounded on the Colegio's recognition of the importance of protecting patient autonomy when obtaining informed consent, the Colegio is invited to propose

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[129] Colegio de Médicos-Cirujanos de Puerto Rico, *Code of Professional Ethics No. 7044*, Canon 1 p. 9 (2005) accessed on: April 8, 2012, *available at* http://www.colegiomedicopr.org/download.php?id=754 (Author's translation; emphasis provided by the original text).

[130] Colegio de Médicos-Cirujanos de Puerto Rico, *Code of Professional Ethics No. 7044*, Canon 1 p. 9 (2005) accessed on: April 8, 2012, *available at* http://www.colegiomedicopr.org/download.php?id=754 (Author's translation).

[131] Colegio de Médicos-Cirujanos de Puerto Rico, *Code of Professional Ethics No. 7044*, Canon 4 p. 10 (2005) accessed on: April 8, 2012, *available at* http://www.colegiomedicopr.org/download.php?id=754.

[132] Colegio de Médicos-Cirujanos de Puerto Rico, *Code of Professional Ethics No. 7044*, Canon 4 p. 10 (2005) accessed on: April 8, 2012, *available at* http://www.colegiomedicopr.org/download.php?id=754.

[133] Clarence H. Braddock III, Kelly A. Edwards, Nicole M. Hasenberg, Tracy L. Laidley, & Wendy Levinson, *supra* n. 90.

amendments to Canon 5 of the Code of Professional Ethics. Canon 5 specifies the procedure that the physician must follow "in order to potentiate in the patient the right to give an informed consent."[134] Canon 5 specifies the following process for ensuring that the patient provides informed consent.

> The physician will provide the patient information related to (I) the diagnosis of his/her condition or illness, (II) the nature of the recommended treatment, (III) probabilities of success of the treatment, (IV) the possible risks, (V) the alternatives, if any, for the recommended treatment, surgery or procedure, (IV) the prognosis of consequences if the patient does not go through with the treatment, or an alternative treatment, surgery or procedure, and (VII) the patient's right to obtain a second opinion with a physician of his/her choice.[135]

Specifically, the Colegio could propose the following amendments to Canon 5 to approach a more patient-centered standard of disclosure and promote patient understanding of the medical decision-making process.

> The physician will provide the patient information related to (I) the diagnosis of his/her condition or illness, (II) the nature of the recommended treatment, (III) probabilities of success of the treatment, (IV) the ***"material risks involved in the possible courses of action from the perspective of a reasonable patient,"*** (V) the alternatives, if any, for the recommended treatment, surgery or procedure, (IV) the prognosis of consequences if the patient does not go through with the treatment, or an alternative treatment, surgery or procedure; (VII) the patient's right to obtain a second opinion with a physician of his/her choice, **"and (VIII) the physician will inquire about the patient's understanding and possible misconceptions about the recommended treatment, surgery or procedure"**.[136]

These amendments would reflect the importance of an informed consent standard that is not dependent on the customary practice of medicine, which generally does not lead to adequate informed consent. These amendments will help engage the patient in the process of obtaining informed consent, in a manner consistent with current notions of patient autonomy and the Colegio's own understanding of

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[134] Colegio de Médicos-Cirujanos de Puerto Rico, *Code of Professional Ethics No. 7044*, Canon 5 p. 10 (2005) accessed on: April 7, 2012, *available at* http://www.colegiomedicopr.org/download.php?id=754. (Author's translation).

[135] Colegio de Médicos-Cirujanos de Puerto Rico, *Code of Professional Ethics No. 7044*, Canon 5 p. 10 (2005) accessed on: April 7, 2012 *available at* http://www.colegiomedicopr.org/download.php?id=754. (Author's translation).

[136] Colegio de Médicos-Cirujanos de Puerto Rico, *Code of Professional Ethics No. 7044*, Canon 5 p. 10 (2005) accessed on: April 7, 2012 *available at* http://www.colegiomedicopr.org/download.php?id=754. (Author's translation; emphasis indicates the author's proposed amendments).

patient autonomy as expressed in other parts of its Code of Professional Ethics. Even if the courts or the legislature in Puerto Rico do not adopt an informed consent Reasonable Patient Standard of Disclosure, the Colegio is invited to take these self-regulatory steps for the benefit of patients, physicians and the general functioning of Puerto Rico's health care system.

V. Conclusion

The Reasonable Patient-Plus Solution proposed in this article calls for a two-step solution to the problem of the pervasive lack of informed consent in the medical practice. The first step is to invite Puerto Rico's courts and legislature to adopt the Reasonable Patient Standard of informed consent. This standard is more protective of patient autonomy than Puerto Rico's Physician-Centered Standard.

Patients are entitled to grant or withhold consent for every medical decision because—as the Supreme Court of Puerto Rico has stated—they have the right "to self-determination, that is, to freely decide what should be done with his/her body"[137] and ultimately the patient is the one who would suffer the consequences if the risks associated with a medical treatment materialized. In order for patients to be able to grant or withhold truly *informed* consent, physicians must comply with their legal duty to disclose the risks and treatment alternatives in every medical decision. Puerto Rico should adopt a Reasonable Patient Standard because, unlike Puerto Rico's Physician-Centered Standard, the Reasonable Patient Standard establishes a minimum level of disclosure (i.e. the physician must disclose those risks that would be considered material to a reasonable patient) that is not dependent on the customary practice in the field of medicine. As discussed in this article, studies have shown that the customary practice in the field of medicine is that during the medical decision-making process physicians generally fail to disclose many of the potential risks of treatment, treatment alternatives and their patients' understanding of this information. Therefore, Puerto Rico's Physician-Centered Standard, which is dependent on the custom in the medical field, simply perpetuates the practice of obtaining inadequate informed consent and the Reasonable Patient Standard can cure this.

The second step in the Reasonable Patient-Plus Solution is to invite the Junta de Lincenciamiento y Disciplina Médica de Puerto Rico and the Colegio de Médicos-Cirujanos de Puerto Rico to adopt amendments to the physicians' Code of Professional Ethics. This article proposes specific amendments to Canon 5 of the Code of Professional Ethics that specifies the process that the physician must follow to ensure that the patient provides truly *informed* consent. The second step also calls for the Junta and the Colegio to prioritize compliance with the informed consent standard by using their investigative and disciplining authority. Finally, the most

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[137] *Sepúlveda de Arrieta,* 137 D.P.R. at 742.

important component of the second step is to invite the Junta to require that medical students and licensed physicians complete courses that combine bioethics and medico-legal education in order to enter the practice of medicine and renew their license. The Colegio can facilitate this training component by offering courses that combine bioethics and medico-legal education through their Institute of Continuing Medical Education.

If adopted, the Reasonable Patient-Plus Solution will establish a solid foundation for promoting positive change in the informed consent culture of Puerto Rico's medical practice. Promoting compliance with the physicians' duty to obtain informed consent and respect for patients' rights and autonomy will empower patients and positively impact Puerto Rico's entire health care system.