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THE FAILURE OF BREAST CANCER INFORMED CONSENT STATUTES

Rachael Andersen-Watts*

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Introduction

Informed consent is a common law concept rooted in the idea that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body." Its aim is to ensure that each patient gets the information she needs to meaningfully consent to medical procedures. Coming of age in the 1970s alongside other important rights movements, informed consent purported to solve medicine's paternalism: doctors too often dictating treatments rather than discussing options. Combating medical paternalism seems a

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Canterbury v. Spence, 464 F.2d 772, 780 (1972) (citing Schloendorff v. Soc'y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914)). For a discussion of the disclosures a physician is required to make in order to enable the patient to make an informed consent see 70 C.J.S. Physicians, Surgeons, and Other Health-Care Providers § 120 (2006).

^{2.} Carl E. Schneider, The Practice of Autonomy 8 (1998).

worthwhile goal, given abuses in the past century,³ but moreover to improve everyday physician-patient encounters. Nevertheless, a lofty goal does not dictate a positive outcome, and some decades later, the law of informed consent is failing.⁴

Breast cancer is an excellent example of the bases for informed consent requirements because it is a medical condition where the treatment options have similar *medical* outcomes but distinctly different non-outcome related traits that will influence the patient's preferences as an individual. Today, when diagnosed with early onset breast cancer, a woman will often face a choice between lumpectomy, known as breast-conserving surgery (BCS), and mastectomy. Informed consent is not about the answer the patient comes to, but about protecting her right to come to a decision after having been duly informed of treatment options and associated risks. Breast cancer patients must weigh their own preferences and values in order to make the best personal decision. Medical research has yielded conclusive results showing that when faced with early stage breast cancer, a woman's survival rate is the same whether she undergoes mastectomy or BCS. The pros and cons of each treatment

See Charity Scott, Why Law Pervades Medicine: An Essay On Ethics In Health Care, 14
 NOTRE DAME J.L. ETHICS & Pub. Pol'y 245, 249 (2000) (discussing the history of informed consent, including historical catalysts such as the Tuskegee Syphilis Study).

^{4.} E.g. Carl E. Schneider, Some Realism About Informed Consent, 145 J. LABORATORY & CLINICAL MED. 289, 289–91 (2005).

^{5.} Susan G. Nayfield et. al., Statutory Requirements for Disclosure of Breast Cancer Treatment Alternatives, 86 J Nat'l Cancer Inst. 1202 (1994). "[B]reast-conserving surgery with postoperative radio-therapy has been recognized as equivalent in medical outcome to that achieved with mastectomy for early-stage disease." Id. at 1204. I will refer to simple mastectomy as mastectomy. This is in contrast to radical mastectomy, discussed in Part I. Though radical mastectomy may still be used in certain cases, the salient decision for the discussion herein is between simple mastectomy and BCS, as breast cancer informed consent statutes are aimed at women faced with this choice. Barron H. Lerner, The Breast Cancer Wars 232–3 (2001).

^{6.} See, e.g., Steven J. Katz et al., Patient Involvement in Surgery Treatment Decisions for Breast Cancer, 23 J. CLINICAL ONCOLOGY 5526, 5526 (2005) ("[T]here is professional consensus that most women with early-stage breast cancer are good candidates for breast-conserving surgery ..."); Ann B. Nattinger, Variation in the Choice of Breast Conserving Surgery or Mastectomy: Patient or Physician Decision Making?, 23 J. CLINICAL ONCOLOGY 5429, 5429 (2005) ("In 1985, the 5-year results were published of the first US randomized trial ... demonstrating equal survival for early-stage breast cancer patients whether they underwent mastectomy or breast-conserving surgery (BCS).") (citing Bernard Fisher et al., Five-year Results of a Randomized Clinical Trial Comparing Total Mastectomy and Segmental Mastectomy With or Without Radiation in the Treatment of Breast Cancer, 312 New Eng. J. Med. 665 (1985)).

choice are very distinct, while survival rates, in many cases, are comparable.⁷

In an ostensible effort to ensure that breast cancer patients are able to make good treatment decisions, twenty-two states have enacted statutes that add a legislative component to the existing protection of the common law informed consent doctrine for patients diagnosed with breast cancer and faced with treatment options. Promulgated at the behest of former breast cancer patients in the 1980s, they are benign statutes on some levels. In general, they compel doctors to provide additional literature to breast cancer patients about treatment options, including the surgical decision between mastectomy and BCS.

Physicians, however, have expressed concerns regarding the negative impact of such legislation on their ability to treat women. ¹¹ And, in spite of their innocuous appearance, patients and lawyers have good reason to be concerned about these statutes as well. These laws do not promote individualistic decision-making. ¹² In fact, they stem in part from the assumption that individual women were making an "incorrect" decision when they chose mastectomy instead of lumpectomy. ¹³ This is not

- 7. Nananda F. Col, Christine Duffy & Carol Landau, Commentary—Surgical Decisions after Breast Cancer: Can Patients Be Too Involved in Decision Making?, 40 HEALTH SERVICES RES. 769 (2005) ("Deciding whether to undergo breast conserving therapy (BCT) or mastectomy remains difficult for women diagnosed with early stage breast cancer. Despite the substantial differences in the side effects of these treatments, no survival differences have been shown up to 20 years later among women with stage I and II cancer."). The choice between BCS and mastectomy is what is known as "preference-sensitive care," which are "care situations in which there are two or more treatment options that are medically justified, [and therefore] the decision process should incorporate and be sensitive to patient preferences regarding the various treatment options." Paula M. Lantz et al., Satisfaction with Surgery Outcomes and the Decision Process in a Population-Based Sample of Women with Breast Cancer, 40 HEALTH SERVICES RES. 745, 746 (2005) (citing J.E. Wennberg, Unwarranted Variations in Healthcare Delivery: Implications for Academic Medical Centres, 325 BRITISH MED. J. 961, 961–64 (2002)).
- 8. Nayfield, *supra* note 5, at 1206. *See infra* text accompanying note 65 for list of statutes.
- 9. Theresa Montini, Resist and Redirect: Physicians Respond to Breast Cancer Informed Consent Legislation, 26 Women & Health 85, 86 (1997).
- 10. Nayfield, supra note 5. See infra Part III.
- 11. Nayfield, *supra* note 5, at 1206 ("The [Massachusetts] Medical Society launched an attempt to repeal the statute . . . citing the law's undue interference in the patient-physician relationship and arguing that all treatment alternatives are not alike.").
- 12. See Schneider, supra note 2, at 9 (noting a number of legal scholars have strongly critiqued the doctrine of informed consent, though these statutes specifically have not been subject to any in depth legal scrutiny).
- 13. See infra Part II (discussing the historical context of breast cancer informed consent statutes).

merely the law overstepping its role by proffering medical advice, but moreover it is a perversion of the goal of informed consent.

Breast cancer informed consent statutes exemplify the extent to which the doctrine, when put into practice, has been perverted into a morally coercive tool, instead of the individual-centered mantra of its aspirations. These statutes are widely perceived as stemming from the commonly held idea that mastectomy is "over-used" in the treatment of breast cancer. ¹⁴ Not only does pushing patients toward a particular course of treatment fly in the face of the goals of informed consent, these laws are rooted in a time that has since passed: doctors are no longer pushing mastectomy over BCS, ¹⁵ and today many patients demand mastectomies based on their personal values and preferences. ¹⁶

Breast cancer informed consent legislation was introduced in response to breast cancer patient discontent with doctor-patient relationships.¹⁷ Physicians do not always believe that explaining treatment alternatives is important,¹⁸ and in this respect, legislation promoting the discussion of alternative treatment *could* be positive for breast cancer patients, many of whom do in fact have several viable medical options.¹⁹ Studies have found, however, that these statutes have no lasting impact on patient decision-making.²⁰ Why aren't these patient-driven statutes affecting patient decision-making? And why is medical advice coming from the law at all?

This Article argues that this legislation is a poor tool for creating positive change in the physician-patient realm of breast cancer treatment. Ideally, informed consent for breast cancer patients²¹ would be an individualistic process. It would be shaped by the specific context of the patient's life, as well as the gender inequities that still pervade medicine. The right kind of laws would see a "good" decision as one in which the patient is left physically and emotionally satisfied. To the contrary, these statutes imply that what women need is more naked information on

^{14.} Paula M. Lantz et al., Satisfaction with Surgery Outcomes and the Decision Process in a Population-Based Sample of Women with Breast Cancer, 40 HEALTH SERVICES RES. 745, 746–47 (2005) ("An explicit assumption in much... policy development [including breast cancer informed consent statutes] is that mastectomy is 'over-used.'").

^{15.} See infra note 93 and accompanying text.

^{16.} See infra notes 97-100 and accompanying text.

^{17.} Theresa Montini, Gender and Emotion in the Advocacy for Breast Cancer Informed Consent Legislation, 10 GENDER & SOC'Y 9, 13-14 (1996).

^{18.} Nayfield, supra note 5, at 1206.

^{19.} Id.

^{20.} Nattinger, supra note 6.

^{21.} This Article is limited in scope to addressing these specific statutes and, by extension, breast cancer patients. I do not mean to suggest, nor does the data support, that breast cancer patients are in any global sense "different" than other patient groups.

treatment options, an idea divorced from what is known about patient decision-making.

Part I of this Article provides social and historical context of the breast cancer issue and argues that non-legal, largely social, forces are responsible for positive changes in the physician-breast cancer patient relationship. Part II contrasts the goals of informed consent to the reality of its unsuccessful application. Part III examines the statutes themselves and the mandatory literature that they have produced, arguing that these statutes are unhelpful to breast cancer patients as well as to their doctors.

I. Breast Cancer History: Social and Medical Evolution

The history of breast cancer in the United States demonstrates both the heavy-handed medical approach to breast cancer treatment that prevailed until the 1970s, and the surgical blindsiding of many women that resulted. The story is richer than that, though. It shows adaptation and movement within the medical field that is reactive to a changing land-scape for women's rights and women's health issues. As pro-patient doctors and activists emerged on the scene, the treatment of breast cancer improved—not only in terms of enhanced medical outcomes, but also in terms of personal interactions and psychological coping with the disease and treatment.

The socio-medical history of breast cancer is a tale not of law (in the form of informed consent) driving pro-woman policy in medicine and society, but of societal changes and medical evolution preceding legal principles. Initially, there was a clear need for reform. Many surgeons' paternalism suppressed the voices and opinions of women during the era of the radical mastectomy, which began at the turn of the eighteenth century and lasted until the 1970s.²³

However, the medical field itself, as evidenced by the work and notoriety of progressive physicians, was not without its own momentum for reform during this time. Indeed, the consumer movement of the 1970s affected patient expectations of their doctors.²⁴ And, not surprisingly, the doctrine of informed consent made its way into state

^{22.} Vicki Lawrence MacDougall, *Medical Gender Bias and Managed Care*, 27 OKLA. CITY U. L. Rev. 781, 800–01 (2002) ("The Women's Health Movement [which] began over thirty years ago . . . created public awareness and spurred the medical profession toward this introspection.").

^{23.} See infra notes 30-32 and accompanying text for a more detailed discussion of radical mastectomy and its implications.

^{24.} Montini, supra note 17, at 14.

legislation during this time.²⁵ Women took action in the debate, encouraging all women to ask questions, to be heard, and to demand the medical treatment that was right for them.

Before the legal adoption of informed consent, physician-patient communication was lacking for the majority of breast cancer patients. Deception was posed as a legitimate option for physicians—some practitioners believed that withholding cancer diagnoses was benevolent and even discussed the tactic in medical publications. During the reign of the radical mastectomy, many surgeons expressed the view that the breast was not of importance to women, especially older women. Medical articles referred to the breast as a "nonvital and functionless gland," "one of the most dispensable parts of the body," or "a superficial easily disposable utilitarian appendage." This attitude of expendability of the breast contributed to the acceptance of the radical mastectomy.

For almost a century, radical mastectomy reigned as the treatment of choice for breast cancer.³⁰ A radical mastectomy is a disfiguring operation, which leaves "women with a deformed chest wall, hollow areas beneath the clavicle and the underarm, and, at times, persistent pain at the operative site and swelling known as lymphedema."³¹ Besides being extensive and painful procedures, they were also routinely done without the patient's express consent. Often upon diagnosing a patient with breast cancer during surgery, the surgeon would proceed with the radical mastectomy right then and there, giving the operation the nickname of the "one-step" procedure.³²

The law itself may have contributed to the persistence of the radical mastectomy as the near lone treatment option because many surgeons feared liability for performing what they viewed as less thorough procedures.³³ Dr. Baron Lerner, a medical doctor and breast cancer historian, states that "[f]rom a legal perspective, certain surgeons believed that recurrent breast cancer following a smaller procedure made them liable—

^{25.} Id. at 9.

^{26.} Lerner, supra note 5, at 88.

^{27.} Id. at 89.

^{28.} Id. (internal quotations omitted).

^{29.} Id. at 88-89. For a related idea, see also Rebecca L. VanCourt, Comment, Uterine Fibroids and Women's Right to Choose, 26 J. Legal Med. 507, 515 (2005) ("Some gynecologists suggest 'the useless uterus' theory has lead to an increase in hysterectomy procedures [in older women].").

^{30.} Lerner, *supra* note 5, at 17–29. Dr. William Halsted is known as the father of the radical mastectomy. *Id.* He was responsible for significant sanitation advances in surgery; for example the use of rubber gloves to prevent infection. *Id.*

^{31.} Id. at 32-33.

^{32.} Id. at 28.

^{33.} Id. at 163.

because they had both done an inadequate procedure and deviated from standard surgical custom."³⁴ And many surgeons simply did not want patients, particularly female patients, telling them what to do.³⁵ Some doctors responded indignantly to breast cancer patients who "march[ed] on clinics and private offices waving copies of *McCall's*, *Good Housekeeping*, *Ms.*, *Playgirl*, or the supplement of their local newspaper" and told their doctors how they wished to be treated.³⁶

In the later part of the twentieth century, doctors began dissenting to the hegemony of the radical mastectomy, however. In the 1960s, Dr. Barney Crile, famed surgeon and critic of the radical mastectomy, compiled substantial data on the outcomes of breast cancer patients who received only simple mastectomies.³⁷ The results were positive and painful side effects were reduced.³⁸ Also during the 1960s, Dr. Vera Peters, a Canadian physician, advocated in favor of a "breast conservation therapy," which included a course of radiation, and gathered positive data in support of this approach.³⁹ The perseverance of progressive individuals like these within the medical field was ultimately an important part of medicine's evolution in its treatment of breast cancer.

In addition to physicians such as Crile and Peters, breast cancer survivors also played an important role in effecting change, especially by articulating first-hand their personal experiences with radical mastectomy. Many women spoke out about their discontent with the pain and disfigurement of radical mastectomy, and some urged women to endure the treatment, proudly declaring it as having rid them of cancer. For example, on the pro-radical mastectomy side, Terese Lasser, a prominent New Yorker, received a one-step, radical mastectomy in 1952. Soon after her own surgery, Lasser founded the group Reach to Recovery, which reached out to other women recovering from radical mastectomies, giving them gifts of "falsies" and letters to their husbands "urg[ing] men to make their wives feel sexually desirable."

^{34.} Id.

^{35.} Id. at 164.

^{36.} Id. (citation omitted).

^{37.} Id. at 116-17.

^{38.} *Id.* at 117. According to studies presented by Dr. Barney Crile, 80% of patients who received a simple mastectomy survived for at least three years compared to 75% of patients receiving radical mastectomy, and *none* of the patients that underwent radical mastectomy developed lymphedema of the arm. *Id.*

^{39.} Id. at 132-33.

^{40.} Id. at 143-44.

^{41.} Id.

^{42.} Id. at 142-43.

^{43.} Id. at 143.

But a more common message on either side of the radical mastectomy debate was the sense that women felt silenced and overridden by the current state of breast cancer treatment. Babette Rosmond, breast cancer survivor and author, published *The Invisible Worm* in 1972 about her experience with breast cancer and surgery. Rosmond, who was treated by Dr. Crile, praised her doctor for communicating well with her, which spared her the severe trauma of remaining uninformed. She believed that doctors who decided *for* instead of *with* their patients were masking arrogan[ce], prejudic[e], [and] disinterest[] in human beings with beneficence. The meaning of being left out, rather than failing to be consulted, evoked the majority of disdain from many women; the disrespect and disregard for women that necessarily undergirded a practice such as the one-step procedure rightly drew harsh criticism from breast cancer patients.

The fall of the radical mastectomy 48 as the standard mode of treatment for breast cancer coincided with an era of radical and progressive changes in many aspects of society during the 1970s. Feminist voices, while present throughout history, were more numerous and outspoken than ever. One such feminist critic posed a provocative question regarding radical mastectomies, asking: Should "amputation, mutilation, and maiming and crippling of a woman's body be considered a cure?" Scientific studies began to take the emotional and psychological ramifications of breast cancer and its treatment more seriously. Many cancer memoirs, such as The Invisible Worm, were published during this time, and women's magazines, such as Ms. and McCall's, became lively forums for discussions about breast cancer and its treatment.⁵¹ The need for reformation of the breast cancer patient's role in medical decision-making was made clear by the medical landscape during this time. In the years leading up to the 1980s, breast cancer treatment improved, and physicians became increasingly sensitive to the needs of their female patients.

^{44.} See, e.g., id. at 144-45. Breast cancer survivor T. Lasser, see supra notes 42-43, encouraged women to speak out about breast cancer and their recovery, whether physicians wanted them to or not.

^{45.} Id. at 151-52.

^{46.} Id. at 154.

^{47.} *Id.* (citing Babette Campion, The Invisible Worm (1972)). Babette Campion was the penname of Babette Rosmond.

^{48.} See id. at 223-40.

^{49.} Id. at 9 (quoting Dorothy Shinder, Mayhem on Women 20 (1972)).

^{50.} See id. at 145.

^{51.} See id. at 158-61, 170-71.

Legal reform, however, was not at the helm of this evolution. Instead, it was breast cancer advocates with their growing clout who turned to the law as a tool for further progress, and they had great success in passing informed consent statutes. The question now is: Why didn't the legal reform efforts work for women? This Article argues breast cancer informed consent statutes failed to properly address the lack of communication between breast cancer patients and their doctors. Instead, these laws gummed up the works even further by giving cookiecutter, often lackluster, medical advice to women who wanted, above all, to be listened to and respected as individuals.

II. Informed Consent: Goals & Reality

Informed consent is a judicial doctrine meant to set standards for physician disclosure to patients. Stated in general terms, the doctrine holds that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body" A set of disclosure standards has developed out of informed consent jurisprudence. Specifically, a physician "must inform the patient of the diagnosis or nature of his or her ailment, as well as the general nature of, and the purpose or reason for, the contemplated treatment or procedure . . ." Additionally, and more salient to the statutes at hand, physicians must inform patients of any alternatives to the proposed procedure and the risks and benefits accompanying such alternatives. ⁵⁴

Inaccurate assumptions about the preferences and practices of patients underlie the doctrine of informed consent. Professor Carl Schneider catalogues the assumptions underlying the doctrine of informed consent as follows: (1) patients want to make their own medical decisions, (2) patients want to receive relevant medical information, (3) physicians are willing and able to convey all relevant information to their patients, (4) patients will be able to understand and remember the information given to them, and (5) patients must reason through medical issues well enough to satisfy standards they have for themselves; that is, that patients are able to apply the information supplied. ⁵⁵ Laid out in

^{52.} Canterbury v. Spence, 464 F.2d 772, 780 (D.C. Cir. 1972) (quoting Schloendorff v. Soc'y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914)).

^{53. 70} C.J.S. Physicians, Surgeons, and Other Health-Care Providers § 120 (2006) (internal citations omitted).

^{54.} Koapke v. Herfendal, 660 N.W.2d 206, 212 (N.D. 2003).

^{55.} Carl E. Schneider, After Autonomy, 41 WAKE FOREST L. REV. 411, 417 (2006).

this fashion, expecting all patients to meet these criteria is clearly unreasonable, ⁵⁶ as documented by numerous studies. ⁵⁷

Many years after the doctrine of informed consent became a legal fixture, studies indicate that law still does not understand what goes on between doctors and patients. Studies on patient decision-making have found that the process is often driven by knee-jerk reactions that are backward rationalized, not determined by analytical weighing of hard data. In fact, decisions may have more to do with presentation than information, considering the inherent dependence of patients on doctors. Moreover, the expectation that patients will be able to understand the information presented to them is not a realistic one. Such legislation also costs more time and money.

Thus, the benefits of the common law informed consent regime do not outweigh its costs. Informed consent is not only premised on unrealistic generalizations about patients, but moreover it has negative impacts on both patients and physicians. And, as will be explored in Part III, these laws do not help breast cancer patients make decisions with which they are more satisfied.

III. Informed Consent and the Legislation that Works Against It

As discussed in Part I, informed consent's aspirations and its reality in implementation stand in stark contrast. The breast cancer informed consent statutes are but one example of this phenomenon. It is not sur-

There is no more poignant example of the difficulties involved in legislating and enforcing a moral concept than the doctrine of informed consent When dealing with fundamental epistemological distinctions (such as the difference between appreciation and understanding, competence and voluntariness, bodily integrity and self-determination, decisional authority and autonomy) it is doubtful, in light of the relevant factors in each particular case, whether there can be any clear objective standards.

Karene Boos & Eric J. Boos, At the Intersection of Law and Morality: A Descriptive Sociology of the Effectiveness of Informed Consent Law, 5 J.L. Soc'x 457, 464 (2004).

- 57. Schneider, supra note 55, at 418-25.
- 58. Id. at 417-26.
- 59. Id. at 420-21.
- 60. Boos & Boos, supra note 56, at 466-67.
- 61. Schneider, supra note 55, at 418-25.
- 62. Id. at 436.

^{56.} Authors Karene and Eric Boos layout some of the many intangible values associated with informed consent:

prising that the authoritative tool that law is—a tool devised to organize society according to dominant ideals and mores—is ill suited to improve the intimate and even idiosyncratic realm of the physician-patient relationship. Legal informed consent sets standards for physician disclosure that do not address the needs of patients because no patient is the generic ideal that the law has invented.

This section will first lay out the requirements of these statutes, and explore some of the literature that has come out of them, focusing on state-to-state variations. Next, it will offer some of the relevant sociomedical research that has been done on patients and physicians, contrasting what these studies have found with the content of the statutes. Finally, drawing on the discussion from all parts of the Article, it will conclude with a vision of what women may actually want during the process of choosing a breast cancer treatment, arguing in part that these laws may have a detrimental effect on breast cancer patients who wish to have, and would be satisfied with, mastectomy instead of BCS.

A. Breast Cancer Informed Consent Statutes: Content and State-to-State Variability

Breast cancer informed consent statutes are prevalent throughout the country. Twenty-two states have enacted informed consent legislation regarding breast cancer treatment options.⁶⁵ While the statutes impact a great number of women facing breast cancer treatment, the parameters of this impact will vary greatly depending on the state. The breast cancer informed consent statutes mandate that certain informa-

^{63.} See Scott, supra note 3.

^{64.} See infra Part III.C.

^{65.} Cal. Health & Safety Code § 109277 (2006); Fla. Stat. Ann. §§ 458.324, 459.0125 (2007); Ga. Code Ann. § 43-34-21 (2005); Haw. Rev. Stat. § 671-3 (1993 & Supp. 2006); 20 ILCS 2310/2310-345 (2006); Kan. Stat. Ann. § 65-2836(M) (2002); Ky. Rev. Stat. Ann. § 311.935 (2007); La. Rev. Stat. Ann. §§ 40:1300.151 to .154 (2001); Me. Rev. Stat. Ann. tit. 24, § 2905-A (2000); Md. Ann. Code, Health-Gen. § 20-113 (LexisNexis 2005); Md. Ann. Code., HEALTH OCC. § 14-404 (LexisNexis 2005); Mass. Gen. Laws Ann. Ch. 111 § 70E(h) (2006); Mich. Comp. Laws § 333.17013–17513 (2001); Minn. Stat. § 144.651(9) (2006); Mo. Rev. Stat. § 376.1250 (2007); Mont. Code Ann. § 37-3-333 (2007); N.J. Stat. Ann. §§ 26:2-168, 45:9-22.3a, .3b; N.Y. Pub. Health Law §§ 2404-2409 (McKinney 2002 & Supp. 2007); 35 Pa. Cons. Stat. Ann. §§ 5641-5642 (West 2007); Tex. Health & Safety Code Ann. § 86.001-.005, .011-.012 (Vernon 2001 & Supp. 2006); VA. CODE ANN. § 54.1-2971 (2005), W. Va. Code § 16-33-1 to -12 (LexisNexis 2006). See National Cancer Institute, State Cancer Legislative Database Program, http://www.scld-nci.net/index.cfml (last visited Oct. 26, 2007), for a helpful database, using "Search Database" function.

tion be given to a breast cancer patient who is considering her treatment options. Compliance most often comes in the form of a booklet or pamphlet. Et al. Wariability exists in the content of information, the breadth and depth of information given, the existence of a private cause of action for noncompliance with the statutes, and in the tone of literature with respect to the patient's duty to make a decision for herself.

The statutes have been enacted during the past thirty years, with the first enactment in Massachusetts in 1979.⁶⁷ The bulk of such legislation was passed during the early 1980s,⁶⁸ which is expected given the social climate brought about by the consumer movement.⁶⁹ The majority of the statutes define valid informed consent for breast cancer treatment via regulatory literature, while a minority only address the issue of informed consent without forcing doctors to provide particular documents to their patients.⁷⁰

The various forms of literature that came out of the statutes contain markedly different medical information regarding surgical treatment options. For example, while some statutes emphasize BCS as a viable treatment option, others lack up to date information on BCS.⁷¹ Only five of the summaries state explicitly that BCS may not be a viable option for all patients.⁷² As to information outside of surgical treatments, the writings vary greatly in the amount of detail given to breast reconstruction surgery,⁷³ a topic that may be of great importance to some patients.

Several other aspects to the mandated information vary greatly from state to state. Several statutes provide a private cause of action for physician noncompliance.⁷⁴ For example, both Kansas and Maryland

^{66.} Nayfield, *supra* note 5, at 1203–04. (noting that in twelve states, standardized written information in the form of booklets or brochures is required).

^{67.} Legislative Data Byte: States with Laws Addressing the Disclosure of Breast Cancer Treatment Options and/or Informed Consent (as of June, 30 1999), St. Cancer Legis. Database Update (Nat'l Cancer Inst., Bethestda, Md.), July 1999, at 23, available at http://www.scld-nci.net/updates/pdf/SCLD%20Update799.pdf.

^{68.} *Id.*; Montini II, *supra* note 17, at 9. Twenty-two such statutes were introduced during this decade. *Id.* Fifteen of the sixteen that were passed were enacted between 1979 and 1986. *Id.* at 10 tbl. 1.

^{69.} Montini, *supra* note 9, at 90 (discussing the convergence of the women's movement and consumer movement of the 1970s as an impetus for breast cancer informed consent legislation, and patient challenges to physician authority generally).

^{70.} The Florida statute, for example, allows for either oral communication or a written summary to satisfy its informed consent requirement. Fla. STAT. § 459.0125 (2007).

^{71.} Nayfield, supra note 5, at 1205.

^{72.} Id.

^{73.} Id.

^{74.} Id. at 1204.

provide that a physician who fails to distribute the standardized literature may have his or her license revoked, suspended, or limited as a result. This may add even more stress onto the physician-patient relationship, which is already affected by the specter of legal threats. Thus many characteristics of the statutes and the resulting literature may be counterproductive for patients. The fact of such variations exist is, in itself, a potentially troubling aspect because it means that women in certain states may be getting out-dated or otherwise inferior information.

In addition to the variations, many of the statutes may actually disempower patients. For example, some of the literature dictates "mandatory autonomy" for the patient. This is the message that a patient must, not should, make the treatment decision independently. Hawaii's brochure, which came out if its breast cancer informed consent statute, states that breast cancer patients "must be well-informed and involved in the decision-making," telling patients: "[i]t is your body and you have the most to gain or lose by how it is treated," which may be a directive not well-received by all patients because not all patients want to feel in charge of their own course of treatment. A more direct example of the disempowering nature of the statutes are provisions that limit future actions against physicians. Michigan and Maine ban patients from bringing civil informed consent suits against their doctors once they have indicated receipt of the breast cancer treatment literature. So, in both subtle and obvious ways, many of these laws are crafted in such a way that patients may lose more than they gain by their existence.

B. The Modern Landscape of Breast Cancer & Informed Consent

These statutes attempt to ameliorate a problem invented by the law—that is, a shortage of facts leading to overuse of mastectomy—with a solution that corresponds to the legal invention. The purported goal of informed consent is to help *individual* patients make more self-satisfying decisions. These informed consent statutes have not had a significant effect on patients' treatment choices. ⁸¹ Part III.B will focus on research

Kan. Stat. Ann. § 65-2836 (2002); Md. Code Ann., Health Occ. § 14-404 (LexisNexis 2005).

^{76.} Schneider, supra note 2, at 31.

^{77.} Schneider, supra note 55, at 413

^{78.} Nayfield, supra note 5, at *3.

^{79.} Schneider, supra note 2, at 114-15.

^{80.} Mich. Comp. Laws § 333.17513 (2001); Me. Rev. Stat. Ann. tit. 24, § 2905-A (2000).

^{81.} Nattinger, supra note 6, at 5430.

on patients and physicians in light of the nature of these statutes, arguing that these laws do not promote, and indeed may impede, treatment decisions that are satisfying for patients because the laws are divorced from reality.⁸²

Paradoxically, by creating an informed consent "plus" standard for breast cancer patients, these statutes push past the goal of the right decision for the individual and toward a pre-conceived "right" answer, period. These statutes are responsible for patient reference documents that are stuck in a moment in history; this array of literature is not only questionable in its variability, but moreover because it does not—and cannot—adjust with the ever-changing socio-medico climate.

Although most conscientious physicians are certainly concerned about communication problems with patients, if for no other reason than the potential legal liability of such deficiencies, physicians are not necessarily optimistic about prescriptive legal attempts to intervene in their patient relationships. Physician authors have noted "[t]hese [breast cancer] laws are of particular interest to medical practice because they prescriptively mandate physician behavior within the patient-physician relationship and potentially define the medical information upon which treatment decisions are based."83 Thus, while physicians may be well aware of still-existing problems in communicating with their patients, they are understandably wary of the law's ability to improve things by usurping the doctor's role at its most critical moment: cancer diagnosis and treatment. This attitude may partially represent a vestige of medical paternalism, but to write it off as nothing more than paternalism would be foolish. After all, doctors are experts on medical issues. Therefore, when an unrelated institution such as law comes in with medical information, it is troublesome from a common sense perspective.⁸⁴

Whatever its faults, the medical system does not make a practice of implementing a procedure without first studying its effects on patients. Several medical doctors published a paper reviewing the content of the then eighteen breast cancer informed consent statutes, looking at the

^{82.} See Schneider, supra note 2, at xv. Prof. Schneider calls this phenomenon "hyperrationalism," which he defines as "essentially the substitution of reason for information and analysis." Id.

^{83.} Nayfield, supra note 5, at 1202.

^{84.} It is interesting and relevant to note that the ABA Model Rules of Professional Responsibility do not require *lawyers* to inform their clients of technical legal details in order to obtain proper informed consent. The rules state that a lawyer must give the client "sufficient information to participate intelligently in decisions concerning the objectives of the representation and the means by which they are to be pursued," but a lawyer need not "ordinarily . . . be expected to describe trial or negotiation strategy in detail." Model Rules of Prof'l Conduct R. 1.4 cmt. 5 (2007).

informational content required by each, and what each requires of physicians. They wrote that "[t]hese statutes represent an unusual policy response in that they address the patient-physician relationship in the context of a particular disease [whose] impact on the process and outcomes of breast cancer care [had] not been undertaken" at the time of enactment." That is, doctors criticized the laws for interceding in the medical realm without first gathering empirical evidence that such actions would be good for patients.

Though chauvinistic attitudes and unequal, disrespectful treatment of breast cancer patients by doctors has been well documented, ⁸⁷ it is misleading and unhelpful to conflate the past with the present. As discussed in Part II, physicians' statements during the era of the radical mastectomy demonstrate their vast misunderstanding of the role of gender in breast cancer treatment. Professor Theresa Montini, a scholar of women's health policy issues, compiled research on the public debate surrounding breast cancer informed consent statutes in the 1980s. ⁸⁸ Montini asserts that physicians opposed the legislation because it would impede their decisional authority, and that their means of attacking the utility of the statutes centered around the medical consensus that the "hyper-emotionality" of women contaminated the breast cancer treatment decision-making process. ⁸⁹ While this criticism should not be ignored, it is important to distinguish popular medical opinion from the 1970s with opinions more prevalent today, which have changed radically in the past several decades. ⁹⁰

Physician attitudes have changed drastically in the past decade. Surgeons were criticized for their slow adoption of BCS in favor of mastectomy in the past. Breast cancer patients who advocated for breast cancer informed consent legislation in the 1970s criticized surgeons for railroading them into having mastectomies and not fully informing them of less invasive BCS. Py contrast, a 2005 study of breast cancer treatment outcomes found, through patient interviews, that when patients reported that they did perceive their surgeon's recommendation of BCS over mastectomy, they more often interpreted the surgeon to be

^{85.} Nayfield, supra note 5, at 1202.

^{86.} Id. at 1207.

^{87.} See, e.g., Montini, supra note 17, at 9, 19.

^{88.} Montini, supra note 17, at 9.

^{89.} Id. at 19.

^{90.} See Schneider, supra note 2, at 4-5 (summarizing several recent studies that demonstrate the changes in doctors' attitudes toward patient autonomy).

^{91.} Nattinger, supra note 6, at 5429.

^{92.} Montini, supra note 17, at 13-16.

endorsing BCS.⁹³ Female surgeons in particular are less likely than male surgeons to believe that BCS is related to a better quality of life prognosis than mastectomy according to the same study.⁹⁴ This view is consistent with the results from multiple studies that have measured quality of life after BCS versus mastectomy.⁹⁵

This is not to say that physician-patient communication about breast cancer treatment has no room for improvement. But an imperfect communication process is not ground for such specific legal measures like the informed consent statutes, especially where the legal prescription is based on assumptions about women and breast cancer instead of research on what exactly is failing between doctors and their breast cancer patients.

In fact, it is now patients, not surgeons, who are responsible for mastectomy's continued popularity. The 2005 Katz study found that "[g]reater patient involvement in [breast cancer patient] decision-making was associated with greater use of mastectomy rather than greater use of BCS." These findings are contrary to the general assumption that surgeons are holding back the popularity of BCS—the general assumption that breast cancer informed consent statutes are based on. Take former anchorwoman Rene Syler. After being diagnosed with atypical ductal hyperplasia, and being informed that this condition would significantly increase her chances of getting breast cancer, she eventually decided to get a prophylactic double mastectomy in order to alleviate her fears over getting cancer in the future. Her decision was influenced by the fear she felt, caused not only by the diagnosis but also by both her mother and father's bouts with breast cancer. In the end, she was satisfied. Syler's story goes to the law's misunderstanding of breast cancer patient decision-making, suggesting at best that the literature does not affect the decision-making of breast cancer patients, and at worst that the literature is pushing a view on women who, as individuals, are inclined to choose mastectomy.

While all wrongs have not yet been righted, the favorable trend that has brought about a physician-patient relationship marked by far better communication, and much greater respect for individual dignity and

^{93.} Nattinger, supra note 6, at 5429.

^{94.} Steven J. Katz et al., Surgeon Perspectives about Local Therapy for Breast Carcinoma, 104 CANCER 1854, 1858 (2005).

^{95.} Id. at 1858-59.

^{96.} Nattinger, supra note 6, at 5429 (citing Katz et al., supra note 94, at 5526)

^{97.} Rene Syler, Defending My Life, O, Oprah Mag., April 2007, at 149, 149-150.

^{98.} Id.

^{99.} Id. at 150-51.

^{100.} Id. at 152.

preference should be studied and emulated. Though many statements made by physicians in response to the passage of breast cancer informed consent statutes are appalling, their shock value does not mean that they should dictate *today's* policy making. To ignore the significant positive changes that have occurred is detrimental for all patients. There is no sense in creating informed consent statutes rooted in bygone nightmares about authority-hungry physicians. As Carl Schneider writes about the failure of informed consent in general: "If the past worshiped false gods and the present's gods have failed, where do we turn? Perhaps we need a skeptical reconsideration of informed consent."

The usefulness of the statutes may be largely outmoded due to positive evolutions in both gender equality and in the physician-patient relationship. A 2005 study of breast cancer patients found that most patients, from a sample of women diagnosed in 2002, were satisfied with both their ultimate treatment choice and the decision-making process. ¹⁰² While the authors of this study did not speculate as to why, in general, the rates were so positive, it may be largely a factor of time. As discussed in Part II of this Article, breast cancer's history during the twentieth century was dynamic, marked with greater patient participation and increased awareness and sensitivity on the part of the medical profession. This trend seems to be continuing into the twenty-first century.

Though physician-patient interactions have improved dramatically during the time that many of the statutes have been on the books, these statutes are not a driving force for this change. Studies found that women living in states with legislation mandating that breast cancer patients receive information on treatment options were, nonetheless, "not fully aware of important differences between the procedures." Literature in the form of pamphlets, brochures, and the like has been of very questionable efficacy or utility. 104

In fact, the very premise of breast cancer informed consent statutes is not justified by research on actual breast cancer patients. The idea that informed breast cancer patients will choose BCS over mastectomy is

^{101.} Schneider, supra note 4, at 91.

^{102.} Lantz et. al., supra note 7, at 745.

^{103.} Steven J. Katz, Paula M. Lantz & Judith K. Zemencuk, Correlates of Surgical Treatment Type for Women with Noninvasive and Invasive Breast Cancer, 10 J. Women's Health & Gender-Based Med. 659, 667 (2001).

^{104.} Nayfield, *supra* note 5, at 1207. In a study of important sources of medical information to women, "[i]mportant sources of information . . . were predominately 'people' sources" while "[c]linic handouts were rated among the three most important sources by only 36% of patients." *Id*.

wrong. Fear of recurrence, concerns about the side effects of radiation therapy, and anecdotal reasoning are among the factors that may lead a woman to ultimately choose mastectomy over BCS. Concerns about physical appearance, or, perhaps, the belief that the removal of a breast equates to sacrificing a fulfilling physical appearance are less significant to breast cancer treatment decision-making than lawmakers seem to have assumed. The current paradigm of informed consent in the law, which is exemplified by the breast cancer informed consent statutes, does not sufficiently account for these female-centered decision-making factors.

While the National Institute of Health (NIH) Consensus Development Conference issued a statement in 1990 coming out in favor of BCS over mastectomy, it has not been shown that BCS results in superior psychosocial outcomes for breast cancer patients. What has been found, on the other hand, is that as a patient's level of involvement in decision-making increased, her chance of choosing mastectomy increased. Or, stated conversely, a more involved patient is significantly less likely to elect BCS.

There are salient differences among women that this cookie-cutter legislation does not address as well. For example, women who elected to have a mastectomy were less likely to report concerns about body image as important factors in their surgical treatment decision. Also, ethnic minorities and women with low incomes were more likely to have low satisfaction with the decision-making process. The problems that remain in the physician-patient relationship with respect to breast cancer treatment are simply not going to be alleviated by a pamphlet.

^{105.} Nattinger, supra note 6, at 5430.

^{106.} Id.

^{107.} Id.

^{108.} Ann B. Nattinger et al., Effect of Nancy Reagan's Mastectomy on Choice of Surgery for Breast Cancer by U.S. Women, 279 J. Am. Med. Ass'n 762 (1998).

^{109.} Katz, supra note 103, at 665.

^{110.} Nayfield, *supra* note 5, at 1205 (citing Nat'l Insts. Health Consensus Dev. Conference Statement, Treatment of Early-Stage Breast Cancer Consensus Statement (July 21, 1990) (on file with author)).

^{111.} Lantz et. al., supra note 14, at 753.

^{112.} Id.

^{113.} Id. at 761.

^{114.} Id. at 760.

C. Medical Decision-Making & Breast Cancer Patients

There are problems that need solutions when it comes to women and medicine. But these solutions need to be conceived of as concerns for women, not merely a bait and switch wherein patriarchal laws purport to fix undue paternalism in medicine. There is still work to be done, and with medical technology always advancing, so too must patient awareness advance. What issues should be given greater consideration for breast cancer patients facing treatment options?

Breast cancer is a socially, historically, and medically complex disease. The breast itself is not merely an anatomical structure. It is a rich and often contradictory symbol. It represents motherhood and nourishment, as well as eroticism and sexuality. Accordingly, cancer of the breast, and its meanings for those afflicted and for society at large, is complicated as well. Breast cancer invokes the fear of disfigurement, the social construct of the female body, and the importance of a female sexual organ, among many other issues. This does not make breast cancer patients a unique group insofar as how they make decisions—no group generalizations can be made in medical decision-making, and this is the root of these laws' failure. However, that is not to say that breast cancer patients are not affected by factors specific to the disease.

Involving patients in the decision-making process is not a clear-cut way to ensure a satisfied patient; patients prefer to be involved in different ways and to differing degrees. Women who were satisfied with their involvement in breast cancer treatment decision-making did not necessarily participate to the fullest extent possible; what was more important for patient satisfaction was that a patient participated to the degree she preferred. Patients whose decision involvement preference—that is, a preference of high involvement versus a preference to have one's surgeon dominate the decision-making—matched what occurred were much more likely to report satisfaction regarding the treatment decision-making process than others. Dissatisfaction resulted not only from a lack of decision-making power, but also from being forced to take a more active role in deciding on a treatment.

^{115.} Paula M. Lantz & Karen M. Booth, *The Social Construction of the Epidemic of Breast Cancer*, 46 Soc. Sci. Med. 907, 910-11 (1998).

^{116.} See Lerner, supra note 5, at 194 (saying that there existed "more than one feminism," discussing how breast cancer exemplified the varying values among women).

^{117.} Lantz et. al., *supra* note 14, at 762 (finding that of the women sampled who reported negative satisfaction outcome, about 30% reported that they had more participation in deciding on a treatment than they wanted).

^{118.} Id.

Research shows that a patient's decision to undergo mastectomy instead of BCS will be influenced by the preference for action when facing cancer. Cancer patients as a non-gender-specific group have been studied in terms of their decision-making process. Fagerlin and others conducted a study in which they "assessed the proportion of people who would choose nonoptimal treatments . . . when presented with hypothetical scenarios describing the need to cure already existent cancers." They reported that respondents' "desire to take action was even stronger when the hypothetical treatment described was a surgical intervention," as opposed to watchful waiting, in spite of the fact that such surgical options actually increase mortality rate and lead to earlier mortality as well. The study found that "[t]o some people, this early mortality was preferable to a slower death from cancer."

These statutes are a shining example of law's disconnect with the reality of breast cancer patients. Moreover, these laws fly in the face of the purported goals of informed consent by actually assuming that meaningful decision-making means making a decision in a manner which is inconsistent with how cancer patients, and women in particular, actually make decisions. These laws presume that "good" decision-making in the breast cancer context will manifest by more women choosing BCS, or lumpectomy. This goal is clearly problematic: it is based on wrong-headed assumptions about women's preferences, outdated surgeon views on BCS and mastectomy, and statutory means that have nothing to do with the sources of communication problems between patients and physicians.

When it comes to improving physician-patient relationships in the realm of breast cancer treatment, we need to go back to basics. What are women unhappy about? They are not crying out to in effect become their own doctors, weighing all available data and then telling their doctors what to do. What they want is to be listened to, communicated with, and above all respected. These wants are not unique to women, but are certainly complicated and often amplified because of gender roles.

Can the law accomplish what needs to be done for patients and physicians? Perhaps not, at least not directly. Legal reform could be used to encourage the type of grass-roots movements that got women talking to each other about breast cancer during the era of the radical mastec-

^{119.} Angela Fagerlin, Brian J. Zikmund-Fisher & Peter A. Ubel, Cure Me Even If It Kills Me: Preferences for Invasive Cancer Treatment, 25 Med. Decision Making 614, 615 (2005).

^{120.} Id. at 618.

^{121.} Id.

tomy¹²² through funding or public education. Governmental organizations such as the National Institute of Health could encourage research on patient decision-making, the likes of which have been cited herein. Patient activism and evolution in medicine work, whereas laws like these do not. And if the efforts of these breast cancer informed consent statutes are fruitless, then the costs and energies that go into them should stop being wasted.

Conclusion

Informed consent statutes may have been advocated for by breast cancer patients, but they do not conform to women's needs. Recall that Montini's interview with breast cancer advocates who were involved in lobbying for such legislation in the early 1980s reported that their dissatisfaction stemmed from an emotional disconnect from doctors, 123 not from a lack of available statistics, or a hard copy of the relevant topics to consider.

There are gender-specific issues in the medical realm that have driven patient rights reformers to push for legal changes aimed at women. Physicians still invoke gender stereotypes with female patients, which in turn adversely affects the relationship. ¹²⁴ On average, women have been found to have worse relationships with their doctors than men. ¹²⁵ Medicine has been slow to abandon its male-centered paradigm. For example, until the 1990s, the Federal Drug Administration mandated that females be precluded from participation in clinical trials for prescription drugs. ¹²⁶ The NIH did not adopt guidelines requiring the inclusion of women in research until the 1990s. ¹²⁷ While the need for change was clear, these laws do not help breast cancer patients.

The statutes are not justifiable under informed consent's original goals. Though appealing in theory, informed consent is often ineffective and at times counterproductive in actual medical settings. We ought to

^{122.} See supra Part I for a detailed discussion of the role of breast cancer survivors in the debate surrounding the radical mastectomy.

^{123.} Montini, *supra* note 17, at 13-14.

^{124.} Lisa Napoli, The Doctrine of Informed Consent and Women: The Achievment of Equal Value and Equal Exercise on Autonomy, 4 Am. U. J. Gender Soc. Pol'y & Law 335, 336–7 (1996); see also Nancy K. Kubasek, Legislative Approaches to Reducing the Hegemony of the Priestly Model of Medicine, 4 Mich. J. Gender & L. 375 (1997) ("[T]he legal culture . . . undergirds the priestly [model of medicine's] hegemony over the therapeutic relationship between a woman and her doctor.")

^{125.} Napoli, supra note 124, at 336.

^{126.} MacDougall, supra note 22, at 809-10.

^{127.} Id.

be concerned about this legislation in terms of its ministerial costs, increased strain on the physician-patient relationship, and lack of efficacy in terms of decision-making habits of breast cancer patients. While laws embody the moral will of a society, laws driven by baseless assumptions about women's decision-making are not furthering society's goals. These laws ought not be pursued, certainly not in the name of informed consent.

If what we want is to help women make a decision that they are content with when faced with breast cancer, then we must abandon these statutes. Trading one paternalism for another will not help matters; especially not a paternalism that disregards scientific data about decision-making and exists outside the realm of medical treatment. Improving the physician-patient relationship is an important societal goal, but legally required pamphlets and the like are not helping women or doctors toward this end. \$\frac{1}{2}\$