

## The Fiduciary Obligation of Physicians to “Just Say No” if an “Informed” Patient Demands Services that Are Not Medically Indicated

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### I. INTRODUCTION

After viewing several television commercials promoting a certain medical treatment and doing some related research on the Internet, a middle-aged man walks into his physician's office and requests a prescription for an advertised “lifestyle” medication.<sup>1</sup> He explains that he is going on a cruise with his girlfriend the following week and he needs the medication as soon as possible. The doctor reminds the patient that he has been treating him for high blood pressure and this drug may cause him some severe problems, possibly even a heart attack. The patient briefly considers the risks and then demands the drug anyway.

The physician thinks to himself: “I just graduated from medical school with \$250,000 of debt. Amanda and I just opened this practice, and we can't afford to alienate patients if we want to stay afloat. I can't believe how much we're paying in rent and salaries, and my family seems to think it's time we start living like a ‘doctor's family.’ As a resident, I wouldn't have given this guy this drug, but now I can't afford to say no. Besides, I've fully explained the risks—it's his call. And the risks aren't *that* high. Plus, maybe his managed care plan will deem it medically unnecessary or impose a huge co-pay, and when he sees how much it's going to cost him, he'll just drop this idea.”

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<sup>1</sup> This hypothetical could just as easily have focused on a middle-aged woman who walks into her physician's office and requests an “improved appearance” medication.

What should the doctor do? If a patient specifically requests a particular treatment, medical device, or diagnostic test, is properly informed of all the associated risks, and is willing to assume those risks, does a physician nonetheless have a responsibility to refuse a request that the physician believes is not medically indicated?

Until the middle of the twentieth century, a physician could and generally would decide unilaterally what was in the “best interest” of a patient and most likely would have refused these types of requests.<sup>2</sup> During the latter half of the twentieth century, however, patient advocates challenged this paternalistic approach and insisted that patients, not their doctors, should make treatment decisions. But should physicians provide requested treatments even when the patient’s request is contrary to the physician’s medical judgment? Furthermore, should doctors be held liable if they fail to exercise independent medical judgment when acceding to a request that poses a material risk to the patient?

The answer to these questions is relatively unclear. Neither courts nor scholars have given much attention to this issue. The primary reason for this void is that this situation seldom arose until the 1990s, even after the doctrine of informed consent gained formal recognition. Patients generally did not know enough about medical care to ask for a specific form of treatment. The proliferation of the Internet and the Food and Drug Administration’s (FDA) release of a Draft Guidance in 1997 permitting direct-to-consumer advertising (“DTCA”), however, have combined to provide patients with a wealth of information that they may not employ wisely and may be leading to a dramatic paradigmatic shift in the nature of the physician-patient relationship. Patients today are far more likely to self-diagnose their ailments and to push for or insist upon certain medications or other medical products or procedures.<sup>3</sup> Notwithstanding their physicians’ concerns about the wisdom of the patients’ views, these patients can place considerable pressure on physicians to order this treatment.

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<sup>2</sup> See *infra* Part II.

<sup>3</sup> A recent report noted that between seventy-five and eighty percent of Internet users have looked online for health information and revealed that seventy-five percent of online patients with a chronic condition “say their last health search affected a decision about how to treat an illness or condition.” SUSANNAH FOX, PEW INTERNET & AM. LIFE PROJECT, THE ENGAGED E-PATIENT POPULATION: PEOPLE TURN TO THE INTERNET FOR HEALTH INFORMATION WHEN THE STAKES ARE HIGH AND THE CONNECTION FAST 2 (Aug. 26, 2008), available at [http://www.pewinternet.org/pdfs/PIP\\_Health\\_Aug08.pdf](http://www.pewinternet.org/pdfs/PIP_Health_Aug08.pdf); see John Schwartz, *Logging On for a Second (or Third) Opinion*, N.Y. TIMES, Sept. 30, 2008, at F2. Another recent report, however, debated whether patients are “swimming” in a sea of health information or “drowning” in it. Tara Parker-Pope, *You’re Sick. Now What? Knowledge Is Power*, N.Y. TIMES, Sept. 30, 2008, at F1.

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This pressure may become particularly salient when patients threaten to go to another doctor if their physicians do not comply with their demands, or when physicians operating under the “crush” of daily practice are unwilling or unable to take the time to engage patients in a discussion as to why the requested medical response is contraindicated.

This Article explores the nature of a physician's obligation to refuse to provide medically contraindicated treatment to an insistent patient, even at the risk of alienating and perhaps losing the patient to another (perhaps less ethical) physician. Part II of this Article details the history of the physician-patient relationship, describing the impact of a shift from the “paternalistic” model to a “patient autonomy” model. Parts III and IV discuss the widespread availability of medical information via the Internet and DTCA, respectively, and their impact on the physician-patient relationship. Part V discusses physicians' current responsibility, driven by the doctrine of informed consent, to involve patients in the decision-making process and to permit them to make treatment decisions for themselves, and examines whether informed consent adequately protects patients in a world of DTCA and the Internet.

Part VI argues that physicians have an ethical and a corresponding legal obligation to exercise independent medical judgment when a patient demands access to products and services that are not medically indicated, and discusses the appropriate legal standard associated with a failure to meet this obligation.<sup>4</sup> Part VII explores the benefits for physicians, patients, and society as a whole of recognizing that physicians have a fiduciary duty to exercise independent medical judgment in response to a patient's demand for a service that is not medically indicated. This Article concludes that it is not enough for a physician to merely inform patients of the risks of requested medical services and products, but that a physician also has an affirmative ethical and legal obligation to exercise independent medical judgment and to refuse to acquiesce to a patient's request that is contrary to the doctor's medical judgment—notwithstanding the patient's “informed” demand for that service or product.

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<sup>4</sup> It is beyond the scope of this Article to discuss the situation where a patient requests a medical service that the physician believes is ethically—as opposed to medically—contraindicated (e.g., a request for an abortion).

## II. HISTORY OF THE PHYSICIAN-PATIENT RELATIONSHIP

Historically, the doctor-patient relationship has been founded upon the principle of beneficence, played out through the doctrine of medical paternalism.<sup>5</sup> Medical paternalism eventually gave way to notions of patient autonomy during the twentieth century when it was determined that patients have the right to make their own treatment decisions.<sup>6</sup> As discussed below, some commentators are now arguing that the era of patient autonomy should, in turn, give way to a shared responsibility where both the physician and patient jointly exercise decision-making authority.

A. *Paternalism*

Medical paternalism can be defined as “an action taken by one person in the best interests of another without their consent.”<sup>7</sup> Since the days of Hippocrates, doctors have been empowered to make decisions *for* their patients.<sup>8</sup> Jay Katz, in his landmark work on the physician-patient relationship, observed that giving patients the liberty to make their own treatment decisions “was never part of the ethos of medicine.”<sup>9</sup> Another scholar has written that “[t]he doctor decided what was best for the patient, and the patient accepted the decision, usually without questioning, [without] understanding, or perhaps even [without] a real choice.”<sup>10</sup>

Ancient Greeks, including Plato and Hippocrates, taught that patients should not play a part in the decision-making process.<sup>11</sup> They viewed such participation as unnecessary and counterproductive because the doctor and the patient presumably had the same ob-

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<sup>5</sup> Charity Scott, *Why Law Pervades Medicine: An Essay on Ethics in Health Care*, 14 NOTRE DAME J.L. ETHICS & PUB. POL'Y 245, 263 (2000).

<sup>6</sup> *Id.*

<sup>7</sup> David C. Thomasma, *Beyond Medical Paternalism and Patient Autonomy: A Model of Physician Conscience for the Physician-Patient Relationship*, 98 ANNALS OF INTERNAL MED. 243, 244 (1983) (citing James F. Childress, *Paternalism and Health Care*, in MEDICAL RESPONSIBILITY: PATERNALISM, INFORMED CONSENT, AND EUTHANASIA 15, 27 (Wade L. Roivison & Michael S. Pritchard eds., 1979)).

<sup>8</sup> JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* 1–2 (Johns Hopkins Univ. Press 2002) (1984).

<sup>9</sup> *Id.* at 2.

<sup>10</sup> Scott, *supra* note 5, at 263.

<sup>11</sup> Julie M. Spanbauer, *Breast Implants as Beauty Ritual: Woman's Sceptre and Prison*, 9 YALE J.L. & FEMINISM 157, 187 (1997) (“Perform [these duties] calmly and adroitly, concealing most things from the patient while you are attending to him . . . revealing nothing of the patient's future or present condition.” (quoting 2 HIPPOCRATES, DECORUM 297 (W. Jones trans., 1967))).

jective: to heal the sick.<sup>12</sup> The physician alone possessed the knowledge and experience needed to make a medical decision, so a patient's input was viewed as unnecessary. In addition, ancient physicians believed that a patient's psychological well-being was critical to the healing process. They thought it would be therapeutically counterproductive for a patient to truly understand their compromised state of health and the risks that they faced, knowledge which in turn would jeopardize, limit, and slow recovery.

The *Corpus Hippocraticum* went so far as to recognize a duty of deceit, which encouraged physicians to conceal the patient's true condition—especially from the patient.<sup>13</sup> Ancient healers justified manipulation of the patient by noting, as Socrates did, “the healing effects of fair words.”<sup>14</sup> Ancient doctors believed optimism and confidence were essential to the healing process. According to Hippocrates, the therapeutic effect of encouraging words was so important that a good doctor should always “promise to cure what is curable and to cure what is incurable.”<sup>15</sup> Needless to say, the patient had little role to play in deciding the course of treatment.

This belief in the therapeutic importance of “fair words,” even when these “words” did not accurately reflect the patient's condition, and the limited involvement of patients in treatment decisions, continued to pervade medical ethics centuries later. In the words of ninth-century Jewish physician Isaac Israeli: “Reassure the patient and declare his safety even though you may not be certain of it, for by this you will strengthen his Nature.”<sup>16</sup> The importance of optimism and the value of deceit continued to justify physicians' paternalistic treatment of their patients.

In addition to the therapeutic impact of limited disclosures and optimism, physicians also insisted that there was an intimate relationship between God and doctors. During the middle ages, Jewish, Arabic, and Christian physicians asserted that God anointed doctors; therefore, any attempt to question the physician would be questioning God, which would be blasphemous.<sup>17</sup> As a result, the paternalistic

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<sup>12</sup> KATZ, *supra* note 8, at 6.

<sup>13</sup> Lori B. Andrews, *The Right and Rite of Informed Consent*, 21 LAW & SOC'Y REV. 765, 766 (1987) (describing one aspect of medical paternalism as “concealing most things from the patient, while you are attending to him . . . turning his attention away from what is being done to him; . . . revealing nothing of the patient's future or present condition”) (citation omitted).

<sup>14</sup> KATZ, *supra* note 8, at 6.

<sup>15</sup> *Id.*

<sup>16</sup> *Id.* at 9.

<sup>17</sup> *Id.* at 8–9.

model for physician-patient interactions was, if anything, stronger during medieval times than its more recent manifestations.<sup>18</sup>

Paternalism continued to pervade the physician-patient relationship throughout the seventeenth,<sup>19</sup> eighteenth,<sup>20</sup> and nineteenth centuries.<sup>21</sup> Until the middle of the twentieth century, doctors—and society—viewed physicians as having an obligation to act in their patients' best interests, with no duty to inform patients of their treatment options.<sup>22</sup>

A particularly striking judicial recognition of paternalism occurred in *John F. Kennedy Memorial Hospital v. Heston*,<sup>23</sup> where the New Jersey Supreme Court found that a physician was justified in ordering a blood transfusion even when a patient's objections were based on a religious belief that this treatment would result in the eternal damnation of the patient's soul.<sup>24</sup> The court stated, "When the [interests of

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<sup>18</sup> Danuta Mendelson, *Historical Evolution and Modern Implications of Concepts of Consent to, and Refusal of, Medical Treatment in the Law of Trespass*, 17 J. LEGAL MED. 1, 15 (1996) ("The essential model of the covenantal physician-patient relationship based on a patient's obedience and trust also was adopted by Moslem and Arabic-speaking Jewish physicians who became the intellectual heirs, custodians, and translators of the works of Hippocrates, Aristotle, and Galen into Hebrew and Arabic.").

<sup>19</sup> KATZ, *supra* note 8, at 10–13.

<sup>20</sup> *Id.* at 13–16. Note that some scholars started to recognize the need to communicate with the patient, but the physician still made the final decision. See Mendelson, *supra* note 18, at 19 ("Every man has the right to speak where his life or his health is concerned . . . . It becomes [the patient] to interpose with politeness, and deference to the judgment of the physician; it becomes [the physician] to hear what they have to say with attention." (quoting J. GREGORY, LECTURES ON THE DUTIES AND QUALIFICATIONS OF A PHYSICIAN 35 (1992) (1772))) (emphasis added)).

<sup>21</sup> KATZ, *supra* note 8, at 16–25. Mendelson defends physicians of this era by asserting that the decision to forego explanations was an expression of "professional honesty" because physicians at that time did not understand the "benefits and risks involved in a particular course of therapy." Mendelson, *supra* note 18, at 22–23. Nevertheless, even Mendelson admits that "modern bioethicists would describe [this] attitude as 'paternalistic.'" *Id.* at 22.

<sup>22</sup> See RUTH R. FADEN ET AL., A HISTORY AND THEORY OF INFORMED CONSENT 100–01 (1986) ("[B]efore the mid-twentieth century, the beneficence model . . . was the only operative model of the physician's responsibility to the patient."). Others argue, however, that the seeds of informed consent existed long before the patient autonomy movement of the twentieth century. See, e.g., Martin S. Pernick, *The Patient's Role in Medical Decisionmaking: A Social History of Informed Consent in Medical Therapy*, in 3 PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MED., MAKING HEALTH CARE DECISIONS: STUDIES ON THE FOUNDATIONS OF INFORMED CONSENT 1, 3 (Gov't Printing Office, 1982) ("[T]ruth-telling and consent-seeking have long been part of an indigenous medical tradition, based on medical theories that taught that knowledge and autonomy had demonstrably beneficial effects on most patients' health.").

<sup>23</sup> 279 A.2d 670 (N.J. 1971). New Jersey later overruled the case to the extent that the court placed greater importance on the physician's rights than the patient's rights. *In re Conroy*, 486 A.2d. 1209, 1224 (N.J. 1985).

<sup>24</sup> *Heston*, 279 A.2d at 673.

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a] hospital and staff are . . . pitted against the belief of the patient, we think it reasonable to resolve the problem by permitting the hospital and its staff to pursue their functions according to their professional standards.”<sup>25</sup>

*B. Patient Autonomy*

In 1914, in *Schloendorff v. Society of New York Hospital*,<sup>26</sup> Justice Benjamin Cardozo wrote, “Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault.”<sup>27</sup> To assert that a physician dedicated to healing the sick could assault a patient in the course of providing care that was neither negligent nor willfully deficient was nothing short of remarkable at that time (a view shared by many physicians now as well) and marked a radical shift toward recognizing patients’ rights in the physician-patient relationship.

The notion that patients should have the legal right to make their own decisions—and that doctors should obtain consent before performing invasive procedures—originated in contract law.<sup>28</sup> Indeed, it has been widely noted that the consent Justice Cardozo called for in *Schloendorff* “had its basis in the prominent and ancient legal principle of consent in contract law.”<sup>29</sup>

Analyzing the physician-patient relationship as merely a contractual arrangement, however, ultimately proved to be inadequate.<sup>30</sup> Under a traditional contractual approach, the physician merely had to show that the patient gave his or her general consent for the treatment provided, even though the patient had not been told about

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<sup>25</sup> *Id.* See also Martha S. Swartz, “Conscience Clauses” or “Unconscionable Clauses”: *Personal Beliefs Versus Professional Responsibilities*, 6 YALE J. HEALTH POL’Y L. & ETHICS 269, 315 (2006).

<sup>26</sup> 105 N.E. 92 (N.Y. 1914).

<sup>27</sup> *Id.* at 93.

<sup>28</sup> See Bryan J. Warren, Comment, *Pennsylvania Medical Informed Consent Law: A Call to Protect Patient Autonomy Rights by Abandoning the Battery Approach*, 38 DUQ. L. REV. 917, 929 (2000) (“Originally, the sufficiency of information provided and the nature of the physician-patient relationship were examined under principles of contract law.”); see also *Wall v. Brim*, 138 F.2d 478, 481 (5th Cir. 1943); Scott, *supra* note 5, at 264 (“Since the early part of this century, the law has expressed society’s view that it was wrong—a violation of autonomy—to treat the patient without some kind of consent.”).

<sup>29</sup> Warren, *supra* note 28, at 929.

<sup>30</sup> See *id.* (noting that the bargaining asymmetry between physician and patient, and the doctor’s potential conflicts of interest are reasons for the unsatisfactory nature of the contractual relationship).

potential treatment alternatives; only a “minimalist expression of autonomy” was required.<sup>31</sup> General consent may be sufficient for contractual parties with equal bargaining power who possess similar insights into and information about a proposed contractual agreement, but the knowledge disparity between a doctor and a patient can result in an enormous asymmetry between the two.<sup>32</sup> Analyzing the formation and implications of a physician-patient relationship under a contractual framework proved insufficient because of this asymmetry, particularly when physicians’ potential conflicts of interest<sup>33</sup> began to be recognized.<sup>34</sup> In addition, patients are typically sick, injured, or worried about their state of health and in no position to engage in a traditional bargaining process. In other words, the physician and patient are not conducting an arms-length transaction in the traditional sense.<sup>35</sup> Contract law provided insufficient protection for the under-informed, vulnerable, distracted, or anxious patient.

Just as a rising tide raises all boats, the increased recognition of civil rights in the 1950s and 1960s permeated and enhanced a range of individual rights, including those of medical patients.<sup>36</sup> Although at first glance they may seem unrelated, the civil rights movement dramatically impacted the physician-patient relationship by creating a social atmosphere in which Americans placed increased value on the rights of individuals, including those of medical patients.<sup>37</sup> Authority was openly questioned—whether it was the authority exercised by state and local officials or by a local physician—and the concept of

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<sup>31</sup> Scott, *supra* note 5, at 264.

<sup>32</sup> *Id.*

<sup>33</sup> For example, the undisclosed financial interests of a physician who recommends a course of treatment to enhance the income of the physician rather than to meet the medical needs of the patient can result in an inappropriate conflict of interests. See, e.g., *Moore v. Regents of Univ. of Cal.*, 793 P.2d 479, 483 (Cal. 1990) (holding that a research physician has an obligation to disclose his financial interest in a course of treatment).

<sup>34</sup> Warren, *supra* note 28, at 929. As will be discussed in Part V, this asymmetry of information is one of the primary bases for courts finding that physicians have a fiduciary duty to their patients.

<sup>35</sup> See *Canterbury v. Spence*, 464 F.2d 772, 782 (D.C. Cir. 1972) (“The patient’s reliance upon the physician is a trust of the kind which traditionally has exacted obligations beyond those associated with arms-length transactions.”).

<sup>36</sup> Swartz, *supra* note 25, at 314–17 (“As the result of the growing consumer and civil rights movements of the 1950s and 1960s, the emphasis among both medical ethicists and the courts began to center on a model of medical decision-making that emphasized patient autonomy and self-determination, rather than physicians’ rights.”).

<sup>37</sup> See Scott, *supra* note 5, at 265; see also FADEN ET AL., *supra* note 22, at 87 (“The issues raised by civil rights, women’s rights, the consumer movement, and the rights of prisoners and of the mentally ill often included health care components.”).



individual autonomy and rights rose to the forefront of social thinking.

In the political and social climate of the 1950s and 1960s, the patient autonomy movement was born. One scholar has gone so far as to describe the resulting rise in patient autonomy as “the greatest revolution of twentieth century American society.”<sup>38</sup> During this time, “Patients began to voice the ethical proposition, founded on the autonomy principle, that they, rather than the doctors, should have the ultimate authority to decide the course of their medical treatment.”<sup>39</sup> In an attempt to secure this newfound “ultimate authority,” patients turned to the American court system.<sup>40</sup>

The courts ultimately endorsed the position espoused by the patients, finding doctors liable if they failed to properly disclose significant risks and obtain “informed consent” before initiating medical treatment.<sup>41</sup> A California court first used the phrase “informed consent” in 1957 in a case where a physician admitted that he failed to disclose the dangers of a surgical procedure to his patient, and the patient awoke from surgery paralyzed.<sup>42</sup> The doctrine was affirmed and further explicated in the seminal case of *Canterbury v. Spence*,<sup>43</sup> where the court ruled that a physician has a duty to disclose to a patient the material risks associated with a proposed procedure that a reasonable patient would need to hear to make an informed decision.<sup>44</sup> The informed consent requirement marked the culmination of the shift in the nature of the physician-patient relationship from a paternalistic approach to one that emphasizes patient autonomy.<sup>45</sup>

Under the patient-autonomy model, patients make the ultimate decisions concerning their healthcare, although these decisions are “based on the physician’s description of the relative risks, benefits, and alternatives available.”<sup>46</sup> To determine which procedures are in their best interest, patients are entitled to know their viable options

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<sup>38</sup> Swartz, *supra* note 25, at 314 (quoting Alan Meisel, *Managed Care, Autonomy, and Decisionmaking at the End of Life*, 35 HOUS. L. REV. 1393, 1397 (1999)).

<sup>39</sup> Scott, *supra* note 5, at 265.

<sup>40</sup> *Id.*

<sup>41</sup> *Id.* at 265–66.

<sup>42</sup> *Salgo v. Leland Stanford Jr. Univ. Bd. of Trs.*, 317 P.2d 170, 181 (Cal. Ct. App. 1957).

<sup>43</sup> 464 F.2d 772 (D.C. Cir. 1972).

<sup>44</sup> *Id.* at 787 (“[A] risk is . . . 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.”).

<sup>45</sup> *Id.*; see *infra* Part V.A for further discussion of the informed consent doctrine.

<sup>46</sup> Swartz, *supra* note 25, at 316.

and the material risks and benefits associated with each option.<sup>47</sup> The doctor is responsible for dispensing information; the patient is responsible for making the decisions.

On its face, alarmists could view this shift as resulting in highly trained professionals being reduced to mere information conduits with little decision-making authority, their extensive knowledge and expertise utilized only to the extent desired by the patient.<sup>48</sup> In practice, however, patients usually seek and follow their doctors' treatment recommendations, and the recognition of patient autonomy did not revolutionize the physician-patient relationship, nor did it dramatically change the nature of the interaction between physicians and patients.<sup>49</sup> For example, although advance directives were and continue to be highly heralded as a means of preserving the decision-making rights of patients, they have been found to have had a limited impact on medical decisions, notwithstanding that the Patient Self-Determination Act of 1991 mandates that patients must be notified of their right to execute such a document prior to every hospital admission.<sup>50</sup>

Nevertheless, the respect afforded patient autonomy in the latter half of the twentieth century did represent an important landmark: society and the courts emphasized that patients have the *right* to make their own medical decisions, even if they do not necessarily exercise it. As one scholar has indicated, "Informed consent has become the legal and philosophical cornerstone of physician-patient relationships."<sup>51</sup> From a doctrinal perspective, the pendulum of power in the physician-patient relationship may appear to have swung almost entirely to the side of the patients, even if it is a right of patients that is infrequently exercised and even more rarely enforced.<sup>52</sup>

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<sup>47</sup> Scott, *supra* note 5, at 266.

<sup>48</sup> Liana Fraenkel & Sarah McGraw, *Participation in Medical Decision Making: The Patient's Perspective*, 27 MED. DECISION MAKING 533, 536 (2007) (reporting on patient interviews in which patients explain that they make the decision after receiving the relevant information and recommendations from the physician).

<sup>49</sup> Simon N. Whitney et al., *A Typology of Shared Decision Making, Informed Consent and Simple Consent*, 140 ANNALS INTERNAL MED. 54, 56 (2004) ("Although patients have broad rights to make their own decisions, . . . many patients, for a variety of reasons, choose to delegate decisional authority to their physicians.").

<sup>50</sup> Angela Fagerlin & Carl E. Schneider, *Enough: The Failure of the Living Will*, HASTINGS CENTER REPORT, Mar.-Apr. 2004, at 30, 30-31.

<sup>51</sup> Jonathan D. Moreno, Arthur L. Caplan & Paul Root Wolpe, *Informed Consent*, in 2 ENCYCLOPEDIA OF APPLIED ETHICS 687 (Ruth Chadwick ed., 2d ed. 1998).

<sup>52</sup> Much of the concern about this perceived shift can be attributed to relatively unjustified assumptions by physicians regarding the impact of this doctrinal change. One prominent medical malpractice attorney has referred to lawsuits based on a failure to obtain informed consent as the "hobgoblins" of physicians. Thomas E. Al-

C. *Shared Duty Between Doctor and Patient*

Some scholars argue that the pendulum has appropriately swung back to a more moderate position and that a shared decision-making model governs today's physician-patient relationship.<sup>53</sup> The terms used more recently to describe physician-patient relationships are "negotiation" and "concordance."<sup>54</sup> Such concepts signify a decision-making process where both parties are actively involved.<sup>55</sup>

Today, it is widely agreed that proper healthcare decision making involves a detailed communication and exchange between patients and physicians: the patients share their symptoms, concerns, goals, personal and family history, and lifestyle; and the physicians share the risks, side effects, alternatives, and probable results of potential treatment options.<sup>56</sup> Neither of the parties can or should shirk their respective responsibilities.

Indeed, "[i]n its purest form, there is a two way exchange of information, [with] both doctor and patient reveal[ing] treatment preferences, and both agree[ing] on the decision to implement."<sup>57</sup> When making decisions, both the physician and the patient have access to important and relevant information, but each also lacks vital information. On the one hand, physicians understand the medical implications, consequences, and risks of various treatment options. Patients, however, know what is important to their lives, what they hope to accomplish, and which risks they are willing to take.

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bro, Former President, Virginia Trial Lawyers Association, Address at University of Virginia School of Law (Nov. 28, 2007). Nevertheless, a deeply entrenched fear of being sued for a failure to obtain informed consent has resulted in informed consent forms becoming ubiquitous, notwithstanding that they are largely ignored by the patients required to complete them as a condition for obtaining medical treatment.

<sup>53</sup> Sydney Morss Dy, *Instruments for Evaluating Shared Medical Decision Making: A Structured Literature Review*, 64 *MED. CARE RESEARCH & REV.* 623, 623 (2007) (describing the shared decision-making model).

<sup>54</sup> Nicola Mead & Peter Bower, *Patient-Centredness: A Conceptual Framework and Review of the Empirical Literature*, 51 *SOC. SCI. & MED.* 1087, 1090 (2000).

<sup>55</sup> See Thomas L. Hafemeister, *End-of-Life Decision Making, Therapeutic Jurisprudence, and Preventive Law: Hierarchical v. Consensus-Based Decision-Making Model*, 41 *ARIZ. L. REV.* 329, 356 (1999) ("[M]any health care scholars and practitioners have promoted a consensus-based or shared decision-making model.").

<sup>56</sup> See, e.g., Ben A. Rich, *Medical Paternalism v. Respect for Patient Autonomy: The More Things Change the More They Remain the Same*, 10 *MICH. ST. J. MED. & L.* 87, 102-03 ("[W]eighing the risks and benefits of any medical procedure or course of treatment involves the consideration of a certain amount of scientific information. But it also involves important normative elements . . .").

<sup>57</sup> Cathy Charles, Tim Whelan & Amiram Gafni, *What Do We Mean by Partnership in Making Decisions About Treatment?*, 319 *BRIT. MED. J.* 780, 781 (1999).

For example, a professional athlete with a particular injury may desire a type of treatment that is likely to involve considerable initial pain and discomfort and carries a high risk of long-term disability, but which will enable the athlete to compete at the highest level and receive enormous compensation for a few more years. However, an office worker with the same injury may want to minimize both current and future pain, with little concern that he or she may not be able to compete at the same level athletically as in the past. Under the shared decision-making model, physicians explain alternative treatment options and offer their opinion as to which option is superior, while patients describe their individual circumstances and desires and, in light of the available options, express their view on which option is best.<sup>58</sup> Such a dialogue is believed to enhance the likelihood of a successful and mutually embraced treatment.<sup>59</sup> At the end of the day, they hopefully can and generally do agree on the proper course of treatment.

### III. THE INTERNET AND ITS IMPACT ON PHYSICIAN-PATIENT RELATIONSHIPS

While preparing for the day's activities and watching a child don a pair of pants, a parent notices that the child's right leg is an inch shorter than the left leg. What is the parent's first action? Does the parent call the child's pediatrician to set up an appointment? Does the parent take the child straight to the emergency room? Or does the parent first perform a quick Internet search to learn more about this condition? A patient may similarly visit the Internet after prescribed medication has not resolved back pain as quickly as hoped or after receiving an adverse diagnosis from a physician.

Patients now regularly seek health information on the Internet and then use this information to treat or otherwise respond to a

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<sup>58</sup> JENNIFER C. JACKSON, TRUTH, TRUST AND MEDICINE 156 (2001) ("The relationship between doctor and patient is based on the concept of partnership and collaborative effort. Ideally, decisions are made through frank discussion, in which the doctor's clinical expertise and the patient's individual needs and preferences are shared to select the best treatment option." (quoting ANN SOMMERVILLE, MEDICAL ETHICS TODAY: ITS PRACTICE AND PHILOSOPHY 1 (1993))).

<sup>59</sup> See Richard L. Kravitz, *Measuring Patients' Expectations and Requests*, 134 ANNALS INTERNAL MED. 881, 881 (2001) ("Meeting patients' expectations produces greater satisfaction with care, which in turn is related to greater adherence to medical advice, less 'doctor-shopping,' and a lower propensity to sue for malpractice.") (citations omitted). Kravitz also cites four empirical studies to demonstrate that patients' expectations are complex but can be determined by paying attention to the patients' "expression of feelings, provision of explanatory models, personal stories, and behaviors suggesting unresolved conflicts." *Id.* at 886-87.

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health concern, which may help them to decide whether and when to ask for the assistance of a physician and may also prepare them for any subsequent visit with a physician.<sup>60</sup> In addition, as out-of-pocket costs and the number of individuals without adequate healthcare coverage grow,<sup>61</sup> even more individuals are likely to turn to the Internet for medical guidance in the hope of minimizing their healthcare expenses. One recent study determined that over sixty percent of Internet users have searched for medical information online.<sup>62</sup> A 2004 Harris Interactive poll found an even higher number of Internet users—seventy-four percent—have searched for medical information.<sup>63</sup> The bottom line is that Americans routinely use the Internet to gain information about their health.

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<sup>60</sup> Sonia W. Nath, *Relief for the E-patient? Legislative and Judicial Remedies to Fill HIPAA's Privacy Gaps*, 74 GEO. WASH. L. REV. 529, 533 (2006).

<sup>61</sup> See Reed Abelson, *Health Care Costs Increase Strain, Studies Find*, N.Y. TIMES, Sept. 24, 2008, at C4 (“Two studies released [on September 24, 2008] provide further evidence of the toll health care is increasingly placing on working families, even for those who have health insurance. And as employees are paying more medical expenses out of their own pockets, they are having a harder time coming up with the money.”); Lisa Girion, *Ranks of Uninsured in U.S. Shrank in '07: The Census Bureau Says the 2007 Decrease Is Mostly Due to Expanded Government Coverage for Children*, L.A. TIMES, Aug. 27, 2008, at A-20 (reporting that the number of Americans without health insurance was 45.7 million in 2007 (15.3% of all Americans)); see also NAT'L COALITION ON HEALTH CARE, FACTS ON HEALTH INSURANCE COVERAGE 1 (2009) [hereinafter FACTS ON HEALTH INSURANCE], available at <http://www.nhc.org/documents/Coverage%20Fact%20Sheet-2009.pdf> (“Nearly 46 million Americans, or 18 percent of the population under the age of 65, were without health insurance in 2007 . . . .”); *id.* at 2–3 (“Employee spending for health insurance coverage . . . has increased 120 percent between 2000 and 2006.”) (citation omitted); *id.* at 4 (“A study found that 29 percent of people who had health insurance were ‘underinsured’ with coverage so meager they often postponed medical care because of costs.”) (citation omitted); Press Release, The Commonwealth Fund, Higher Costs and Stagnant Incomes Increase Financial Burden of Health Care, at 1 (Jan. 8, 2008) [hereinafter Higher Costs and Stagnant Incomes], available at [http://www.commonwealthfund.org/usr\\_doc/HA\\_Financial\\_Burden\\_NewsRelease.pdf?section=4059](http://www.commonwealthfund.org/usr_doc/HA_Financial_Burden_NewsRelease.pdf?section=4059) (“45.4 Million Americans in Families Spending More than 10 Percent of After-Tax Income on Health Care in 2004—Almost 6 Million More than in 2001.”).

<sup>62</sup> Michael B. Eisen & Andy Gass, *Public Access to Public Science: Recommendations for the California Stem Cell Institute's Policies Regarding Grantee-Produced Journal Articles*, 21 BERKELEY TECH. L.J. 1177, 1182 (2006).

<sup>63</sup> Humphrey Taylor & Robert Leitman, *No Significant Change in the Number of “Cyberchondriacs”—Those Who Go Online for Health Care Information*, HEALTH CARE NEWS, Apr. 12, 2004, at 1, available at [http://harrisinteractive.com/news/newsletters/healthnews/HI\\_HealthCareNews2004Vol4\\_Iss07.pdf](http://harrisinteractive.com/news/newsletters/healthnews/HI_HealthCareNews2004Vol4_Iss07.pdf). The discrepancy between the two statistics can likely be explained by the year in which the study was performed. Every year, more and more people turn to the Internet for information. FOX, *supra* note 3, at 1. An even more recent study estimated that between seventy-five percent and eighty percent of Internet users have looked online for health information. *Id.*

This use is particularly pronounced among individuals who are already receiving healthcare from a physician. One study found that patients frequently use the Internet to search for specific medical conditions (sixty-three percent) or a certain medical treatment or procedure (forty-seven percent).<sup>64</sup> Another study indicated that eighty percent of all patients go online, and that ninety percent of these patients have used the Internet to help understand their medical conditions.<sup>65</sup>

Because patients routinely perform Internet searches to learn more about their condition or symptoms, it is worth considering what impact the Internet has on their healthcare decisions.<sup>66</sup> In one study, respondents were asked various questions concerning the impact of the Internet on their interactions with their physicians.<sup>67</sup> The study found that thirty-six percent of those who frequently use the Internet sometimes or often suggested a specific illness when visiting a physician.<sup>68</sup> In contrast, only sixteen percent of patients who hardly ever use the Internet made similar suggestions.<sup>69</sup> In addition, forty-five percent of frequent Internet users sometimes or often request a specific treatment, while only nineteen percent of “hardly ever” Internet users make similar requests.<sup>70</sup> In other words, Internet users are more likely to actively seek to shape the course of diagnosis and treatment with their physicians.<sup>71</sup>

The same study asked patients how they use information from physicians when making healthcare decisions. The data showed that some patients still abdicate complete decision-making authority to their physicians: eight percent of patients relied entirely on physi-

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<sup>64</sup> Nath, *supra* note 60, at 534.

<sup>65</sup> Vinod Podichetty & David Penn, *The Progressive Roles of Electronic Medicine: Benefits, Concerns, and Costs*, 328 AM. J. MED. SCI. 94, 96 (2004).

<sup>66</sup> See *The Increasing Impact of eHealth on Consumer Behavior*, HEALTH CARE NEWS, June 26, 2001, at 1 [hereinafter *Impact of eHealth*], available at [http://www.harrisinteractive.com/news/newsletters/healthnews/HI\\_HealthCareNews2001Vol1\\_iss21.pdf](http://www.harrisinteractive.com/news/newsletters/healthnews/HI_HealthCareNews2001Vol1_iss21.pdf) (“As our . . . study revealed, those who use the Internet to explore health issues report that the information they find online has an impact on how they manage their overall health and comply with prescribed treatments.”).

<sup>67</sup> *Id.*

<sup>68</sup> *Id.* at 2.

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

<sup>71</sup> It is beyond the scope of this Article to determine whether a patient’s accessing the Internet for medical information leads to better or to worse care. This Article only addresses—regardless of the source of the patient’s beliefs—whether obligations are imposed on a physician when a patient demands a specific course of care that is medically contraindicated.

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cians for health decisions.<sup>72</sup> In contrast, nine percent used online resources to diagnose themselves and determine the proper treatment, and then to persuade their physicians to provide the treatment they sought.<sup>73</sup> Most people fell somewhere in the middle: fifty-five percent relied on physicians to make healthcare decisions but used the Internet to learn more about the physician's diagnosis, and twenty-eight percent sought information online to present to and discuss with their doctor but still relied on the physician to make the ultimate decision.<sup>74</sup>

These results demonstrate that over ninety percent of patients still rely considerably (and some entirely) on their physicians for help and advice in making proper medical decisions. For most patients, this is likely to be consistent with a collaborative decision-making process and, arguably, the help of the Internet is likely to result in more informed decisions. Of concern, however, are the nine percent of patients who self-diagnose and who may, with the acquiescence of the physician, treat the physician as a mere vehicle for obtaining services that they desire but that are medically contraindicated. These individuals may demand medically inappropriate services and give physicians ultimatums to provide requested care or lose their business. The problem, as noted by one physician, is that the demanded care is not necessarily the proper care: "[Y]ou know the old lawyer's [saying] about a person who represents himself has a fool for a client? That applies in medicine, too."<sup>75</sup>

#### IV. DTCA AND ITS IMPACT ON PHYSICIAN-PATIENT RELATIONSHIPS

The marketing of medical products to consumers has a lengthy history. Prior to the enactment of the Food and Drug Act of 1906, itinerant peddlers and other scam artists were free to advertise their "snake oil" and other self-proclaimed "miracle" cures directly to the public.<sup>76</sup> In part to counteract these marketing abuses, the federal government established the FDA in 1906.<sup>77</sup> The FDA was authorized to screen proposed medications for safety and efficacy and to review

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<sup>72</sup> *Impact of eHealth*, *supra* note 66, at 4.

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> Nancy K. Plant, *Prescription Drug Promotion on the Internet: Tool for the Inquisitive or Trap for the Unwary?*, 42 ST. LOUIS U. L.J. 89, 151-52 (1998).

<sup>76</sup> See, e.g., Zachary T. Bloomgarden, *American Diabetes Association Annual Meeting 1999: Diabetes and Obesity*, 23 DIABETES CARE 118, 123 (2000) (explaining that the use of "sanitized tapeworms" was widely advertised as an easy weight loss program in the early 1900s).

<sup>77</sup> See Food and Drug Act of 1906, 21 U.S.C. §§ 1-26 (2006).

the marketing of medical products to ensure that the American public was not deceived into purchasing untested or dangerous medications.<sup>78</sup> The development of, potential profit from, and competition among medical products has increased dramatically in recent years, however, which in turn has driven a desire to market medical products much more extensively. This desire led to calls from the promoters of these products to allow direct advertising once more to the American public.<sup>79</sup>

A. *The FDA's Relaxed Standards*

The FDA has permitted direct-to-consumer advertising since the early 1980s, yet until recently companies seldom utilized DTCA due to the costs and burdens of complying with FDA disclosure requirements.<sup>80</sup> The FDA, among other things, required pharmaceutical companies to explain in considerable depth the risks associated with their products.<sup>81</sup> This condition was based on the FDA's assertion that it was vital for prospective patients to know the risks to which they were exposing themselves—which was entirely consistent with the notions of informed consent that dominated this era.<sup>82</sup>

The FDA's requirements were greatly relaxed in 1997 with the release of a Draft Guidance by the FDA.<sup>83</sup> The FDA's Draft Guidance

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<sup>78</sup> 21 C.F.R. § 202 (2006); see Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 97, 100 (2002) (“[T]he FDA oversees the labeling and the advertising of prescription drugs. The FDA also regulates the labeling of all medical devices and the advertising of ‘restricted’ medical devices.”).

<sup>79</sup> Most developed countries, however, have withstood these calls. New Zealand and the United States have been reported to be the only developed nations allowing DTCA. Milt Freudenheim, *Showdown Looms in Congress over Drug Advertising*, N.Y. TIMES, Jan. 22, 2007, at C1.

<sup>80</sup> See Jaclyn Carole Hill, Note, *The Learned Intermediary Doctrine and Beyond: Exploring Direct-to-Consumer Drug Advertising Liability in the New Millennium*, 72 DEF. COUNS. J. 362, 362 (2005).

<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> Yonni D. Fushman, Case Comment, *Perez v. Wyeth Labs, Inc.: Toward Creating a Direct-to-Consumer Advertisement Exception to the Learned Intermediary Doctrine*, 80 B.U. L. REV. 1161, 1173–74 (2000); see also Sheryl Calabro, Note, *Breaking the Shield of the Learned Intermediary Doctrine: Placing the Blame Where it Belongs*, 25 CARDOZO L. REV. 2241, 2270 (2004). The FDA and Congress are currently considering reversing the 1997 relaxation of the regulation of DTCA and “[i]n the face of this pressure, the pharmaceutical industry has voluntarily agreed to abstain from advertising a new drug within the first six months of its release.” W. David Bradford et al., *The Impact of DCA on the Use and Effectiveness of Statin Drugs*, Presentation at the Conference of the American Society of Health Economists (June 5, 2006), <http://healthconomics.us/conference/2006/abstracts/issues-in-the-promotion-and-advertising-of-medicines/the>



marked a fundamental shift in the FDA's policy on advertisements for prescription drugs and dramatically changed the restrictions on DTCA. These guidelines noted the "inability of broadcast advertisements of reasonable length to present and communicate effectively the extensive [disclosure] information" previously deemed necessary by the FDA to prevent patients from being inappropriately swayed by this marketing.<sup>84</sup> As a result, currently a pharmaceutical company "merely has to identify the major side effects and 'contraindications [of a medical product] in lay language during the broadcast.'"<sup>85</sup> Instead of forcing companies to find a way to fully disclose the risks associated with their product, the FDA permits these advertisements to gloss over these risks by, for example, hiring an actor to speak very fast to convey a difficult to comprehend warning.<sup>86</sup> As will be discussed, despite assertions from manufacturers that the information from these advertisements will improve medical decision making, arguably the opposite has resulted.

#### B. *Prevalence of DTCA*

The effect of the FDA's relaxed standards was an absolute flood of DTCA. In 1996, the year before the FDA issued its Draft Guidance, pharmaceutical companies spent \$595.5 million on DTCA.<sup>87</sup> By 1999, following the FDA's 1997 issuance of its Draft Guidance, DTCA

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[\\_impact\\_of\\_dca\\_on\\_the\\_use\\_and\\_effectiveness\\_of\\_statin\\_drugs](#) (last visited Mar. 20, 2009).

<sup>84</sup> Consumer-Directed Broadcast Advertisements, 62 Fed. Reg. 43,171 (Dep't of Health & Human Servs. Aug. 12, 1997) (notice of draft guidance for industry).

<sup>85</sup> Calabro, *supra* note 83, at 2270–71. Specifically, in 1997 broadcast advertisements were required to contain "(1) a toll-free number that provides more specific information about a drug; (2) an alternative means of dispensing package labeling for consumers not connected to the internet; (3) a statement directing consumers to pharmacists and/or physicians; and (4) an internet web page address with specific information about the drug." Fushman, *supra* note 83, at 1174. The final version of the FDA's draft guidance was issued in 1999, adding the requirement that broadcast advertisements "be accompanied by more extensive print ads." *Id.*

<sup>86</sup> Lawmakers and others have criticized the FDA's enforcement of DTCA regulations. See Julie M. Donahue, Marisa Cevasco & Meredith B. Rosenthal, *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 NEW ENG. J. MED. 673, 674 (2007) (citing Gov't Accountability Office, *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising* (November 2006)). Since these criticisms, legislators have considered bills to place greater restrictions on DTCA. See, e.g., David C. Vladeck, *The Difficult Case of Direct-to-Consumer Drug Advertising*, 41 LOY. L.A. L. REV. 259 (2008) (analyzing two proposals before Congress that would require disclaimers on DTCA and place a moratorium on the DTCA of certain medications); Matthew Perrone, *Bill Could Block Some Ads for New Drugs*, SFGATE.COM, Apr. 17, 2007, <http://www.sfgate.com/cgi-bin/article.cgi?f=/n/a/2007/04/17/national/w083226D34.DTL&type> (last visited Mar. 20, 2009).

<sup>87</sup> Fushman, *supra* note 83, at 1170 n.60.

spending nearly quadrupled to a then-record \$1.9 billion.<sup>88</sup> The expanded use of DTCA has continued during the ensuing years. Spending by pharmaceutical companies on DTCA reached \$5.4 billion in 2006.<sup>89</sup>

Companies are using television commercials, as well as virtually all other media outlets, to promote everything from antidepressant medications to specific surgical procedures.<sup>90</sup> Medtronic Inc., for example, spent \$100 million on an advertising campaign to encourage consumers/patients to ask their doctors about the possible need for a surgically-implanted \$30,000 heart defibrillator.<sup>91</sup>

### C. *Effects of DTCA*

Proponents of DTCA—mostly pharmaceutical companies—defend these expenditures as an important method to “raise aware-

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<sup>88</sup> *Id.*

<sup>89</sup> Linda A. Johnson, *Consumer Drug Ads Down This Year, Report Says*, USATODAY.COM, Nov. 14, 2008, [http://www.usatoday.com/money/economy/2008-11-14-4021946389\\_x.htm](http://www.usatoday.com/money/economy/2008-11-14-4021946389_x.htm) (last visited Mar. 20, 2009). Spending is reported to have declined three percent in 2007 to \$5.3 billion, a still sizeable sum, and to have decreased six percent over the first eight months of 2008. *Id.* This drop has been alternatively attributed to fewer blockbuster drugs coming on the market, overall industry cost-cutting, “heat from lawsuits and critics claiming [drug company] ads overstate benefits and understate risks of some drugs,” and “the Food and Drug Administration now requir[ing] a few drug companies to get preapproval before airing ads.” *Id.* Despite this diminishment, concerns about the adverse impact of DTCA continue to proliferate. See Dingell, *Stupak Send Five Letters Regarding Questionable DTC Advertising of Prescription Drugs*, 6(40) HEALTH LAW WKLY. (Oct. 17, 2008), available at <http://www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Pages/2008/October%202008/October%2017%202008/Dingell,StupakSendFiveLettersRegardingQuestionableDTCAdvertisingOfPrescriptionDrugs.aspx> (“Congressman John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce, and Bart Stupak (D-MI), Chairman of the Oversight and Investigations Subcommittee, sent five letters October 14[, 2008,] in furtherance of their investigation into direct-to-consumer (DTC) advertising of prescription drugs.”); Bruce Japsen, *Medical Ads Aim Straight for the Heart*, CHI. TRIB., Jan. 23, 2007, at C1; Francesca L. Kritz, *Promises, Promises: As Efforts to Rein in TV Ads for Drugs Have Stumbled, Experts Worry That Too Many of Them Go Unchecked*, L.A. TIMES, Feb. 11, 2008, at F-3.

<sup>90</sup> See, e.g., Marshall H. Chin, *The Patient’s Role in the Choice of Medications: Direct-to-Consumer Advertising and Patient Decision Aids*, 5 YALE J. HEALTH POL’Y L. & ETHICS 771, 772 n.5 (2005) (noting that DTCA markets drugs directly to consumers through television, newspapers, magazines, direct mail, and the Internet); David M. Fritch, *Should the Purple Pill by Any Other Drug Company Still Be as Purple? The Changing Face of Trade Dress Protection for Pharmaceutical Manufacturers*, 47 IDEA 171, 188 (2006) (describing the “marketing blitz” of the drug Prilosec on television, the Internet, and print ads); Louis Boyarsky, Note, *Stealth Celebrity Testimonials of Prescription Drugs: Placing the Consumer in Harm’s Way and How the FDA Has Dropped the Ball*, 28 LOY. L.A. ENT. L. REV. 101, 102 (2008) (noting pharmaceutical companies’ use of celebrity talk shows to advertise their products).

<sup>91</sup> Japsen, *supra* note 89.

ness” of medical conditions and the availability of related medical treatments.<sup>92</sup> Critics, however, insist that the purpose—and effect—of DTCA is to sell drugs and other medical products, not to inform the public. These critics claim the advertisements misinform patients, not to mention enhance healthcare costs.<sup>93</sup> Even the former Commissioner of the FDA, David Kessler, who oversaw the implementation of the revised guidelines of the FDA, seems to regret the FDA’s decision, stating that direct-to-consumer ads “do not effectively or consistently convey important information about product risks and benefits.”<sup>94</sup>

Regardless of whether DTCA benefits society by increasing awareness of medical conditions and treatments, or harms society by misinforming and misleading patients into pursuing unduly expensive and unneeded medical products, an important question to address is whether DTCA is indeed having the effect its producers intend. Specifically, are patients requesting, and in some cases insisting, on particular medical products and services after viewing these advertisements, and is the medical judgment of physicians compromised as a result of the pressure they feel to order them? Various studies give reason for concern.

A 1998 study found that sixty-three percent of patients requested a specific prescription medication by name.<sup>95</sup> Another study, however, found that only thirty percent of patients knew which drug they wanted before walking into a doctor’s office, with forty percent of them receiving the requested drug.<sup>96</sup> But even this more conservative

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<sup>92</sup> *Id.* One Medtronic executive goes so far as to say, “This is about trying to save more lives. . . . There are people dying every day because they are not protected and they do not know they have a problem.” *Id.*

<sup>93</sup> *Id.*; see Rita Rubin, *Analysis: Prescription Drug Ads Leave Out Risks, Alternatives*, USA TODAY, Jan. 30, 2007, at D7. Although critics of DTCA have focused on their promotion of pharmaceuticals, concerns have also been raised about the use of DTCA to promote medical devices. Barry Meier, *Consumer Ads for Medical Devices Subject of Senate Panel*, N.Y. TIMES, Sept. 16, 2008, at C12 (“As makers of medical devices like artificial knees and heart stents increasingly pitch their products directly to consumers, some lawmakers, medical groups, and others are calling for restrictions on such advertisements, claiming they mislead patients.”); Emily P. Walker, *Medical Device Direct-to-Consumer Ads Said to Need More FDA Oversight*, MEDPAGE TODAY, Sept. 20, 2008, <http://www.medpagetoday.com/PublicHealthPolicy/HealthPolicy/10989> (last visited Mar. 20, 2009) (“The FDA should expand its oversight of direct-to-consumer ads to include medical devices, a prominent orthopedic surgeon and cardiologist told a congressional panel here this week.”).

<sup>94</sup> Rubin, *supra* note 93.

<sup>95</sup> Fushman, *supra* note 83, at 1171.

<sup>96</sup> *Id.* But see Meredith B. Rosenthal et al., *Promotion of Prescription Drugs to Consumers*, 346 NEW ENG. J. MED. 498, 504 (2002) (referring to an *international* study that found that twenty-five percent of patients initiated conversations with their physicians

finding indicates that twelve percent of patients requested and received specific prescription drugs from their physicians.

Furthermore, as described below, DTCA seems to result in increased prescriptions and pressures for those prescriptions, creates the potential for unwarranted prescribing of medications notwithstanding the risks they may impose, and appears to augment health-care costs.

### 1. Increase in Prescriptions

Perhaps not surprising in light of the significant investment in DTCA, studies strongly indicate that DTCA does in fact increase the use of the advertised product.<sup>97</sup> For example, in a nationally representative telephone survey conducted in January 2008 by the Harvard School of Public Health, Kaiser Family Foundation, and *USA Today*, ninety-one percent of the adults contacted said they had heard or seen DTCA and thirty-two percent said they had discussed the advertised drugs with their physicians.<sup>98</sup> Furthermore, of those who talked to their doctor about an advertised drug, forty-four percent were given a prescription for that drug.<sup>99</sup>

Similarly, the American Medical Association (AMA) conducted a randomized trial to determine “the effects of patients’ DTCA-related requests on physicians’ initial treatment decisions.”<sup>100</sup> While portraying symptoms of either a major depressive disorder or an adjustment disorder during their appointments with a physician, patients made a general request (that is, a particular type of medication was requested but a brand-specific request was not made), a brand-specific request, or did not request medication.<sup>101</sup> The study found that patients who requested medication were much more likely to receive a medication than patients who made no such request.<sup>102</sup> Furthermore, fifty-five

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concerning drugs they saw on television, and just under six percent actually received the prescription).

<sup>97</sup> See, e.g., Vladeck, *supra* note 86, at 270 (describing a National Institute for Health Care Management study that found that the number of prescriptions for the fifty most advertised drugs rose 24.6% from 1999 to 2000).

<sup>98</sup> USA TODAY, KAISER FAMILY FOUND. & HARV. SCH. OF PUB. HEALTH, THE PUBLIC ON PRESCRIPTION DRUGS AND PHARMACEUTICAL COMPANIES 4 (2008), available at <http://www.kff.org/kaiserpolls/upload/7748.pdf>.

<sup>99</sup> *Id.* In addition, these conversations were likely to result in the physician prescribing at least some medication, with eighty-two percent of these patients receiving the drug they asked about or some other prescription. *Id.*

<sup>100</sup> Richard L. Kravitz et al., *Influence of Patients’ Requests for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial*, 293 JAMA 1995, 1995 (2005).

<sup>101</sup> *Id.* at 1996.

<sup>102</sup> *Id.* at 2000.

percent of patients who presented with an adjustment disorder and made a brand-specific request linked to DTCA received this prescription, compared to only ten percent of those who did not make such a request.<sup>103</sup> In other words, patients in this category were five times more likely to receive a given medication if they specifically requested it. With regard to patients who portrayed major depression, “[a]ntidepressant prescribing rates were highest for visits in which [patients] made general requests for medication (76%), lowest for visits in which [patients] made no medication request (31%), and intermediate for visits in which [patients] made brand-specific requests linked to DTC advertising (53%[]).”<sup>104</sup> The study concluded that “DTC advertisement-driven requests (along with general requests) dramatically boost prescribing.”<sup>105</sup>

A study on the impact of DTCA on osteoarthritis medications similarly found that such advertising led to an increase in the prescribing of these medications.<sup>106</sup> Specifically, the DTCA produced by pharmaceutical giants Merck and Pfizer significantly increased the number of Vioxx prescriptions.<sup>107</sup> The researchers found that Vioxx DTCA also had a significant effect on the number of physician visits.<sup>108</sup> The study concluded that DTCA increased the rate at which advertised medications were prescribed.<sup>109</sup>

Supporters of DTCA argue that increased levels of prescriptions resulting from DTCA lead to more informed patients, improved diagnoses, and possibly even increased adherence to doctors' recommendations.<sup>110</sup> Supporters further claim that the ads may lead to heightened awareness of under-treated, under-diagnosed conditions.<sup>111</sup>

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<sup>103</sup> *Id.* at 1998.

<sup>104</sup> *Id.*

<sup>105</sup> *Id.* at 2000.

<sup>106</sup> W. David Bradford et al., *How Direct-to-Consumer Television Advertising for Osteoarthritis Drugs Affects Physicians' Prescribing Behavior*, 25 HEALTH AFFAIRS 1371, 1376 (2006).

<sup>107</sup> *Id.* The study was performed in 2000. Merck withdrew Vioxx from the market in September 2004 due to evidence of increased risk of heart attacks and stroke associated with its use. *Id.* at 1372.

<sup>108</sup> *Id.* at 1375. But note that Celebrex advertising had little effect on the number of Celebrex prescriptions. *Id.*

<sup>109</sup> *Id.* at 1376.

<sup>110</sup> See Rosenthal et al., *supra* note 96, at 504.

<sup>111</sup> Rob Stein, *Marketing the Illness and the Cure?: Drug Ads May Sell People on the Idea That They Are Sick*, WASH. POST, May 30, 2006, at A3.

Critics respond, however, that many of the ensuing prescriptions are unnecessary and even dangerous.<sup>112</sup> Adverse effects from prescription medication in general are the leading cause of iatrogenic injury and death, claiming more victims than car accidents, illegal drugs, or diabetes.<sup>113</sup> Given the risks associated with prescription medications and their respective side effects, doctors should, at a minimum, thoroughly explore and consider the need for and likely impact of any medication or other form of medical treatment before complying with the requests of patients for a given treatment regime.<sup>114</sup>

## 2. Inappropriate Treatment

One commentator noted that “[t]he potential costs [of DTCA] are inappropriate prescribing driven by the demands of misinformed patients and time wasted by physicians in explaining why a particular therapy or product is not appropriate.”<sup>115</sup> The AMA maintains that DTCA creates demand based on wants rather than needs, which can lead to “disease-mongering.”<sup>116</sup>

Disease-mongering has been described as “taking [a condition] that is within normal bounds and labeling it a disease needing pharmaceutical treatment.”<sup>117</sup> Television, Internet, and print ads for a new drug manufactured to treat restless leg syndrome, for example, have been criticized as creating “disease-mongering” among normal, healthy individuals.<sup>118</sup> Critics of these ads worry that people who simply have a hard time sitting still will request and receive an inappropriate prescription medication.<sup>119</sup> In general, as one medical scholar explains, “[t]he ordinary experiences of life become a diagnosis,

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<sup>112</sup> See Devin Taylor, Note, *Importing a Headache for Which There's No Medicine: Why Drug Reimportation Should and Will Fail*, 15 J.L. & POL'Y 1421, 1467 (2007).

<sup>113</sup> See Jason Lazarou et al., *Incidence of Adverse Drug Reactions in Hospitalized Patients*, 279 JAMA 1200, 1204 (1998). This study published in the Journal of the American Medical Association (JAMA) found that adverse drug reactions “may rank from the fourth to sixth leading cause of death” in the United States, following heart disease, cancer, and stroke. *Id.*

<sup>114</sup> What distinguishes prescription medications from the over-the-counter drugs is that they have been established to carry a certain level of risk in addition to the benefit they may provide.

<sup>115</sup> See Rosenthal et al., *supra* note 96, at 504.

<sup>116</sup> Japsen, *supra* note 89. Sick people demanding medication is also a serious concern. They may as a result not be receiving the treatment they need, as well as potentially suffering possible side effects from the treatment they do receive.

<sup>117</sup> Stein, *supra* note 111.

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

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which makes healthy people feel like they're sick."<sup>120</sup> By definition, a medication that requires a prescription carries with it a risk of deleterious side effects.<sup>121</sup> If healthy patients demand and receive prescription medication, they unnecessarily incur the risks and side effects associated with the drugs, as well as simultaneously increasing healthcare costs for the rest of society.

### 3. Increase in Healthcare Costs

Unlike most non-medical products, prescription medications and other medical treatments are paid for largely by employers, insurance companies, and society. Although out-of-pocket costs have increased, patients still pay a relatively small percentage of the costs of their healthcare.<sup>122</sup> Because patients have few incentives to limit expenditures and society as a whole is largely left holding the bill for prescribed medications (as well as other medical treatments), the advent of DTCA and the resulting increased number of prescriptions or other medical treatments administered may inevitably lead to increased healthcare costs for all. Following the FDA's relaxation of its restrictions on DTCA, for example, some insurers reported double-digit increases in prescription costs.<sup>123</sup>

#### *D. DTCA's Impact on the Physician-Patient Relationship*

When paternalism was the controlling principle governing the physician-patient relationship, patients simply followed the instructions of their doctor. Forty years ago, it was rare for a patient to contact a doctor and demand a certain medication or treatment. In general, patients would not even have known which medication to request.

With the advent of DTCA, the Internet, and the patient autonomy movement, patients now frequently diagnose themselves and decide upon a needed course of treatment before contacting their physician. As one commentator noted, "Where once patients relied on doctors to decide which drugs to treat an ailment, now patients have

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<sup>120</sup> *Id.*

<sup>121</sup> See *supra* notes 112–13 and accompanying text.

<sup>122</sup> FACTS ON HEALTH INSURANCE, *supra* note 61, at 2 ("nearly 15 percent of employees had no employer-sponsored health coverage available to them, either through their own job or through a family member"); Higher Costs and Stagnant Incomes, *supra* note 61, at 2 (reporting that the share of total health spending paid for out-of-pocket was 33.6% in 2004). These out-of-pocket costs can nevertheless be considerable for a given individual and are generally increasing, but they still remain only a fraction of the total healthcare bill. See *supra* note 61 and accompanying text.

<sup>123</sup> Japsen, *supra* note 89.

foreknowledge of the drugs they want and go to doctors as one would go to any vendor.”<sup>124</sup>

This patient insistence on a course of treatment can have a significant impact on physicians. One study found that ninety percent of doctors reported feeling pressured to prescribe certain medications, eighty percent assented to patient requests, and thirty-one percent admitted to prescribing drugs that were not their first choice.<sup>125</sup> Similarly, it has been reported that “71 percent of family physicians believe that direct-to-consumer advertising pressures physicians into prescribing drugs that they would not ordinarily prescribe.”<sup>126</sup> Such findings have led “[c]ritics [to] despair that direct-to-consumer advertising causes physicians to waste valuable time during encounters with patients and encourages the use of expensive and sometimes unnecessary medications.”<sup>127</sup> These critics assert that “consumer-directed advertisements are having their intended effect—consumers are asking their doctors for the advertised products and doctors are responding positively.”<sup>128</sup>

Increased patient requests for medication due to DTCA and information available on the Internet<sup>129</sup> can create an atmosphere in which physicians feel pressured to acquiesce to their patients’ requests rather than employ their own medical judgment. This atmosphere is potentially injurious to patients and physicians alike. Physicians should always provide clinical advice and order treatment that is consistent with their medical judgment,<sup>130</sup> and they should not be allowed to abdicate this responsibility, even in the face of direct pressure from the patient.

The allure of succumbing to patient pressure becomes more apparent when one considers the financial pressures that physicians face today. Managed care organizations require physicians to hold down costs;<sup>131</sup> immense overhead is associated with, among other

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<sup>124</sup> Fushman, *supra* note 83, at 1171.

<sup>125</sup> *Id.* at 1172.

<sup>126</sup> Rosenthal et al., *supra* note 96, at 498 (citing M.S. Lipsky & C.A. Taylor, *The Opinions and Experiences of Family Physicians Regarding Direct-to-Consumer Advertising*, 45 J. FAM. PRACT. 495, 495–99 (1997)).

<sup>127</sup> *Id.*

<sup>128</sup> Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829, 844 (1991).

<sup>129</sup> See *supra* notes 97–109 and accompanying text.

<sup>130</sup> Note that the concerns identified in this Article do not arise when a patient chooses or suggests a viable treatment plan that coincides with the physician’s medical judgment, even if it is not the physician’s first choice.

<sup>131</sup> See, e.g., John P. Little, Note, *Managed Care Contracts of Adhesion: Terminating the Doctor-Patient Relationship and Endangering Patient Health*, 49 RUTGERS L. REV. 1397,



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things, maintaining state-of-the-art healthcare facilities and adhering to strict record-keeping requirements;<sup>132</sup> the need for revenue places greater pressure to sustain and increase “patient flow”—that is, to process a given number of patients within a given allotted period of time;<sup>133</sup> and the federal government deeply discounts payments for services provided to Medicare, Medicaid, and other government-funded patients.<sup>134</sup> In addition, physicians are subject to financial pressures from their own expectations and needs, as well as those of their spouses and children, who often feel entitled to a nice home, expensive vacations, and a high standard of living after sacrificing for many years during their medical training.<sup>135</sup> These financial stresses are only compounded by physicians’ potentially astronomical student loans, which can be the equivalent of a home mortgage, or other forms of accumulated debt.<sup>136</sup> As a result, physicians often feel pressure to satisfy and retain patients as if they were customers in a retail business.<sup>137</sup> Nevertheless, physicians must resist these financial pres-

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1402 (1997) (“Financial penalties and the threat of being terminated from an MCO network provide strong incentives for physicians to restrict medical care . . .”).

<sup>132</sup> See, e.g., Deborah J. Meyers, *Are You Hip with HIPAA? The Health Insurance Portability and Accountability Act Is in Place to Benefit Employees, but Comes with Some High Costs to Employers*, ALASKA BUS. MONTHLY, Mar. 1, 2003, available at <http://www.allbusiness.com/human-resources/benefits-insurance-health/488237-1.html> (“One of the downsides of HIPAA is the increased cost . . .”). See generally Peggy Peck, *Survey Reveals Large Numbers of Practicing Physicians Ready to Call It Quits*, MEDPAGE TODAY, Nov. 18, 2008, <http://www.medpagetoday.com/PublicHealthPolicy/HealthPolicy/11823> (reporting that “only 17% [of practicing physicians] said their practices were financially healthy and profitable”).

<sup>133</sup> John D. Blum, *The Evolution of Physician Credentialing into Managed Care Selective Contracting*, 22 AM. J.L. & MED. 173, 185 (1996).

<sup>134</sup> COMM. ON PEDIATRIC EMERGENCY MED., AMERICAN ACAD. OF PEDIATRICS, OVERCROWDING CRISIS IN OUR NATION’S EMERGENCY DEPARTMENTS: IS OUR SAFETY NET UNRAVELING?, 114 PEDIATRICS 878, 879 (2004) (“This incredible economic burden [for physicians and hospitals] is exacerbated by insufficient Medicare reimbursement, which frequently fails to cover the direct costs of either the hospital facility or the emergency physician.”); Peck, *supra* note 132 (finding that sixty-six percent of practicing physicians said “Medicaid doesn’t pay enough to cover the cost of providing care and 36% said the same of Medicare”).

<sup>135</sup> See Jacob Goldstein, *As Doctors Get a Life, Strains Show: Quest for Free Time Reshapes Medicine; A Team Approach*, WALL ST. J., Apr. 29, 2008, at A1 (“63% of medical residents said the availability of free time was causing them a ‘significant level of concern’ as they entered the profession, up from 15% in 2001.”).

<sup>136</sup> Editorial, *Repair Student Loan Repayment Now: A Federal Legislative Change in How Medical School Graduates Repay Their Loans Leaves Residents in a Financial Pinch*, AM. MED. NEWS, Nov. 19, 2007, available at <http://www.ama-assn.org/amednews/2007/11/19/edsa1119.htm> (“Medical school graduates carry an average of \$130,571 in debt.”).

<sup>137</sup> This analogy to the commercial world and the forces of the “market” is being compounded by the recent trend to make available to prospective medical care con-

tures and provide treatment and services that reflect their medical judgment—even when faced with patients threatening to take their “business” elsewhere.

Physicians also should not abdicate their all-important responsibility of exercising sound medical judgment just because they are not fully informed about a patient’s condition and have limited time available to do related research. Richard Kravitz explains, “[P]hysicians don’t know much about [certain illnesses] and may be wanting to follow the path of least resistance [i.e., acquiesce to the patient’s request] and prescribe a medication for a condition that a patient might not have.”<sup>138</sup>

Whether physicians are following the “path of least resistance,” trying to maintain physician-patient relationships for fiscal purposes, or simply abdicating decision-making responsibility to their patients, studies indicate that some physicians inappropriately assent to patient demands.<sup>139</sup> Due to DTCA and the Internet, patients often now believe they are *informed* regarding the appropriate course of treatment, so they enter the doctor’s office seeking a specific treatment rather than medical advice. At times, patients may act as though they have already received an examination and diagnosis, and all that is needed is the physician’s signature to receive a particular treatment.<sup>140</sup> Even when patient autonomy was at its zenith under the doctrine of informed consent, the physician was nonetheless expected to be the one recommending a course of treatment, with the patient deciding among proffered options. In the current era of DTCA and the Internet, there is evidence that on some occasions it is the patient that both recommends the course of treatment and makes the final deci-

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sumers comparative rankings of healthcare providers. *See, e.g.*, Top American Hospitals—US News Best Hospitals, <http://health.usnews.com/sections/health/best-hospitals> (last visited Mar. 20, 2009).

<sup>138</sup> Stein, *supra* note 111.

<sup>139</sup> The studies indicate that most physicians assent to patient demands. *See supra* notes 97–109 and accompanying text. Assent itself, however, is not necessarily wrong or dangerous. Assent is only problematic when the physician fails to exercise his or her own medical judgment and subsequently provides the patient with medically contraindicated treatment. This Article contends that only some of these physicians are violating their fiduciary duty when they provide assent—that is, those who are abdicating their responsibility to exercise sound medical judgment.

<sup>140</sup> *See* Caroline L. Nadal, Note, *The Societal Value of Prescription Drug Advertisements in the New Millennium: Targeted Consumers Become the Learned*, 9 J.L. & POL’Y 451, 504 (2001) (“[P]atients often tell their physicians which prescription medication they wish to take, sometimes reducing physicians into mere purveyors of prescription slips.”).

sion.<sup>141</sup> The doctor has potentially gone from being the sole decision-maker, to being a joint decision-maker, to being an educated adviser and consultant, to being at most an inconvenient “speed bump” and at worst an irrelevant formality.

The emergence of DTCA and the Internet has resulted in a fundamental change in the interactions between physicians and patients with patients playing a much more active role.<sup>142</sup> The following questions must now be answered. What role should physicians play in these interactions? And what bounds are or should be placed on related physician behavior by medical ethics and governing law?

## V. THE DOCTOR'S OBLIGATIONS

### A. *Informed Consent*

The term “informed consent” was coined and explained in *Salgo v. Leland Stanford Jr. University Board of Trustees*,<sup>143</sup> where a California Court of Appeals declared that “[a] physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment.”<sup>144</sup> Within the next few decades, obtaining informed consent became an ethical and legal duty imposed on physicians throughout the country.<sup>145</sup> The core ethics committee of the American Medical Association (AMA), the Judicial Council (renamed the Council on Ethical and Judicial Affairs in 1985), announced the AMA's stance on informed consent in 1982:

The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The patient should make his own determination on treatment. . . . Social policy does not accept the paternalistic

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<sup>141</sup> See, e.g., *Perez v. Wyeth Labs.*, 734 A.2d 1245, 1260 (N.J. 1999) (“[Physicians] claim pushy patients, prodded by the DTC advertisements, pressed, wheedled, begged and berated them for quick treatments.”).

<sup>142</sup> See, e.g., Calabro, *supra* note 83, at 2272 (“Direct-to-consumer advertising [places pressure on physicians] by changing the physician-patient relationship such that the physician may no longer be in a superior position to warn his patient about the risks associated with the drug.”).

<sup>143</sup> 317 P.2d 170 (Cal. Dist. Ct. App. 1957).

<sup>144</sup> *Id.* at 181.

<sup>145</sup> The American Hospital Association included the following statement regarding informed consent in its Patient's Bill of Rights: “The patient has the right to receive from his physician information necessary to give informed consent prior to the start of any procedure and/or treatment.” AMERICAN HOSP. ASS'N, PATIENT'S BILL OF RIGHTS para. 3 (Feb. 6, 1973), *reprinted in* DIETER GIESEN, INTERNATIONAL MEDICAL MALPRACTICE LAW appx. IV (1988).

view that the physician may remain silent because divulgence might prompt the patient to forego needed therapy. Rational, informed patients should not be expected to act uniformly, even under similar circumstances, in agreeing to or refusing treatment.<sup>146</sup>

Informed consent, which started as a legal duty imposed by the courts, is now viewed as so integral to minimally adequate healthcare that it has been transformed into an obligation incumbent upon and universally accepted by physicians.<sup>147</sup> Physicians now have an ethical and legal responsibility to inform patients of the potential material risks and benefits of any proposed treatment and any viable alternatives to treatment before obtaining a patient's consent to perform a medical procedure, with patients generally given the right to make the ultimate decisions regarding the commencement and course of their treatment for themselves.<sup>148</sup> Physicians, nevertheless, are not absolved from responsibility or liability simply because a patient expresses a certain treatment choice, particularly if the patient's choice is inconsistent with the physician's judgment of what constitutes appropriate medical practice.

*B. Informed Consent Alone Is Inadequate in a World of DTCA/Internet*

Pursuant to the requirements of the informed consent doctrine, physicians generally describe various possible courses of action to their patients, with patients choosing from among the options provided but often acquiescing in the judgment of their physician regarding the best course of treatment.<sup>149</sup> The emergence of DTCA and other information "aids" has created the potential for a fundamental shift in this process. Now, after exposure to DTCA or conducting research on the Internet, a patient is much more likely to re-

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<sup>146</sup> FADEN ET AL., *supra* note 22, at 96.

<sup>147</sup> *Id.* at 101.

<sup>148</sup> *Id.* at 100.

<sup>149</sup> Whitney et al., *supra* note 49, at 54. Critics have argued that informed consent, as it was designed, rarely occurs because physicians exercise considerable control over the decision-making process, in part by shaping the information provided the patient and in part because the patient relies heavily on cues and direction provided by the physician. They assert that beneficence still dominates the physician-patient relationship and that doctors continue to make virtually all of the treatment decisions. GEORGE ANNAS, SOME CHOICE: LAW, MEDICINE, AND THE MARKET 61, 66 (1998) ("[A]fter almost three decades of legal and ethical debate, neither the idea nor the ideal of informed consent governs the doctor-patient relationship. . . . [While] informed consent is well entrenched in theory . . . in practice patient autonomy continues to be elusive.").

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quest or perhaps demand a specific treatment option—including options that the physician did not or would not have raised and that the physician does not support.

This potential shift in the nature of the interaction between the physician and the patient necessitates a corresponding recognition that merely informing patients of their treatment options does not mark the end of physicians' responsibility to their patients.<sup>150</sup> Even at its apex—when it afforded the greatest weight to patient autonomy—the informed consent doctrine only required a physician to provide a patient with material information regarding the various alternative treatment options available before the patient “consented” to a given course of treatment.<sup>151</sup> It did not establish that the physician must inevitably acquiesce to whatever course of treatment the patient desires.

As discussed, before the advent of DTCA and the Internet, the question of who exercises ultimate decision-making authority in a physician-patient relationship would largely have been irrelevant, as patients rarely knew enough to independently generate and appraise treatment options, and physicians would have been unlikely to raise treatment options that they did not think were viable or were unwilling to perform. Indeed, physicians generally are not required in the course of obtaining informed consent to raise treatment options that contain significant risks but lack corresponding benefits. In essence, because physicians only introduced what they considered to be viable treatment options, physicians exercised their independent medical judgment, provided their “implied consent” to the discussed options, and maintained their critical role in medical decision making.<sup>152</sup>

This critical role, however, is not fulfilled when the patient requests and the physician acquiesces in a treatment that the physician believes is medically contraindicated. As will be discussed, physicians cannot satisfy their ethical and legal obligation to their patients simply by providing all material information regarding the options discussed. When a physician acquiesces to a patient's request for treatment that the physician believes is medically contraindicated, the

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<sup>150</sup> As will be discussed, this Article asserts that this more stringent duty already exists in the form of the physician's fiduciary duty. See *infra* Part VI.

<sup>151</sup> See Rich, *supra* note 56, at 102 (outlining the requirements of informed consent).

<sup>152</sup> Because of fewer financial pressures, physicians also may have felt freer to reject a course of treatment requested by a patient and, if the patient insisted on this course of treatment, to terminate the physician-patient relationship.

physician has failed to fulfill his or her fiduciary obligation as a healthcare provider.<sup>153</sup>

Before addressing the rationale for and the nature of this fiduciary obligation, it is worth emphasizing that the focus here is the scenario where the physician provides access to requested services that the physician believes are medically contraindicated. The existing informed consent doctrine adequately addresses situations where a patient proposes a viable medical alternative. For example, if a patient who suffers from high cholesterol enters a doctor's office and requests the prescription medication Lipitor after viewing commercials touting its effectiveness, and it is the physician's medical judgment that the patient is a good candidate for the drug—even though the doctor might prefer that the patient first attempt to lower his or her cholesterol through diet and exercise—the doctor has satisfied the requirements of the informed consent doctrine, as well as the physician's fiduciary obligation to the patient, by explaining the material risks and benefits of these alternative options and then respecting the patient's choice between two medically viable options. That is, the physician should explain the relative advantages of exercise and healthy eating as opposed to using this medication, but the physician is free to acquiesce and order the patient's requested treatment as long as (1) the physician has exercised his or her independent medical judgment and believes the drug is reasonably likely to be effective, and (2) the patient's medical history or other factors do not make the ordering of this drug medically contraindicated.

If, however, the treatment being sought is not medically indicated in the physician's judgment, the doctor has, as will be discussed, an ethical and a legal duty to refuse to comply with the patient's request. The doctor, not the patient, has the education and training necessary to determine when treatment is medically contraindicated under such a scenario and, thus, the responsibility to refuse

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<sup>153</sup> See *supra* Part V.A. This may give rise to a cause of action based on medical malpractice or lack of informed consent. These causes of action, however, are ill-equipped to handle the given situation for a variety of reasons. See Thomas L. Hafemeister & Selina Spinos, *A Physician's Fiduciary Duty to Disclose Emergent Medical Risk*, 86 WASH. U. L. REV. (forthcoming June 2009) (manuscript at 38–44, on file with authors); see also Caroline Anne Forell & Anna Sortun, *The Tort of Betrayal of Trust*, U. MICH. J.L. REFORM (forthcoming 2009) (manuscript at 14–16), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1112073#](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1112073#). Here, informed consent is insufficient because the patient herself is seeking the treatment and thus providing consent, while medical malpractice is insufficient due to its focus on the standard of care, rather than the standard of conduct. See *infra* Part VI.C.2.

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to provide access to a treatment simply because it was requested or demanded by a patient.<sup>154</sup>

*C. Professional Judgment*

The doctor should not be a passive participant in medical decision making and become a mere formality needed to finalize the exchange between a pharmaceutical company and the target of its television advertising or Internet promotions. Physicians are well-educated, well-trained professionals who are and should be responsible for determining whether a requested course of treatment is medically appropriate. Whether they are administering prescription medications, performing surgical procedures, or providing or facilitating the delivery of other medical services and products, physicians must be ultimately responsible for treatment. They must appraise whether a requested treatment is medically indicated for a given patient.

As demonstrated by federal laws that limit access to controlled substances<sup>155</sup> and state licensing requirements that limit who may prescribe medications,<sup>156</sup> society has made a collective decision not to allow the general public to gain unfettered access to many medications and other forms of medical treatment. For example, an individual cannot simply walk into a pharmacy and obtain a regulated medication; rather, the patient must give the pharmacist a prescription signed by a physician. This signed prescription indicates to the pharmacist that a licensed physician has consulted with the patient, performed any necessary tests and obtained any needed information, and determined that the patient should receive the prescribed medication. This prescription process is designed to ensure that a licensed physician has determined that it is safe and appropriate for someone to take a certain drug. Because physicians are charged by society with ensuring that medications and other forms of medical treatment are only made available when medically appropriate, physicians are obligated to exercise their professional judgment when providing treatment to their patients.

Society's decision to prevent broad, unfettered access to medications and other forms of medical treatment by the public has received ample support from the courts. For example, in *Reyes v. Wyeth Labora-*

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<sup>154</sup> Edwin Leap, *I'm the Doctor, Not You!*, EMERGENCY MED. NEWS, May 2007, at 19.

<sup>155</sup> See 21 U.S.C. § 829(a)–(c) (2006) (describing when and how controlled substances may be dispensed).

<sup>156</sup> See, e.g., FLA. STAT. ANN. § 458.345 (West 2007); IOWA CODE ANN. § 147.107 (West 2005); KAN. STAT. ANN. § 65-2837a (2007).

*tories*,<sup>157</sup> the United States Court of Appeals for the Fifth Circuit held that a pharmaceutical company is not liable for injuries caused by the prescription medications it manufactures and advertises as long as a “learned intermediary”—a doctor—authorized and implicitly recommended the medication through a prescription. The court explained that

in the case of a prescription drug which is unavoidably unsafe, and as to which there is a certain, though small, risk throughout the population, there must be either a warning—meaningful and complete so as to be understood by the recipient—or an *individualized medical judgment* that this treatment or medication is necessary and desirable for this patient.<sup>158</sup>

The ruling in *Reyes* gave birth to the learned intermediary rule, under which the proposition was endorsed that physicians are the least cost avoider—that is, doctors are in a better position to prevent adverse drug effects from contraindicated prescription medication than the pharmaceutical industry or the patient. The learned intermediary rule demonstrates that society desires and needs a qualified gatekeeper—the physician—to shoulder the responsibility of ensuring that various medical treatments, particularly prescription medications, are ordered and consumed only when medically indicated.

Despite society’s recent emphasis on respecting and promoting patient autonomy, doctors must continue to play a significant role in ensuring that appropriate decisions are made regarding medical treatment. Patients may have become “consumers’ . . . with . . . [a] right . . . to be actively involved in decision-making about treatment,”<sup>159</sup> but being involved in and unilaterally making a medical decision are two very different scenarios.

The physician must remain a knowledgeable and trained expert who exercises independent professional judgment before ordering or performing an agreed-upon treatment. The physician is not a subservient pawn in the patient’s life, but an erudite and trustworthy partner dedicated to promoting and protecting a patient’s medical well-being.

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<sup>157</sup> 498 F.2d 1264 (5th Cir. 1974).

<sup>158</sup> *Id.* at 1295 (emphasis added).

<sup>159</sup> Mead & Bower, *supra* note 54, at 1090.



## VI. THE PHYSICIAN'S OBLIGATION TO EXERCISE INDEPENDENT PROFESSIONAL JUDGMENT<sup>160</sup>

A physician's failure to exercise independent professional judgment by ordering treatment that is not medically indicated but is demanded by a patient brings into play an often overlooked and arguably underdeveloped doctrine—a physician's fiduciary obligation to a patient.<sup>161</sup> This section will address (1) the nature of fiduciary duties in general; (2) why a physician should be considered a fiduciary in general and with regard to medically contraindicated demands by a patient; (3) what is entailed by a cause of action for breach of a physician's fiduciary duty to exercise independent medical judgment; and (4) the impact of the cause of action for breach of fiduciary duty.

### A. *Fiduciary Duties: Development and Focus in General*

The doctrine of fiduciary duty has “deep roots” in the common law.<sup>162</sup> This doctrine was originally developed to help govern the ad-

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<sup>160</sup> See generally Thomas L. Hafemeister & Sarah Payne Bryan, *Beware Those Bearing Gifts: Physicians' Fiduciary Duty to Avoid Pharmaceutical Marketing*, 57 U. KAN. L. REV. 491, 519–28 (2009) (providing general overview and discussion of a physician's fiduciary duty to a patient); Hafemeister & Spinos, *supra* note 153 (manuscript at 24–33) (providing general overview and discussion of a physician's fiduciary duty to a patient); Charity Scott, *Doctors as Advocates, Lawyers as Healers*, 29 HAMLINE J. PUB. L. & POL'Y 331, 337 (2008) (“This concept of the physician as fiduciary has become well accepted in both U.S. law and the ethical tenets of American professional medical associations.”).

<sup>161</sup> See generally Tamar Frankel, *Fiduciary Law*, 71 CAL. L. REV. 795, 796 (1983) (“Little has been written about the origin of fiduciary law, the rationales behind the creation of fiduciary duties, the remedies for violations of these duties, and the methods by which courts fashion such remedies.”).

<sup>162</sup> Hafemeister & Bryan, *supra* note 160, at 519–20 (“Originally, fiduciary doctrine was the courts' response ‘to the absence of a remedy . . . for beneficiaries injured by the disloyalty of [their] trustees.’ Over time, this doctrine has been extended beyond the trustee-beneficiary relationship to other relationships in which a party (the fiduciary) is entrusted with the responsibility to act and make decisions on behalf of another individual (the beneficiary), with the expectation that the fiduciary will seek to promote the beneficiary's welfare. Fiduciary relationships have been found to exist between partners of a company, directors and companies, attorneys and clients, agents and principals, stockbrokers and clients, and, directly relevant to this discussion, physicians and patients.”) (citations omitted); Hafemeister & Spinos, *supra* note 153 (manuscript at 25) (“Fiduciary duties have deep roots in the common law. Within the law governing the administration of trusts—where a trustee has been appointed to administer a corpus or an estate on behalf of a beneficiary—courts developed the concept of fiduciary duty. Originally an equitable remedy to correct the harm done by a disloyal trustee, fiduciary duties now apply to many relationships in which a party is entrusted with the welfare of someone who is relatively vulnerable.”) (citations omitted).

ministration of trusts,<sup>163</sup> with the goal of remedying harm caused by a disloyal trustee.<sup>164</sup> The doctrine was later expanded to include other agency relationships.<sup>165</sup> It now encompasses a range of relationships where one party (the fiduciary) is “entrusted with the welfare of someone [i.e., the beneficiary] who is relatively vulnerable,” including transactions between attorneys and clients, guardians and wards, financial advisors and clients, and corporate officers and shareholders.<sup>166</sup>

Currently, a fiduciary duty is generally construed to be “[a] duty of utmost good faith, trust, confidence, and candor owed by a fiduciary . . . to the beneficiary; a duty to act with the highest degree of honesty and loyalty toward another person and in the best interests of the other person.”<sup>167</sup> Additionally, a fiduciary must “promote the interests of [the] beneficiar[y] rather than [the fiduciary’s] own interests.”<sup>168</sup>

As noted, fiduciary obligations have been imposed on various professionals,<sup>169</sup> and generally stem from (1) the beneficiary’s vulnerability and dependence on the fiduciary, (2) the superior knowledge and related skills of the fiduciary, and (3) the trust placed in the fiduciary to protect and promote the best interests of the beneficiary.<sup>170</sup>

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<sup>163</sup> Andrew Grubb, *The Doctor as Fiduciary*, 47 CURRENT LEGAL PROBS. 311, 311 (1994).

<sup>164</sup> Hafemeister & Bryan, *supra* note 160, at 519; Hafemeister & Spinos, *supra* note 153 (manuscript at 25).

<sup>165</sup> E. Haavi Morreim, *The Clinical Investigator as Fiduciary: Discarding a Misguided Idea*, 33 J.L. MED. & ETHICS 586, 588–89 (2005); Hafemeister & Bryan, *supra* note 160, at 519–20; Hafemeister & Spinos, *supra* note 153 (manuscript at 25).

<sup>166</sup> Hafemeister & Bryan, *supra* note 160, at 519–20; Hafemeister & Spinos, *supra* note 153 (manuscript at 25); Morreim, *supra* note 165, at 588–89.

<sup>167</sup> BLACK’S LAW DICTIONARY (8th ed. 2004).

<sup>168</sup> Sharona Hoffman & Jessica Wilen Berg, *The Suitability of IRB Liability*, 67 U. PITT. L. REV. 365, 393 (2005).

<sup>169</sup> See *supra* note 166 and accompanying text. See also Frankel, *supra* note 161, at 795 (“Fiduciaries appear in a variety of forms, including agents, partners, directors and officers, trustees, executors and administrators, receivers, bailees, and guardians.”); Hafemeister & Bryan, *supra* note 160, at 519–20; Hafemeister & Spinos, *supra* note 153 (manuscript at 25).

<sup>170</sup> Frankel, *supra* note 161, at 796; Hafemeister & Bryan, *supra* note 160, at 520 (“Fiduciary rules are designed to ensure that the fiduciary fulfills his or her obligations and does not neglect, abuse, exploit, or otherwise take advantage of the relatively vulnerable and dependent beneficiary.”); *id.* at 524 (Fiduciary duties exist “because of the dependence and vulnerability of the beneficiary and the level of trust imbued in the fiduciary.”); *id.* at 526 (“The fiduciary duty doctrine was applied to trustees to control three aspects of the typical trustee-beneficiary relationship: the disparity of knowledge between the trustee and the beneficiary, the trustee’s ability to act relatively unilaterally, and the vulnerability and dependence of the beneficiary on the trustee.”).

*B. Physicians as Fiduciaries*

## 1. Physicians' Fiduciary Obligation to Their Patients

In 1956, a California Court of Appeals declared that “[t]he doctor-patient relationship is a fiduciary one.”<sup>171</sup> Many courts over the years have determined that physicians owe a fiduciary obligation to their patients,<sup>172</sup> stemming from the intrinsic nature of the physician-patient relationship.

The physician-patient relationship embodies all three bases routinely cited as the rationale for concluding that a fiduciary duty exists between two parties. As the following discussion demonstrates, physi-

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<sup>171</sup> *Wohlgemuth v. Meyer*, 293 P.2d 816, 820 (Cal. Ct. App. 1956) (“[I]t is incumbent on the doctor to reveal all pertinent information to his patient.”). The recognition of a fiduciary relationship between physicians and patients can be further traced back to at least 1931 when the Minnesota Supreme Court specifically noted that a fiduciary relationship exists between physicians and patients. *Schmucking v. Mayo*, 235 N.W. 633, 633 (Minn. 1931). In support of this proposition, the court cited *Groendal*—a ruling from 1912 by the Michigan Supreme Court. *Groendal v. Westrate*, 137 N.W. 87, 96 (Mich. 1912) (“[T]he relation of physician and patient, which, of itself, begets confidence and reliance on the part of the patient.”).

<sup>172</sup> See, e.g., *Lambert v. Park*, 597 F.2d 236, 239 n.7 (10th Cir. 1979) (“The duty of the doctor to inform the patient is in the nature of a fiduciary duty.”); *Canterbury v. Spence*, 464 F.2d 772, 782 (D.C. Cir. 1972) (“[W]e ourselves have found in the ‘fiducial qualities of [the physician-patient] relationship the physician’s duty to reveal to the patient that which in his best interests it is important that he should know.’”) (citations omitted); *Salis v. United States*, 522 F. Supp. 989, 997 n.10 (M.D. Pa. 1981) (finding that the doctrine of informed consent is based partially on the fiduciary relationship between physician and patient); *Hammonds v. Aetna Cas. & Sur. Co.*, 237 F. Supp. 96, 102 (N.D. Ohio 1965) (“It is axiomatic that the physician-patient relationship is a fiduciary one.”); *Mull v. String*, 448 So. 2d 952, 953 (Ala. 1984) (“Alabama recognizes [a] cause[] of action for breach of fiduciary duty . . . resulting from a physician’s *unauthorized disclosure* of information acquired during the physician-patient relationship.”); *Cobbs v. Grant*, 502 P.2d 1, 12 (Cal. 1972) (“Any defense . . . must be consistent with . . . the ‘fiducial’ qualities of the physician-patient relationship.”) (citation omitted); *Berkey v. Anderson*, 1 Cal. App. 3d 790, 804 (Cal. Ct. App. 1969) (“The relationship between a physician and his patient is fiduciary, which, like all such relationships, imposes a duty of full disclosure.”); *Wohlgemuth*, 293 P.2d at 820 (“The doctor-patient relationship is a fiduciary one . . . .”); *Petrillo v. Syntex Laboratories*, 499 N.E.2d 952, 960–61 (Ill. App. Ct. 1986) (“The fiducial nature of the physician-patient relationship flows not from the physician’s ethical duties, but rather as a result of the physician’s unique role in society. Like the confidentiality of the physician-patient relationship, we believe that our society has an established and beneficial interest in the fiduciary quality of the physician-patient relationship.”); *Woolley v. Henderson*, 418 A.2d 1123, 1128 n.3 (Me. 1980) (“The historical underpinnings of the doctrine of informed consent are frequently attributed to the fiduciary character of the physician-patient relationship.”); *Borderlon v. Peck*, 661 S.W.2d 907, 908 (Tex. 1983) (“[T]he physician-patient relationship is one of trust and confidence . . . .”); *Nixdorf v. Hicken*, 612 P.2d 348, 354 (Utah 1980) (noting the “fiduciary nature of the physician-patient relationship”). See also Hafemeister & Bryan, *supra* note 160, at 527; Hafemeister & Spinosa, *supra* note 153 (manuscript at 26).

cians owe their patients a fiduciary obligation due to (1) the vulnerability of patients and their dependence on physicians for their medical care, (2) the considerable and superior knowledge and related skills of physicians, and (3) the trust that patients and society imbue in physicians to protect and promote their patients' best interests.<sup>173</sup>

a. Vulnerability and Dependence on the Physician

The features of a physician-patient relationship closely resemble those of the typical fiduciary relationship.<sup>174</sup> For example, physicians control access to and the use of important resources that patients need.<sup>175</sup> Just as a trustee controls those funds and other assets designated to help the specified beneficiary of an established trust,<sup>176</sup> the physician controls a patient's ability to obtain needed resources to which the patient is otherwise entitled—namely, medical services, such as diagnostic tests and treatment, prescriptions for medications, admission to a hospital on a non-emergency basis, and referrals to a specialist, as well as third party payments for healthcare costs.<sup>177</sup> Just as a trustee must protect the resources dedicated to the welfare of the beneficiary, a physician must promote and protect the health of patients, who have entrusted physicians with their safety and well-being.<sup>178</sup> Simply put, patients cannot access medical services pivotal to their health and survival without the aid of a physician. This dependence is enhanced by the fact that patients tend to contact physicians when they are ill or suffering and in great need of the services to which only the physician can provide access.<sup>179</sup> This vulnerability

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<sup>173</sup> Marc. A. Rodwin, *Strains in the Fiduciary Metaphor: Divided Physician Loyalties and Obligations in a Changing Health Care System*, 21 AM. J.L. & MED. 241, 245–46 (1995).

<sup>174</sup> *Id.* at 245.

<sup>175</sup> *Id.*

<sup>176</sup> RESTATEMENT (SECOND) OF TRUSTS § 2 cmt. h (1959) (“[A] trust involves three elements, namely, (1) a trustee, who holds the trust property and is subject to equitable duties to deal with it for the benefit of another; (2) a beneficiary, to whom the trustee owes equitable duties to deal with the trust property for his benefit; (3) trust property, which is held by the trustee for the beneficiary.”).

<sup>177</sup> *Id.*

<sup>178</sup> See Maxwell J. Mehlman, *Fiduciary Contracting Limitations on Bargaining Between Patients and Health Care Providers*, 51 U. PITT. L. REV. 365, 389 n.76 (1990) (“Since providers often act for patients in situations wherein patients are unable to act for themselves, the fiduciary obligation might be said to arise in part because of the patient’s delegation of control, similar to the control delegated . . . by a beneficiary to a trustee.”).

<sup>179</sup> Hafemeister & Spinos, *supra* note 153 (manuscript at 26) (“Because patients generally seek the services of a physician when they are sick, injured, or concerned about their health, because doctors have unique access to a patient’s medical information and superior insight into a patient’s medical condition, and because physi-

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and dependence creates a significant need for the physician's superior knowledge and related specialized skills.<sup>180</sup>

b. Information and Skill Disparity

In addition, the physician-patient relationship "must be subject to fiduciary requirements because of the information disparity between the parties."<sup>181</sup> While it is true that laypersons today have greater access to medical information than ever before (through the Internet, television, books, magazines, and so forth), such resources cannot compete with four years of medical school, completion of a residency, internships and fellowships, and years of firsthand experience. In addition, physicians are required to obtain and maintain a license to practice medicine, which includes meeting educational requirements, passing standardized exams, and satisfying continuing education requirements.<sup>182</sup>

This knowledge discrepancy between physicians and patients is only exacerbated—not alleviated—by the misinformation and misunderstanding that may result from DTCA and from unfettered access to Internet-based medical information.<sup>183</sup> The essential point is that the medical knowledge of a patient who has spent time on WebMD.com, or who has viewed an emotionally evocative commercial does not remotely compare to that of a well-educated physician. While patients focused on their own symptoms and conditions can perform useful related research, gain relevant insights, and convey germane information to their physician, patients are rarely equipped to independently understand or apply this information, nor do they have the diagnostic and treatment skills needed to adequately and appropriately respond to this information. Patients' relative lack of medical knowledge and skills, as well as their vulnerability and de-

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cians control patients' ability to obtain needed medical treatment, patients are highly dependent on their physicians and should be able to rely on their physicians to protect and promote their well-being." (citing *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997) (noting that "trust . . . is essential to the doctor-patient relationship"))). Patients generally do have the option of contacting a different physician to gain access to needed services, but pursuing this option, with its delay and potential additional cost or disruption of an existing physician-patient relationship or delivery of services, can be highly burdensome for a patient—particularly if the patient is currently sick or injured.

<sup>180</sup> *Id.*

<sup>181</sup> Mehlman, *supra* note 178, at 366 n.6; *see also* Rodwin, *supra* note 173, at 245 (explaining that physicians are similar to other fiduciaries because they "have specialized knowledge and expertise").

<sup>182</sup> *See* 1 BARRY R. FURROW ET AL., *HEALTH LAW* 62–63 (2000).

<sup>183</sup> *See supra* Parts III & IV.

pendence on physicians, necessitate a relationship with their physician that is imbued with loyalty and trust. This expectation of trust forms the foundation of the physician's fiduciary obligations to a patient.<sup>184</sup>

c. Patients' Trust in Their Physicians

In *Cobbs v. Grant*,<sup>185</sup> the California Supreme Court recognized that "the patient, being unlearned in medical sciences, has an abject dependence upon and trust in his [or her] physician for the information upon which [the patient] relies during the decisional process, thus raising an obligation in the physician that transcends arms-length transactions."<sup>186</sup> Practically speaking, few professional relationships, if any, require more trust than a patient's relationship with a physician. Patients, for example, rely on their physicians' advice in determining whether to undergo an invasive procedure or ingest potent medications that may have significant risks, including possible adverse side effects. In making these decisions, patients—and society in general—must be able to trust physicians, rely on their loyalty, and rest assured that physicians will place the patient's best interests above all other potentially competing interests.<sup>187</sup>

As in California, an Illinois Court of Appeals similarly determined that patients place a "special confidence" in their physicians when they seek medical assistance and that physicians, in turn, owe their patients a duty of "good faith" consistent with their fiduciary obligations.<sup>188</sup> The court contended that "[t]he patient should . . . be able to trust [that] the physician will act in the [patient's] best interests[,] thereby protecting the sanctity of the physician-patient relationship."<sup>189</sup>

The AMA itself has recognized that the physician-patient relationship is "based on trust" and thus physicians have an obligation to "place patients' welfare above their own self-interest."<sup>190</sup> Due to the

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<sup>184</sup> Rodwin, *supra* note 173, at 245–46 ("The patient-physician relationship presupposes patients entrusting physicians to act on their behalf and physicians remaining loyal to their patients."); *see also infra* notes 189–94 and accompanying text.

<sup>185</sup> 502 P.2d 1 (Cal. 1972).

<sup>186</sup> *Id.* at 9.

<sup>187</sup> Hafemeister & Bryan, *supra* note 160, at 530 ("[T]he purpose behind recognizing a breach of fiduciary duty claim in this context is to deter disloyal conduct on the part of the physician.")

<sup>188</sup> *Taber v. Riordan*, 403 N.E.2d 1349, 1353 (Ill. App. Ct. 1980).

<sup>189</sup> *Id.*

<sup>190</sup> AM. MED. ASS'N, CODE OF MEDICAL ETHICS, OPINION 10.015: THE PATIENT-PHYSICIAN RELATIONSHIP (2001) [hereinafter AMA PATIENT-PHYSICIAN RELATIONSHIP],

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level of trust that patients must be able to place in their physician, patients' vulnerability to and dependence on physicians, and the disparity in information and skills that exists between patients and physicians, physicians have a fiduciary obligation to protect the best interests of their patients.<sup>191</sup>

## 2. A Physician's Fiduciary Obligation to Refuse to Provide Treatment That Is Not Medically Indicated

The AMA has stated that "[p]hysicians are not ethically obliged to deliver care that, in their best professional judgment, will not have a reasonable chance of benefiting their patients[,] [and p]atients should not be given treatments simply because they demand them."<sup>192</sup> Because the AMA generally recognizes that physicians have an ethical duty to exercise independent medical judgment,<sup>193</sup> the question becomes whether a doctor's fiduciary obligation *legally* requires the doctor to "just say no" to a demanding patient.

As indicated previously, a fiduciary is required to promote the interests of the beneficiary rather than the fiduciary's own interests.<sup>194</sup>

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*available at* [http://www.ama-assn.org/ama1/pub/upload/mm/Code\\_of\\_Med\\_Eth/opinion/opinion10015.html](http://www.ama-assn.org/ama1/pub/upload/mm/Code_of_Med_Eth/opinion/opinion10015.html).

<sup>191</sup> See *Taber*, 403 N.E.2d at 1353 ("There can be little dispute that a doctor occupies a condition of trust and confidence, a fiduciary relationship with his [or her] patient.") (citation omitted).

<sup>192</sup> AM. MED. ASS'N, CODE OF MEDICAL ETHICS, OPINION 2.035: FUTILE CARE (1994), *available at* [http://www.ama-assn.org/ama1/pub/upload/mm/Code\\_of\\_Med\\_Eth/opinion/opinion2035.html](http://www.ama-assn.org/ama1/pub/upload/mm/Code_of_Med_Eth/opinion/opinion2035.html). This statement by the AMA relates to the delivery of futile care, but it is just as applicable, if not more so, in the case of DTCA. Generally speaking, futile care involves treatment that is unnecessary or wasteful, but not harmful. In contrast, DTCA may involve treatment that is not only unnecessary or wasteful, but also potentially harmful—or at least may involve drugs or procedures that involve unnecessary risks.

<sup>193</sup> See AM. MED. ASS'N, PRINCIPLES OF MEDICAL ETHICS (2001), *available at* <http://www.ama-assn.org/ama/pub/category/2512.html> ("As a member of this profession, a physician must recognize responsibility to patients first and foremost . . . . A physician shall be dedicated to providing competent medical care . . . . A physician shall, while caring for a patient, regard responsibility to the patient as paramount."); AM. MED. ASS'N, CODE OF MEDICAL ETHICS, OPINION 8.03: CONFLICTS OF INTEREST: GUIDELINES (1994), *available at* [http://www.ama-assn.org/ama1/pub/upload/mm/Code\\_of\\_Med\\_Eth/opinion/opinion803.html](http://www.ama-assn.org/ama1/pub/upload/mm/Code_of_Med_Eth/opinion/opinion803.html) ("Under no circumstances may physicians place their own financial interests above the welfare of their patients. . . . If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit."); William J. Plested III, President, Am. Med. Ass'n, A Declaration of Independence (June 23, 2007), *available at* <http://www.ama-assn.org/ama/pub/category/17781.html> ("The time has come for the Physicians of America . . . to issue our own Declaration of the Independence, the independence of our profession.").

<sup>194</sup> *Supra* note 168 and accompanying text.

As fiduciaries, physicians must “hold[] the best interests of the patient . . . paramount,” even when they may face adverse financial consequences as a result.<sup>195</sup> As described in the scenario at the beginning of this Article, physicians may, for example, have a financial interest in keeping their patients happy—that is, they may find it in their self-interest to give their “consumers” what they want in the way of medical services to ensure that they will receive their patients’ future business.<sup>196</sup> Because of patients’ limited ability to make medical decisions for themselves, however, physicians—to properly serve the best interests of their patients—must always exercise their independent medical judgment and provide access only to appropriate medical services.

Thus, to satisfy their fiduciary obligation, physicians should authorize access only to those services that reflect and represent the exercise of their independent medical judgment and that are medically indicated for the patient—that is, provide access consistent with the patient’s medical needs and condition. To ensure that physicians retain their valued and valuable role in the physician-patient relationship, physicians must always exercise their independent medical judgment, even when doing so is contrary to the expressed wishes of the patient and may jeopardize the physician’s financial well-being or other self-interests. If physicians fail to exercise their medical judgment, they violate their fiduciary obligation to the patient and should be subject to potential *legal* liability.

C. *What Is Entailed by a Cause of Action for Breach of a Physician’s Fiduciary Duty to Exercise Independent Medical Judgment*

Physicians who do not exercise independent medical judgment in the face of a specific request from a patient for treatment that is medically contraindicated fail to meet their fiduciary obligation to that patient. Physicians who fail to meet this obligation may be subject to a cause of action for breach of their fiduciary obligation.

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<sup>195</sup> AMA PATIENT-PHYSICIAN RELATIONSHIP, *supra* note 190.

<sup>196</sup> As interest increases in making “consumer” ratings publically available, the satisfaction of a physician’s patients with the services provided may shape the willingness of other prospective patients to utilize the physician’s services. *See generally* Reed Abelson, *National Standards to Rank Physicians Planned*, N.Y. Times, Apr. 1, 2008, at C3; *Could CMS Start ‘Physician Profiling’ in the Near Future?* CONTEMP. OB/GYN, Aug. 1, 2007.



### 1. Elements of a Claim for Breach of Fiduciary Duty

A claim for breach of fiduciary duty generally sounds in tort.<sup>197</sup> As a result, to successfully pursue such a claim, generally four elements must be shown: (1) the existence of a fiduciary duty, (2) a breach of that duty, (3) damages (harm) incurred by the person to whom that duty was owed, and (4) a causal link between the breach and the resulting harm.<sup>198</sup>

As established earlier, physicians owe their patients a fiduciary obligation in general.<sup>199</sup> To satisfy the first element of a cause of action for breach of fiduciary duty, a plaintiff has to show that a physician-patient relationship existed between the plaintiff and the defendant at the time of the alleged misconduct, that the physician was acting within the scope of that relationship, and that the fiduciary duty in question is inherent in physician-patient relationships. Also, the physician as a fiduciary is obligated, among other things,<sup>200</sup> to exercise his or her independent medical judgment during the course of the physician-patient relationship, notwithstanding that the patient

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<sup>197</sup> It can be argued that a breach of fiduciary duty claim should sound in contract rather than in tort, or should reflect a combination of the two doctrinal foundations. For example, it can be contended that a breach of fiduciary duty claim constitutes a contractual violation because a fiduciary breach is a violation of the expectations of the two parties. In addition, it might be noted that, historically, the fiduciary duty—with its focus on trustees and the designated beneficiaries of a trust—was based in trust law, a third possible foundation for a cause of action focused on a breach of a physician's fiduciary obligations. An exploration of the strengths, weaknesses, and appropriateness of each of these alternative doctrinal approaches is beyond the scope of this Article. Because the approach predominantly used currently is a tort claim, this Article will employ that approach in conjunction with the analysis provided here. For a brief discussion of these alternative doctrinal foundations, see Hafemeister & Bryan, *supra* note 160, at 519 n.168).

<sup>198</sup> 1615 PLI CORP. LAW & PRACTICE HANDBOOK 521, 548 (2007); *see also* Gracey v. Eaker, 837 So. 2d 348, 353 (Fla. 2002) (“The elements of a claim for breach of fiduciary duty are: the existence of a fiduciary duty, and the breach of that duty such that it is the proximate cause of the plaintiff's damages.”). *But see* Hafemeister & Bryan, *supra* note 160, at 524 (“[M]any states do not have either a causation requirement or an actual harm requirement associated with their fiduciary causes of action. This is in part because (1) the breach of loyalty is the harm and (2) the purpose behind recognizing breach of fiduciary duty claims is to remove the incentive for disloyal conduct on the part of the fiduciary by confiscating the profits gained by fiduciaries as a result of their conduct, not necessarily to restore beneficiaries to their position *ex ante* by compensating their losses.”) (citations omitted).

<sup>199</sup> *See supra* Part VI.B.1.

<sup>200</sup> For example, a physician may have a fiduciary duty to keep medical records and information received in the course of the physician-patient relationship confidential and private, to not engage in a sexual relationship with a current patient, to avoid conflicts of interests that may compromise medical judgment, and to disclose to a patient adverse medical conditions of which the patient is unaware. *See* Hafemeister & Bryan, *supra* note 160, at 527.

has made a specific request for, and in some cases demanded, a particular medical service.

As for the second element, physicians breach their fiduciary duty to patients when they abdicate their responsibility to exercise independent medical judgment and provide their patients with access to medical services that are not medically indicated.<sup>201</sup> A breach of this duty occurs even though the patient has requested or demanded these services and the physician has disclosed to the patient the risks associated with these services. A physician cannot abdicate this responsibility and permit the patient to assume the risk associated with a medical service that the physician, exercising independent medical judgment, believes is not medically indicated.<sup>202</sup> A patient who strongly desires such a medical service is of course free to seek this service from some other physician who may conclude that it is medically indicated.<sup>203</sup> But a physician who has failed to exercise independent medical judgment in response to a request or demand from a patient for a specific medical service has breached the physician's fiduciary obligation to that patient.

The damages element in tort law generally requires that the plaintiff suffered actual harm as a result of the breach of duty.<sup>204</sup>

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<sup>201</sup> See *supra* Part VI.B.2.

<sup>202</sup> Under this standard, because a placebo by definition is not expected to pose a risk to a patient, it could be argued that a physician who, unbeknownst to the patient, substitutes a placebo for a requested but medically contraindicated prescription could thereby avoid a potential cause of action for breach of fiduciary duty. The use of placebos in medical practice is not uncommon. See Laura Blue, *Is Your Doctor Prescribing Placebos?* TIME, Jan. 3, 2008, <http://www.time.com/time/health/article/0,8599,1700079,00.html> (last visited Mar. 20, 2009) (reporting that forty-five percent of responding physicians "said they had prescribed placebos in [their] regular clinical practice and . . . just over half had prescribed a placebo in the previous year. Among the reasons the doctors gave: to calm a patient down, to respond to demands for medication that the doctor felt was unnecessary, or simply to do something after all other treatment options had failed." (citing Rachel Sherman & John Hickner, *Academic Physicians Use Placebos in Clinical Practice and Believe in the Mind-Body Connection*, 23 J. GEN. INTERNAL MED. 7 (2008))). However, prescribing a placebo without the patient's knowledge may represent a breach of the physician's duty to obtain informed consent before administering treatment. *Id.*

<sup>203</sup> This physician, if independent medical judgment was exercised, would not be subject to a cause of action for a breach of fiduciary duty. However, if the physician provided access to a medical service that was medically contraindicated, the physician may be subject to a cause of action for medical malpractice if damages to the patient result from this access. See I FURROW ET AL., *supra* note 182, at 264 ("Malpractice is usually defined as unskillful practice resulting in injury to the patient, a failure to exercise the 'required degree of care, skill and diligence' under the circumstances.").

<sup>204</sup> DAN B. DOBBS, *THE LAW OF TORTS* 405 (2000) ("[D]amages are not presumed [in a claim based upon negligence] as they are in the case of some intentional torts; the plaintiff who is not harmed by negligence cannot even recover nominal damages.

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However, unless specifically required within a given jurisdiction, the law governing causes of action for a breach of a fiduciary relationship may not require a plaintiff to show that the patient experienced actual harm.<sup>205</sup> This variation “is in part because (1) the breach of loyalty is the harm and (2) the purpose behind recognizing breach of fiduciary duty claims is to remove the incentive for disloyal conduct on the part of the fiduciary[,] . . . not necessarily to restore beneficiaries to their position *ex ante* by compensating their losses.”<sup>206</sup> The absence of actual harm may greatly diminish the award that is available,<sup>207</sup> but a physician’s failure to exercise independent medical judgment could result in an award of nominal compensatory damages, with the possibility of an additional award of attorney’s fees or punitive damages.<sup>208</sup> Although a breach of this fiduciary duty may not result in any physical harm to the patient, an award of damages may be appropriate in some cases to deter this type of breach.

To prove causation, a possible fourth element of this cause of action, the patient may have to show that “but for” the physician’s breach the resultant harm would not have occurred.<sup>209</sup> Within the context of this Article, the question could become whether the harm to the patient would have occurred even if the physician had said “no” to the patient’s request or demand for a particular medical service. If a physician can demonstrate that the harm would have occurred anyway (for example, that the patient would have had a myocardial event even if he had not taken the medication), the physician

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More significantly, the statement means that the plaintiff must prove not merely that she suffered harm sometime after the defendant’s negligent act occurred but that the harm was caused in fact by the defendant’s conduct.”).

<sup>205</sup> Hafemeister & Bryan, *supra* note 160, at 524.

<sup>206</sup> *Id.*

<sup>207</sup> There can, of course, be actual harm associated with a physician providing a patient with access to a contraindicated medical service (such as medication). For example, building upon the hypothetical that opened this Article, it should be noted that the FDA has posted on its web site the results of studies that indicate that there is a small but measurable risk of a heart attack in individuals with high blood pressure who ingest certain drugs widely prescribed to increase sexual performance. Press Release, U.S. Food and Drug Admin., Patient Information: CIALIS (See-AL-iss) (tadalafil) Tablets (2007), *available at* [http://www.fda.gov/medwatch/safety/2007/Oct\\_PI/Cialis\\_PPI.pdf](http://www.fda.gov/medwatch/safety/2007/Oct_PI/Cialis_PPI.pdf). Ordering contraindicated medical services can also expose a physician to a medical malpractice claim. *See infra* Part VI.C.2.

<sup>208</sup> *See* Hafemeister & Bryan, *supra* note 160, at 524–25.

<sup>209</sup> 1 FURROW ET AL., *supra* note 182, at 302 (“Tests [in medical malpractice claims] for causal connections between the plaintiff’s injury and the defendant’s negligence are usually described by the courts in terms of the ‘but for’ test. ‘But for’ the defendant’s conduct, the plaintiff would not have suffered injury. The plaintiff must present testimony that the defendant’s acts or omissions probably caused the plaintiff’s injuries.”).

might not be found liable.<sup>210</sup> However, for the same reasons, as discussed above, that a showing of actual harm may not be required, in some jurisdictions a causation requirement may not be mandated for a breach of fiduciary duty claim.<sup>211</sup>

## 2. A Fiduciary Duty as Opposed to a Medical Malpractice Cause of Action

While the elements of a fiduciary duty claim can be very similar to the elements of the more frequently pursued medical malpractice claim (duty, breach of duty, causation, and damages), they are distinct causes of action.<sup>212</sup>

The fundamental difference between a medical malpractice claim and a fiduciary duty claim is that the former reflects an asserted breach of the physician's *duty of care*, while the latter focuses on a purported breach of the physician's *duty of conduct*.<sup>213</sup> Negligence doctrine, the foundation for a medical malpractice claim, seeks to enhance the quality of healthcare and to make physicians more prudent in their delivery of medical services by holding them liable for a failure to exercise the degree of care, skill, and diligence of a competent physician under similar circumstances (i.e., to do what is customary within the profession in a given context).<sup>214</sup> In contrast, the recognition of a fiduciary duty indicates that certain conduct is unacceptable even if the fiduciary can identify other fiduciaries who acted in a similar manner or articulate other possible justifications for the behavior. Fiduciary doctrine does not seek to make physicians more

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<sup>210</sup> One of the drawbacks to relying on a tort approach, as seen here, is that it allows the physician to avoid legal liability despite violating a fundamental expectation associated with the privilege of being a physician, namely, that a physician will exercise independent medical judgment before authorizing medical services. It is beyond the scope of this Article, but it is arguable that a lawsuit for breach of a fiduciary duty should be a quasi-contractual action rather than a tort action to avoid impediments resulting from a required showing of actual harm resulting from the breach (that is, damages and causation).

<sup>211</sup> See *supra* note 198 and accompanying text.

<sup>212</sup> The similarities are such that at least one commentator has argued that the "breach of fiduciary duty" claim should be eliminated altogether when its functions are served by a professional malpractice claim. See Charles W. Wolfram, *A Cautionary Tale: Fiduciary Breach as Legal Malpractice*, 34 HOFSTRA L. REV. 689, 690-92 (2006).

<sup>213</sup> *Id.* at 691 ("[W]hile negligence is based on a claim of breach of a standard of care, fiduciary breach is properly based on a claim of breach of a standard of conduct . . .").

<sup>214</sup> See I FURROW ET AL., *supra* note 182, at 264.

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“careful,”<sup>215</sup> but rather seeks to establish what is minimally necessary behavior and, conversely, what behavior will not be tolerated regardless of the circumstances. Fiduciary doctrine establishes that there are some actions by a physician (as with any fiduciary) that are by consensus (within and outside the profession) so expected or repugnant that excuses (that is, legal defenses) for failing to act in the expected manner should not be available.

Thus, when a patient has demanded medically contraindicated care, even though a medical malpractice claim may be untenable due to the defenses of assumption of risk or contributory or comparative negligence,<sup>216</sup> such defenses should not be available as a response to a breach of fiduciary duty claim if the physician failed to exercise independent medical judgment in responding to this demand. A fiduciary cause of action does not focus on “fault” (as in where due care was not exercised); rather, it addresses behaviors in which no physician should engage. There are simply some things that a fiduciary cannot do. When the fiduciary crosses that line, regardless of the explanation given for that behavior or whether harm directly resulted from it (the *sine qua non* of a negligence cause of action), consequences should flow, and a cause of action for breach of fiduciary duty should be available.<sup>217</sup>

Another important difference between the two causes of action is the nature of the proof necessary for the plaintiff to prevail.<sup>218</sup> Because medical malpractice involves a failure to exercise due care (that is, the level of care customarily expected of members of that profession under the circumstances), expert testimony is required to demonstrate what the standard of care is and that a physician failed to meet that standard.<sup>219</sup> An action for breach of fiduciary duty, however, does not require the patient to demonstrate that the physician failed to exercise due care. Instead, the plaintiff need only show that the physician’s conduct violated basic rules of conduct regarding how

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<sup>215</sup> See, e.g., Ray Ryden Anderson & Walter W. Steele, Jr., *Fiduciary Duty, Tort, and Contract: A Primer on the Legal Malpractice Puzzle*, 47 SMU L. REV. 235, 249 (1994) (“[Fiduciary] duties may be violated without any showing of negligence.”).

<sup>216</sup> See, e.g., *Ostrowski v. Azzara*, 545 A.2d 148, 151–53 (N.J. 1988); see also 1 FURROW ET AL., *supra* note 182, at 294–97.

<sup>217</sup> Anderson & Steele, *supra* note 215, at 249.

<sup>218</sup> *Id.* at 254.

<sup>219</sup> *Id.*

all physicians are expected to act, for which expert testimony may not be required.<sup>220</sup>

*D. The Impact of a Fiduciary Cause of Action Requiring Physicians to Exercise Independent Medical Judgment*

Expressly recognizing that physicians have an obligation to exercise independent medical judgment when a patient asks them to authorize access to services that are not medically indicated does not necessitate a change in existing substantive law. Instead, it merely requires an embracement and explication of the doctrine that physicians owe a fiduciary duty to their patients. The effect of recognizing a cause of action for failing to “just say no” to a patient should be to provide clearer guidance to medical practitioners and to encourage them to fulfill their responsibility to reject requests from patients for services that are not medically indicated.<sup>221</sup>

Because of recent developments in the doctrine of informed consent, some physicians may believe that as long as the patient has been informed of the potential risk of the requested service and reasonable alternatives, physicians have an obligation to permit patients to choose whatever course of medical services they desire. The physician’s fiduciary duty, however, does not permit the physician to abdicate his or her obligation to exercise independent medical judgment on behalf of a patient. When the service requested by the patient is not medically indicated, the physician must refuse to authorize access to that service.

VII. THE BENEFITS OF RECOGNIZING THAT PHYSICIANS  
HAVE A FIDUCIARY DUTY TO EXERCISE INDEPENDENT MEDICAL  
JUDGMENT IN RESPONSE TO A PATIENT’S DEMAND FOR A SERVICE  
THAT IS NOT MEDICALLY INDICATED

Recognizing that doctors have a fiduciary duty to resist a patient’s demand for a service that is not medically indicated will be beneficial to the doctor, the patient, and society as a whole.

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<sup>220</sup> *Id.* (“[B]ecause an action based on breach of fiduciary duty raises the issue only of whether the [fiduciary]’s conduct violated rules governing the profession, an expert’s testimony is not required to show violation of those rules.”).

<sup>221</sup> Recognizing a cause of action for breach of fiduciary duty in this instance can also empower physicians to speak when a contentious request for “futile” care is made. See *supra* note 192 and accompanying text; see also COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, AM. MED. ASS’N, MEDICAL FUTILITY IN END-OF-LIFE CARE: REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, *in* 281 JAMA 937, 940 (1999) (arguing for a “fair process approach” to resolve questions regarding futile medical care).

*A. Benefits to Physicians*

Although it may seem counter-intuitive on its face, physicians will enjoy a distinct benefit as the result of recognizing physicians' fiduciary duty to refuse to comply with a patient's request for a service that is not medically indicated. It will empower members of the profession to fully exercise their training and skills and will minimize financial incentives that might otherwise lead them to diminish and perhaps even abdicate their role in medical decision making.

Charging physicians with a responsibility to refuse requested treatment that is inconsistent with their medical judgment inherently gives them the *right* to refuse patient demands for medically contraindicated treatment. Just as a patient has a general right to refuse treatment that a physician recommends, physicians have a general right to refuse to provide treatment on which a patient inappropriately insists.<sup>222</sup> As a result, both can be active participants in medical decision making—the doctor can reject a patient's proposal if it does not represent “good” medicine, and the patient can reject a doctor's proposal if it does not match what the patient believes is needed under the circumstances. This is likely to enhance the quality of and satisfaction with the medical care provided, while protecting and promoting the autonomy of both the patients and the physicians involved in these decisions. In sum, imposing liability on physicians for a failure to “say no” to a patient's request or demand for treatment that is not medically indicated duly empowers physicians to decline to provide access to such treatment.<sup>223</sup>

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<sup>222</sup> See Rahul K. Parikh, *Showing the Patient the Door, Permanently*, N.Y. TIMES, June 10, 2008, at F6 (asserting that the physician-patient compact “gives a doctor the right to dismiss a patient”). It should be noted that this Article does not advocate that physicians return to an inherently dominant role in their relationships with patients. Such a relationship is not therapeutic or “good” medicine. This Article strongly support a collaborative relationship between physicians and patients where both have vital roles to play.

<sup>223</sup> It should be emphasized that this power to “say no” to a patient's request or demand for treatment only recognizes treatment refusals that are not medically indicated (that is, those that do not reflect the medical interests of the patient). It does not embrace refusals that are based on the physician's personal preference, convenience, or financial advantage. Requiring a patient to seek services from an alternative healthcare provider can entail considerable inconvenience and risk for the patient. A patient may not be able to find a healthcare provider readily available. For example, there may be a limited pool of healthcare providers willing to provide services to Medicare or Medicaid patients because of the deep discounts in payments for services afforded these patients. See *supra* note 134 and accompanying text. An alternative healthcare provider may be located farther away or at a location that is difficult for the patient to access, which can cause considerable hardship for an ailing patient. The patient must introduce the alternative healthcare provider to the nature of his or her medical problem and provide relevant medical history, which may

During this era of DTCA and Internet access to medical information, physicians may be concerned that they will lose patients critical to the physicians' financial well-being if they refuse to provide requested medication or access to other medical services. Their concern may be justifiable. One survey found that seventy-five percent of polled patients said they would switch doctors to get the medicine they wanted.<sup>224</sup> With a clear legal obligation to refuse requests that are not medically indicated, physicians will be less likely to fear that they will experience financial disadvantage if they fail to acquiesce to such patient requests. Because every physician will now have a responsibility to refuse these requests, all physicians will be in the same financial position, and patients will not be able to "shop around" for a physician who is willing to disregard his or her fiduciary responsibility.

*B. Benefits to Patients*

A primary benefit to patients from recognizing a physician's fiduciary duty to exercise independent medical judgment is that a check will be placed on imprudent, sometimes impulsive, and perhaps even dangerous requests by patients. Importantly, this check will be provided by an independent professional with the expertise and skill needed to appropriately review the request. As discussed, patients, as lay persons with access to a growing, albeit frequently incomplete or even misleading body of information that they may not adequately understand,<sup>225</sup> are often not equipped to identify all of the risks and benefits of a possible course of medical action. If their physicians abdicate their responsibility to independently review and determine access to medical services, patients may be harmed by their requests or incur other losses needlessly, such as delayed access to more appropriate services or expenditures on costly but ineffective services. Although the input of the patient should be encouraged and the patient's choice regarding the course of treatment respected,<sup>226</sup> the patient's interests will ultimately be promoted best if the physician is also an active participant in the medical decision making.

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delay the delivery of needed services. Medical records must be transferred and vital information conveyed in the past that was not entered into those records may be lost. Medical "handoffs" in general tend to increase the risk of harm to patients. See ROBERT M. WACHTER & KAVEH G. SHOJANIA, INTERNAL BLEEDING: THE TRUTH BEHIND AMERICA'S TERRIFYING EPIDEMIC OF MEDICAL MISTAKES 159-79 (2005).

<sup>224</sup> Fushman, *supra* note 83, at 1172.

<sup>225</sup> See *supra* notes 93-94 and accompanying text.

<sup>226</sup> See *supra* notes 41-49 and accompanying text.



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In addition, providing a cause of action to a patient whose physician has breached the fiduciary duty to exercise independent medical judgment will supply such patients with a legal remedy that can award compensation for this breach. It might be argued that a physician's failure to exercise independent medical judgment when providing access to services that are not medically indicated would be better addressed by approaching this as a breach of the physician's ethical obligations.<sup>227</sup> A physician's violation of an ethical duty may result in reprimand by a board of licensure, suspension of the physician's license to practice medicine, or even revocation of the right to practice medicine.<sup>228</sup> However, these sanctions do not provide a remedy to the patient. The patient will not be able to initiate or be directly involved in related proceedings to ascertain whether the physician has breached his or her ethical obligation, and thus the patient will not receive the satisfaction that may result from being an active participant in these proceedings. Also, the patient will only be compensated for any harm incurred as the result of a breach of the physician's fiduciary duty if the duty owed the patient is part of a recognized legal cause of action, as boards of licensure focus exclusively on whether a reported wrongdoer should be sanctioned and do not provide an award of damages to individuals who have been harmed by the unethical actions of the licensed professional.<sup>229</sup>

It might be argued that empowering physicians to reject patient requests for a desired course of treatment harms patients by diminishing their right to direct the course of their treatment. However, the patient's autonomy generally will not be compromised as a result. First, the physician cannot impose his or her preferred course of treatment on the patient but can only refuse to provide access to the services requested. Second, a physician's fiduciary obligation does not encompass a right to refuse requested services capriciously;

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<sup>227</sup> See generally Catherine T. Struve, *Doctors, the Adversary System, and Procedural Reform in Medical Liability Litigation*, 72 *FORDHAM L. REV.* 943, 972–75 (2004).

<sup>228</sup> See generally I FURROW ET AL., *supra* note 182, at 75–76 (discussing physician licensure and disciplinary actions and their respective goals). It is also worth noting that there is an ongoing debate over whether these sanctions are issued sufficiently frequently to deter inappropriate behavior by physicians. Cf. Darren Grant & Kelly C. Alfred, *Sanctions and Recidivism: An Evaluation of Physician Discipline by State Medical Boards*, 32 *J. HEALTH POL., POL'Y & L.* 867 (2007) (evaluating data on sanction frequency and repeat offenders). There is little, if any, indication that such sanctions have been imposed on physicians for failing to exercise independent medical judgment in the face of a patient's request for services that are not medically indicated.

<sup>229</sup> Comment, *Professional Negligence*, 121 *U. PA. L. REV.* 627, 683 (1973) (“The board [of licensure] has no power to order compensation to an injured party; in effect its power is limited to revocation of the license or lesser variants thereof.”).

treatment refusals are required only when the physician is seeking to protect and promote the patient's best interests. Third, if the patient disagrees with the physician's refusal to order a requested medical service, the patient remains free to attempt to find a physician who believes the request is medically indicated.

In general, as long as the requested course of treatment is medically indicated, the physician's fiduciary obligation does not encourage a physician to reject the patient's treatment request. If a patient has a medically viable request, the recognition of this cause of action should not make it any more difficult for a patient to find a doctor who will honor the request. The only time the patient will not receive requested access to services is when the request is not medically indicated. Overall, patients are protected from harm but continue to be able to exercise adequate control over the medical decision making germane to their well-being.

Critics of this fiduciary cause of action may assert a "clean hands" argument, claiming that it is inappropriate to permit a patient to benefit from a lawsuit for actions by a physician when it was the patient who "compelled" the physician to breach his or her fiduciary obligation. The law, however, requires that a physician be a gatekeeper for medical treatments, including prescription medications.<sup>230</sup> It does not matter how hard someone knocks on the gate; the gatekeeper must only allow those through the gate who medically should enter. Simply put, a greater obligation is imposed on a highly educated, trained, and skilled licensed professional than on an uninformed patient. Physicians should not be able to avoid liability for their actions simply because a patient "insisted" on a certain treatment. By analogy, an automobile driver cannot defend a lawsuit against a passenger by stating that the passenger encouraged him to drive recklessly. As a matter of law, the physician is and should be responsible for his or her medical decisions.

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<sup>230</sup> Every state has enacted laws that authorize licensed physicians to prescribe medications and generally exclude other individuals from doing so. James L.J. Nuzzo, *Independent Prescribing Authority of Advanced Practice Nurses: A Threat to the Public Health?*, 53 FOOD & DRUG L.J. 35, 41 (1998) ("[P]hysicians . . . have enjoyed a pharmaceutical prescription monopoly in fact since the early part of the century and in law since the [federal Food, Drug, and Cosmetic Act] was passed in 1938 . . ."). Further enhancing physicians' gate-keeping function, the Controlled Substances Act of 1970 provides an exhaustive list of drugs that are available only by prescription. Pub. L. No. 91-513, 84 Stat. 1236 (1970).

*C. Benefits to Society*

Society has an interest in the protection of the health and well-being of its members.<sup>231</sup> As discussed, in the case of potentially dangerous prescription medications, for example, gatekeepers are necessary to ensure the safety of those seeking these drugs.<sup>232</sup> Approximately 200,000 Americans die each year from adverse reactions to prescription medications.<sup>233</sup> Furthermore, 2.2 million injuries occur annually as a result of adverse drug events.<sup>234</sup> In fact, adverse drug reactions are responsible for an astounding five percent of all hospital visits in the United States.<sup>235</sup> Society has a strong interest in protecting its members from and minimizing the occurrence of these adverse events. Because of their risk, medications and other medical services should only be prescribed when medically indicated. Furthermore, in light of continuing concerns regarding the escalating costs of healthcare,<sup>236</sup> providing physicians with a legal incentive to refrain from providing patients with access to services that are not medically indicated may help to control these costs.

Physicians are in a better position to protect individuals from potentially harmful medications that are not medically indicated than the individuals themselves. Physicians have the expertise and training to accurately diagnose the patient's condition and to understand the relative risks and benefits of the courses of treatment being considered. Placing a legal duty on physicians to utilize their knowledge to protect the health and safety of their patients provides a benefit to all of society.

In the scenario addressed by this Article, there is an inevitable tension present. Society must weigh the potential diminishment of the autonomy of the patient (that is, the patient's right to exercise complete control over the medical decision making relevant to that patient's body) against the need to ensure appropriate medical deci-

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<sup>231</sup> See Lawrence O. Gostin, *Health of the People: The Highest Law?*, 32 J.L. MED. & ETHICS 509, 509 (2004).

<sup>232</sup> See *supra* notes 112–14 and accompanying text. For a discussion of the role of the FDA in ensuring the safety of prescribed medications, see Barbara A. Noah, *Adverse Drug Reactions: Harnessing Experiential Data to Promote Patient Welfare*, 49 CATH. U. L. REV. 449, 449 (2000).

<sup>233</sup> Calabro, *supra* note 83, at 2241.

<sup>234</sup> The Center for Drug Safety, *Facts of the Day*, [http://www.centerfordrugsafety.org/Home\\_AllFacts.asp](http://www.centerfordrugsafety.org/Home_AllFacts.asp) (last visited Mar. 21, 2009).

<sup>235</sup> *Id.*

<sup>236</sup> NAT'L COAL. ON HEALTH CARE, *FACTS ON HEALTH CARE COSTS 1* (2008), <http://www.nchc.org/documents/Cost%20Fact%20Sheet-2009.pdf> (last visited Mar. 21, 2009).

sion making (that is, to discourage physicians from abdicating their valuable role in this decision making). Patients can and should properly determine factors such as how valuable a given treatment is to them in light of surrounding circumstances, how a proposed treatment plan will disrupt or enhance their life, and the magnitude and relative weight of the benefits and risks involved. Giving physicians a legal obligation to resist patient demands for services that are not medically indicated does not and should not diminish the role of the patient in medical decision making. It only mandates that physicians not abdicate their obligation to ensure that the treatment provided is medically indicated.

#### VIII. CONCLUSION

In a world saturated with medical information through DTCA and the Internet, physicians must know how to respond to “informed” patients. Physicians often face the difficult decision of whether to provide a requested treatment that is not medically indicated or risk losing a revenue-generating patient. Physicians, however, should not lose sight of their overriding fiduciary obligation to promote and protect the best interests of their patients, and they should not permit any potential conflicting interest to overcome this responsibility, including the possible adverse financial consequences to their practice that may result from their refusing a patient’s request for a given service. By including within the ambit of the physician’s fiduciary duty a legal obligation to “say no” to a patient requesting services that are not medically indicated, the law empowers physicians to exercise their medical judgment, an empowerment that best serves us all.