REPORT OF THE
JOINT SUBCOMMITTEE STUDYING

The Informed Consent for Treatment of Breast Cancer

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

Senate Document No. 23

COMMONWEALTH OF VIRGINIA
RICHMOND
1984

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Report of the Joint Subcommittee
Studying the Informed Consent for

Treatment of Breast Cancer
To
The Governor and the General Assembly of Virginia
Richmond, Virginia
February, 1984

To: Honorable Charles S. Robb, Governor of Virginia
and

The General Assembly of Virginia

Origin of the Study

The Joint Subcommittee Studying the Informed Consent for Treatment of Breast Cancer was authorized to conduct its study by Senate Joint Resolution No. 41 agreed to during the 1983 Session of the General Assembly. The resolution may be found in Appendix A of this report.

Senate Joint Resolution No. 41 of 1983 requested that the Joint Subcommittee examine the issue to determine:

1. If the Commowealth should codify informed consent and, if so, what standards should be established;

2. Feasible ways to communicate, to women and physicians, valid information on the treatment available for breast cancer; and

3. Whether unnecessary operations are being performed in the Commonwealth and the means to prevent such operations if they are being performed.

Appointed to serve on the Joint Subcommittee were Senators John C. Buchanan of Wise, Richard L. Saslaw of Annandale, and Edward E. Willey of Richmond, Chairman; Delegates John C. Brown of Bristol, Bernard S. Cohen of Alexandria, Vice-Chairman, Benjamin J. Lambert, III, of Richmond, Phoebe M. Orebaugh of Broadway, and Julie L. Smith of Virginia Beach. Citizen members appointed to the Joint Subcommittee were Robert L. Adeson, M.D., of Falls Church, Tapan Aditya Hazra, M.D., of Richmond, Elise Brookfield Heinz of Arlington and Anita A. Rimler of Richmond.

Legislative History of the Study

During the 1982 Session of the General Assembly, Delegate Edythe C. Harrison introduced House Bill No. 406, relating to informed consent for treatment of breast cancer. The original version of the bill was amended by the House Committee on Health, Welfare and Institutions and reported out of committee. This version of the bill was passed by the House, communicated to the Senate and referred to the Senate Committee on Education and Health. The Senate Committee on Education and Health heard considerable testimony on the bill, most of which was favorable. The Chairman appointed a subcommittee to consider the bill and delayed the vote until the subcommittee's recommendations could be received. A third version of the bill was developed and presented in typewritten form to the Committee, but was never officially introduced as a substitute (see attached copies of the three versions of the bill in Appendix A). The House version of H.B. 406 was passed by indefinitely by the Senate Committee during the final hours of its deliberations.

During the meeting in which the bill was PBI'd, a commitment was made to the Committee by the medical community to work with the Cancer Society in designing a brochure to educate

women about the available alternative treatments for breast cancer. This brochure has been developed and printed and is now available to women in Virginia .

Although this pamphlet has assisted in assuaging the fears of some women about treatment for breast cancer, many women in Virginia remain concerned about this issue. In response to these concerns, Senate Joint Resolution No. 41, which was introduced by Senator Richard L. Saslaw, was passed by the General Assembly establishing this study.

The Virginia Standard for Informed Consent

A patient's right to disclosure of the risks of adverse effects from a proposed treatment or procedure is recognized in Virginia; however, a physician's failure to provide this information does not constitute negligence per se. In other words, the lack of disclosure will not by itself provide proof of negligence, Bly v. Rhoads , 222 S.E.2d 783 (1976); Cunningham v. U.S. , 683 F.2d 847 (1982).

The patient can establish through his testimony that the risks were not disclosed to him, that he did not know of the risks and, to a limited degree, that the consequences were adverse. In order to determine negligence or the lack of it, however, expert medical testimony must be presented to establish the "existence and extent of the duty in his particular case by a preponderance of evidence." 222 S.E.2d at 786. The cases in Virginia clearly establish "a general duty to warn" (Id .), but the breadth of the information which the physician has a duty to provide can only be proven through testimony by another physician concerning the "disclosures which a reasonable medical practitioner would make under the same or similar circumstances...." Dietz v. King , 184 F.Supp. 944 (1960).

A physician in Virginia is held to a statewide standard of practice unless the court finds that the standard of practice in the "same or similar" community is more appropriate (see § 8.01-581.20 of the Code of Virginia). Prior to the enactment of the statute providing a statewide standard, the rule was that the expert had to testify to the standard for reasonable practice in the "same or similar" community. This meant that if the expert witness was from another locality, he had to be familiar with the standards of practice in the community in which the alleged negligence took place. Because this community standard is so familiar to the judges and the statute provides them with the option to use it, it appears that it is still often applied.

If the patient can prove "that prevailing medical practice requires disclosure of certain information" (222 S.E.2d at 788), then he must still convince the court that he would not have consented to the procedure if he had been informed of the possible consequences, 683 F.2d at 849. It should be noted that this question must be answered in its relationship to the circumstances as they existed before the procedure was performed. No hind sight! The question is would "a reasonable man in the patient's position... have consented to the treatment, even if informed of possible adverse consequences." 683 F.2d at 849.

Although the Virginia standard for informed consent is a stringent one, it appears to be the majority view (see Appendix A for diagram of Virginia's common law test). Informed consent is presently and will probably continue to be a matter of great concern to both physicians and patients in Virginia. Physicians and patients alike should bear in mind that many factors other than the common law standard influence the quality and extent of the disclosure which must be accorded the patient. For example, the Accreditation Manual for Hospitals (1983 edition, page XIV) provides that "The patient has the right to obtain from the practitioner responsible for coordinating his care, complete and current information concerning his diagnosis (to the degree known), treatment, and any known prognosis. This information should be communicated in terms the patient can reasonably be expected to understand. When it is not medically advisable to give such information to the patient, the information should be made available to a legally authorized individual." This requirement, hospital bylaws and professional ethics have profound effects on the amount of information that a physician should or must disclose.

Informed Consent and Patients' Rights Laws in Other States

The doctrine of informed consent is a common law concept, i.e., one created by judges presiding over malpractice suits. In fact, the concept of informed consent is said to have first been stated in 1914 by Justice Cardozo: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body...." (Schloendorff v. Society of New York Hospital , 105 N.E. 92, 93 (N.Y. 1914). The doctrine of informed consent can be defined as the requirement that physicians explain the alternatives to and the possible consequences of a proposed treatment or procedure to their patients, Bly v. Rhoads , 222 S.E.2d 783, 785 (1976). The standards by which this judicial doctrine is applied vary from state to state and possibly even from jurisdiction to jurisdiction within a given state.

In approximately twenty-two states, informed consent has been codified. Most of these statutes can be described as "patients' rights laws." However, the structure of these laws varies widely. For example, the Ohio statute requires a comprehensive disclosure of the facts as follows: "the nature and purpose of the procedure or procedures, and what the procedures are expected to accomplish, together with the reasonably known risks, and, except in emergency situations,... the names of the physicians who shall perform the intended surgical procedures." (Ohio Rev. Code Ann. § 2317.54 (1975, amended 1977). On the other hand, the Texas statute established a panel which has developed a list of procedures requiring disclosure and procedures not requiring disclosure. It is profoundly disturbing to note that among the procedures placed on list B (not requiring disclosure) is diagnostic or therapeutic dilation and curettage of the uterus. Richard, E.P. and K.C. Rathbun, "A Procrustean Approach to Informed Consent: The Texas Medical Disclosure Panel" Law, Medicine & Health Care , Vol. 10, No. 4, Sept. 1982 at p. 160). Currently the efficacy of the D & C procedure is the subject of some controversy among medical experts.

In the last two years, Massachusetts, California (see Appendix B for the California statute) and Wisconsin have enacted laws requiring informed consent specifically for breast cancer treatment (these states are listed in the order in which the laws were enacted). Hawaii also requires that alternative treatment information be provided to breast cancer patients.

Most of the informed consent laws, whether general patients' rights laws or specific disclosure laws for breast cancer treatment, are less than ten years old; therefore, their effects are difficult to evaluate. Some experts believe "...anything that increases the scrutiny of a provider's treatment of a patient will increase the probability that a negligent act will be detected." Id. at 162. Some evidence may be accumulating which appears to refute this opinion. Whatever the results of the new wave of controversy surrounding informed consent, it appears that many legal experts will be monitoring the frequency and issues of medical malpractice suits in these states.

It must be stressed that the purpose of enacting an informed consent statute may not be to protect the patient or promote self-determination, but to protect the provider from liability (e.g., the Texas statute). In any event, these laws have not changed the fact that "the basic conflict over whose judgment is to be respected" rests at the center of the controversy over informed consent. Katz, J. "Informed Consent: A Fairy Tale: Law's Vision," University of Pittsburgh Law Review , 39: 173.

Scope of the Joint Subcommittee's Work

The first meeting was called to order by the Deputy Clerk of the Senate, Robert F. Doutt. Elections of the Chairman and Vice-Chairman were held, with Senator Edward E. Willey named as Chairman and Delegate Bernard S. Cohen as Vice-Chairman.

The Joint Subcommittee adopted the following objectives to accomplish its goals:

a. hear testimony from women, physicians and others; and

b. examine the laws of selected other states.

To satisfy these objectives, the Joint Subcommittee held a public hearing in September and directed staff to survey the laws of other states and prepare a summary of this material.

The public hearing was held on September 26, 1983, at 1:30 p.m. in Senate Room B. The Joint Subcommittee heard testimony from a number of women and representatives of women's groups concerning their experiences with surgery of the breast, particularly radical mastectomy. These speakers expressed their belief in the need for the patient to participate in the treatment decision. Most of them felt that use of the one-step procedure (biopsy and surgery performed at the same time) was no longer justified and stated the need for an adjustment period between the time of diagnosis and the treatment decision. These speakers also noted that patients should be given information about alternative treatments. It was stated that women who participate in their treatment decision do not experience as much trauma as those who do not.

Several speakers representing the medical profession commented that current common law covers informed consent and a legislative solution was not necessary. These speakers favored education of women and physicians and continued cooperation with the American Cancer Society. It was also stated that the one-step procedure is rarely performed in Virginia and that there are cases for which the one-step procedure is still appropriate. There is nothing wrong with the one-step procedure, it was stated, if it is properly explained to the patient or if the patient has specified a desire for a one-step procedure. Legislation, these speakers felt, could not accommodate the vast changes occurring in medicine.

Twenty-two state's laws on informed consent were reviewed for the Subcommittee. Elements which were frequently present in these laws were that:

1. The patient must prove by preponderance of the evidence that information customarily given was not provided;

2. Informed consent is not required for emergency treatment;

3. The standard of physician conduct is set out as "same or similar community";

4. Written consent raises the presumption of sufficiency of the information;

5. If a reasonable person would understand risks, etc., then information is sufficient;

6. The burden of proof is on the patient/plaintiff; and

7. Certain defenses are accepted, i.e., if the risks are commonly known, if actual knowledge existed, if treatment would have been accepted regardless of the risks, if the patient did not wish to be informed or if complete disclosure would have caused adverse effects (see Appendix B for summaries of state laws).

Conclusions and Recommendations

The Joint Subcommittee engaged in a lengthy discussion of the pros and cons of legislation related to informed consent. Some of the points made were that:

1. Women appeared to be unanimously in favor of legislation on informed consent for breast cancer treatment;

2. There was no desire to tell the medical profession through legislation how to conduct their practice;

3. People seemed to be saying the common law does not work;

4. Alternatives to surgery were available and do work well for many women;

5. Patients frequently view the process by which informed consent is obtained as merely a legal maneuver to provide doctors with legal protection; and

6. Two approaches could be taken to this problem, i.e., a statutory requirement making it illegal to perform the one-step procedure unless the patient waived the right to the two-step procedure in writing or a provision setting forth a specific consent form for breast cancer treatment.

The members of the Joint Subcommittee were requested by the Chairman, Senator Edward E. Willey, to submit their thoughts on legislation for informed consent for breast cancer treatment to staff by December 1, 1983 (see Appendix C for these comments).

Staff was directed to draft alternatives for the December meeting (see Appendix D for these drafts). The Joint Subcommittee discussed these alternatives at the meeting held on December 13, 1983, and a majority of the members approved the concept of a specific consent form for breast cancer treatment. Staff was directed to work with the Virginia Medical Society, the Attorney General's Office, the Cancer Society, women's groups and others to develop a draft acceptable to all. Senate Bill number 350 (see Appendix D) was the result of this coordination and represents the recommendation of the Joint Subcommittee. This bill sets out three options for the patient:

1. to consent to biopsy only (option (a); or

2. to consent to such operations or procedures, including breast removal, which are deemed necessary (option (b); or

3. to consent to biopsy and such operations or procedures, including breast removal, which are deemed necessary (option (a) and option (b)).

Respectfully submitted,

Edward E. Willey, Chairman

Bernard S. Cohen, Vice-Chairman

John C. Buchanan

Richard L. Saslaw

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APPENDIX A

SENATE JOINT RESOLUTION NO. 41

Requesting the Senate Committee on Education and Health and the House Committee on Health, Welfare and Institutions to establish a joint subcommittee to study informed consent for treatment of breast cancer.

Agreed to by the Senate, February 7, 1983
Agreed to by the House of Delegates, February 24, 1983

WHEREAS, the fear of breast cancer and the dread of possible disfigurement as a result of treatment for it are common to all women; and

WHEREAS, recent medical developments have rendered it unnecessary for many women with breast cancer to undergo the drastic operation commonly known as radical mastectomy; and

WHEREAS, some physicians are not aware of these developments or conversant with these methods of treatment for breast cancer; and

WHEREAS, the physician has the ultimate responsibility for choosing a treatment which is tailored for the individual patient under the circumstances; and

WHEREAS, disfigurement through operations has occurred with many women who have had breast cancer; and

WHEREAS, it is alleged that physicians frequently do not communicate to women with breast cancer the diagnosis, the description and purpose of the treatment proposed, the probability of success of the treatment, the risks involved in the treatment, feasible alternative treatments available and the possible consequences if the woman refuses the treatment; and

WHEREAS, the right of a patient to grant prior consent to a medical procedure has long been recognized in the common law; and

WHEREAS, the most important element of valid informed consent to any medical treatment is the communication by the physician of adequate information to enable the patient to make a truly voluntary and knowledgeable decision; and

WHEREAS, many jurisdictions have codified the common law right to informed consent; and

WHEREAS, the theoretical legal foundation for a lack of consent suit has shifted in many jurisdictions from the earlier theory of battery to a theory predicated on the physician's negligent failure to comply with acceptable standards of practice, if the physician's failure has proximately caused injury to the patient; and

WHEREAS, the most accepted standard of lack of consent suits is the "reasonable physician" standard, under which test, the sufficiency of the physician's disclosure is determined by comparing it with the scope of information that would have been disclosed to the patient under similar circumstances by a reasonable physician; and

WHEREAS, full disclosure, i.e., provision of all known information regarding the treatment proposed and alternatives, provides the best defense for a physician against a lack of informed consent claim; and

WHEREAS, although no jurisdiction has adopted a standard of full disclosure, rapid medical developments and sophisticated technology have created a situation in which the patient is vulnerable to inappropriate treatment without an unambiguous communication of the known facts; now, therefore, be it

RESOLVED by the Senate, the House of Delegates concurring, That the Senate Committee on Education and Health and the House Committee on Health, Welfare and Institutions are hereby requested to establish a joint subcommittee to study informed consent for breast cancer. The subcommittee shall examine the issue to determine:

1. If the Commonwealth should codify informed consent and, if so, what standards should be established;

2. Feasible ways to communicate, to women and physicians, valid information on the treatment available for breast cancer; and

3. Whether unnecessary operations are being performed in the Commonwealth and the means to prevent such operations if they are being performed.

The joint subcommittee shall consist of twelve members, three to be appointed from the membership of the Senate Committee on Education and Health by the Senate Committee on Privileges and Elections and five to appointed from the membership of the House Committee on Health, Welfare and Institutions by the Chairman thereof. Four members, two of whom shall be licensed physicians and two of whom shall be concerned citizens, shall be appointed by the Governor.

The joint subcommittee shall complete its work in time to submit recommendations to the 1984 Session of the General Assembly.

1982 REGULAR SESSION

LD1025480

HOUSE BILL NO. 406

Offered January 27, 1982

A BILL to amend the Code of Virginia by adding a section numbered 54-325.2:2, relating to informed consent for treatment of breast cancer.

Patrons–Harrison, Robinson, Dillard, Marshall, Van Landingham, Van Yahres, Keating, Watts, Heilig, Munford, Jennings, Terry, Washington, Cody, Callahan, Joannou, Wilson, Wilkins, Brickley, and Marks

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Referred to the Committee on Health, Welfare and Institutions

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Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 54-325.2:2 as follows:

§ 54-325.2:2. Informed consent for treatment of breast cancer.—A. Upon making a diagnosis of breast cancer, the physician shall provide the patient with complete and current information concerning the diagnosis and prognosis in terms the patient can be reasonably expected to understand. Prior to initiation of treatment, a full, reasonable, and comprehensible medical explanation as to the meaning, consequences and risks of the proposed course of treatment, as well as all alternative methods of treatment, shall be given by the physician to the patient. This information shall be given by the physician to the patient in order for her to participate actively in the choice of treatment, to make an informed consent to the treatment proposed, or to refuse the proposed course of treatment and request one of the alternative methods.

B. If the physician believes in good faith that it is not medically advisable to give the information required in subsection A of this section to the patient or to expect her to participate in the choice of her treatment, the physician shall make a full, reasonable, and comprehesible medical explanation as to the meaning, consequences and risks of the proposed course of treatment, as well as all alternative methods of treatment, to an appropriate person on behalf of the patient.

Official Use By Clerks	
Passed By The House of Delegates	**Passed By The Senate**
without amendment ☐	without amendment ☐
with amendment ☐	with amendment ☐
substitute ☐	substitute ☐
substitute w/amdt ☐	substitute w/amdt ☐
Date: _____	Date: _____
_____	_____
Clerk of the House of Delegates	Clerk of the Senate

HOUSE BILL NO. 406

House Amendments in [ ] - February 18, 1982

A BILL to amend the Code of Virginia by adding a section numbered 54-325.2:2, relating to informed consent for treatment of breast cancer.

Patrons–Harrison, Robinson, Dillard, Marshall, Van Landingham, Van Yahres, Keating, Watts, Heilig, Munford, Jennings, Terry, Washington, Cody, Callahan, Joannou, Wilson, Wilkins, Brickley, and Marks

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Referred to the Committee on Health, Welfare and Institutions

---

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 54-325.2:2 as follows:

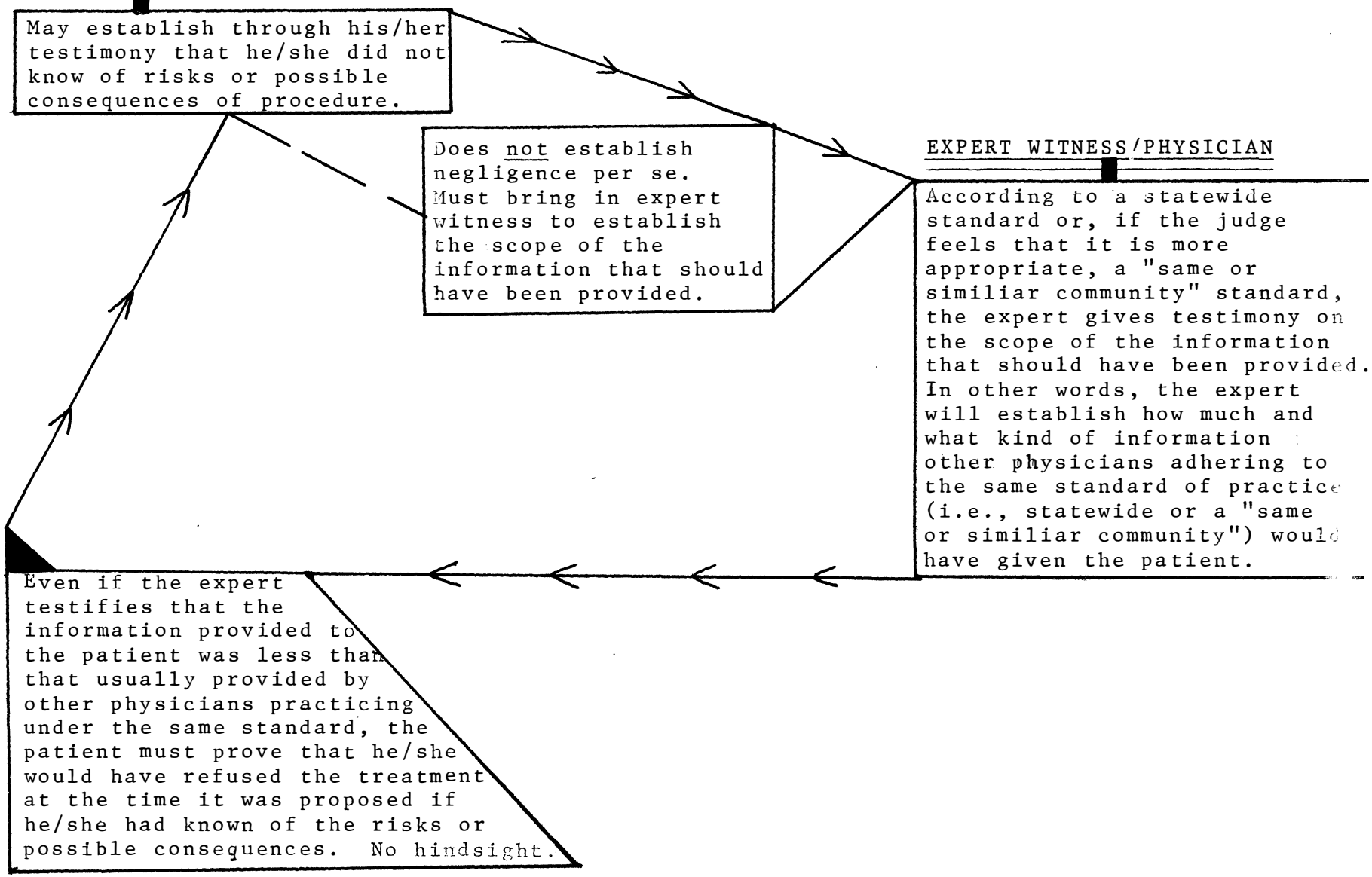
§ 54-325.2:2. Informed consent for treatment of breast cancer.– [~~*A.*~~] *Upon making a diagnosis of breast cancer, the physician shall provide the patient* [*or the patient's legal guardian*] *with complete and current information concerning the diagnosis and prognosis in terms the patient* [*or legal guardian*] *can be reasonably expected to understand. Prior to initiation of treatment, a full, reasonable, and comprehensible medical explanation as to the meaning, consequences and risks of the proposed course of treatment, as well as* [~~*all*~~ *other medically recognized*] *alternative methods of treatment, shall be given by the physician to the patient* [*or the patient's legal guardian*] *. This information shall be given by the physician* [~~*to the patient in order for her*~~ *in order for the patient or the patient's legal guardian*] *to participate actively in the choice of treatment, to make an informed consent to the treatment proposed, or to refuse the proposed course of treatment and request one of the alternative methods.*

[~~*B. If the physician believes in good faith that it is not medically advisable to give the information required in subsection A of this section to the patient or to expect her to participate in the choice of her treatment, the physician shall make a full, reasonable, and comprehensible medical explanation as to the meaning, consequences and risks of the proposed course of treatment, as well as all alternative methods of treatment, to an appropriate person on behalf of the patient.*~~]

Official Use By Clerks			
Passed By			
The House of Delegates		**Passed By The Senate**	
without amendment	☐	without amendment	☐
with amendment	☐	with amendment	☐
substitute	☐	substitute	☐
substitute w/amdt	☐	substitute w/amdt	☐
Date: _____		Date: _____	
Clerk of the House of Delegates		Clerk of the Senate	

§ 54-325.2:2. Informed consent for treatment of breast cancer. -- Upon making a potential diagnosis of breast cancer, the physician shall provide the patient or the patient's legal guardian with a reasonable and comprehensible medical explanation as to the meaning, consequences and risks of the proposed course of treatment as well as any other method of treatment that, in the reasonable opinion of the physician, should be considered by the patient under the circumstances.

THE COMMON LAW TEST FOR LACK OF INFORMED CONSENT IN VIRGINIA



Szakal, 1983

Senate Bill No. 1893

CHAPTER 916

An act to add Section 1704.5 to the Health and Safety Code, relating to physicians and surgeons.

[Approved by Governor September 17, 1980. Filed with Secretary of State September 17, 1980.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1893, Roberti. Physicians and surgeons.

Existing law provides that a physician and surgeon may be disciplined for conduct which constitutes unprofessional conduct and specifies the grounds for unprofessional conduct.

This bill would add to the grounds for unprofessional conduct the failure of a physician and surgeon to inform a patient, by means of a standardized written summary to be developed by the State Department of Health Services on the recommendation of the Cancer Advisory Council in layman's language and in a language understood by the patient, of alternative efficacious methods of treatment which may be medically viable, as specified, when the patient is being treated for any form of breast cancer.

The people of the State of California do enact as follows:

SECTION 1. Section 1704.5 is added to the Health and Safety Code, to read:

1704.5. The failure of a physician and surgeon to inform a patient by means of a standardized written summary, as developed by the department on the recommendation of the Cancer Advisory Council, in layman's language and in a language understood by the patient of alternative efficacious methods of treatment which may be medically viable, including surgical, radiological, or chemotherapeutic treatments or combinations thereof, when the patient is being treated for any form of breast cancer constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code.

A standardized written summary in layman's language and in a language understood by the patient, to be developed by the department on the recommendation of the Cancer Advisory Council and printed and made available by the Board of Medical Quality Assurance to physicians and surgeons, informing the patient of the advantages, disadvantages, risks and descriptions of the procedures with regard to medically viable and efficacious alternative methods of treatment, which is given to the patient shall constitute compliance with the requirements of this section.

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Alaska

§ 09.55.556

Provider will be held liable for failure to obtain informed consent if the patient can establish by a preponderance of the evidence that he/she was not informed of common risks and reasonable alternatives and that if he/she had been informed, he/she would have refused the proposed treatment.

This statute provides for the following defenses to an action for malpractice based on lack of informed consent: the risk which was not disclosed was one commonly known or very remote; the patient had indicated his/her intent to undergo the procedure regardless of the risks or had indicated a desire "not to know;" consent was not possible or the provider believed that full disclosure would have substantial adverse effects on the patient.

Delaware

18 § 68-52

No recovery for lack of informed consent unless the patient underwent a none emergency procedure and could prove by preponderance of the evidence that information customarily given was not provided. This statute provides a "same or similar health care communities" standard for the provider. Expert medical testimony is required under most circumstances to establish a deviation from the standard.

This statute provides the following as defense against a malpractice action for lack of informed consent: a reasonable person would understand the inherent danger of the treatment; the patient expressed intent to undergo treatment regardless or a desire "not to know;" or full disclosure would adversely effect the patient.

Florida

§ 768.46(1975)

Provides that no recovery will be allowed if physician has complied with an accepted standard of medical practice "in the same or similar medical community" and a reasonable person would have a general understanding of the procedure, alternatives and risks from the information provided or if the reasonable patient would have undergone the procedure if he had been provided the information.

A written consent form establishes a conclusive presumption of consent which can only be rebutted by proof of fraud.

Hawaii

§ 671-3(1976)

Recently amended to provide that "Breast cancer patients must be provided with comprehensive alternative treatment information."

This law provides for the establishing of reasonable standards of medical practice for the content of the information to be given. These standards are established by the Board of Medical Examiners. Statute does not mention alternatives except as noted above. No informed consent is required for emergency treatment. Physician may use his compliance with the Board's standards as a defense. The standards constitute prima facie evidence - in other words, this can be rebutted.

Idaho

§§ 39-4301 et seq.

Statute provides for more detail in terms of who can give consent for whom. The patient need only be supplied enough information on "significant risks" to make a "reasonably informed decision." The standard is of a physician in a "same or similar community."

Consent does not have to be in writing, but, if it is, then will raise a presumption of sufficiency of the information.

Although obtaining consent is considered the duty of the attending physician, his employees or agents may obtain the "completion and execution of a form or statement."

It is interesting to note this law was passed as emergency legislation.

Illinois Bill - introduced, but never left committee.

Any physician licensed to practice medicine in all of its branches or any person licensed to treat human ailments without the use of drugs or medicines and without operative surgery shall inform patients suffering from any form of breast cancer of complete information on all alternative treatments which are medically viable.

Iowa

§ 147.137(1975)

A written consent raises presumption of informed consent if it meets these requirements:

1. states nature and purpose of the procedure, any risks of death, brain damage, quadriplegia, paraplegia, loss of an organ or limb, loss of use of an organ or limb, disfigurement and the probability of these risks if determinable;

2. acknowledges that the above information has been given and all questions answered satisfactorily and

3. is signed.

Kentucky

§ 304.40-320

This law provides that informed consent has been given if the provider has adhered to the "accepted standard" of others with similar training and experience and a reasonable person would have had a general understanding of the risks and possible alternatives from the information given.

No consent is required in an emergency.

Louisiana

§ 40:1299.40 (1976)

This statute sets out the requirements for a valid written consent form as follows:

1. Explains general purpose of procedure, what the procedure is and the known risk of death, brain damage, quadriplegia, paraplegia, loss of an organ or limb, loss of use of an organ or limb or disfigurement; and

2. Acknowledges that disclosure has been made and questions answered; and

3. is signed.

Only evidence of misrepresentation of material facts will overturn such a statement.

Consent can be obtained by other means than a written statement.

Nebraska

§ 44-2816 (1976)

This statute is found in the Nebraska Insurance Law. It provides for a physician-based standard "in the locality or in similar localities." Lack of informed consent is absence of "express or implied consent."

Nevada

Provides a set of standards for informed consent which are conclusive. Physician has obtained consent if he: has "explained to patient in general terms without specific details;" has described alternative methods of treatment; noted the "general nature and extent of the risks involved, without enumerating such risks;" and obtained the signature of patient on a statement containing all of this information.

The Nevada law further defines implied consent in any case in which the procedure complies with accepted medical practice or a reasonable person would have agreed to treatment regardless.

New Hampshire

§ 507-C:3

This statute places the burden on the patient/plaintiff of proving by affirmative evidence supplied by an expert witness, that the information was inadequate. The standard appears to be that of "medical care providers with similar training and experience" or "same or similar community".

The court must consider the following in determining if the plaintiff has satisfied the burden of proof: if risks or hazards are commonly known; if actual knowledge existed; if treatment would have been accepted regardless of the risks; if the person did not wish to be informed; or if the complete disclosure would have caused adverse effects.

New York

§ 2805-d.

This statute approaches the issue by defining "lack of informed consent" rather than "informed consent." "Failure... to disclose...alternatives...reasonable foreseeable risks and benefits..."

The right of action is restricted to non-emergency and invasive procedures.

The plaintiff is required to prove that, if fully informed, a reasonable person would not have consented and that lack of consent was cause of the injury.

The defenses provided the practitioner are:

1. Commonly known risks;
2. Patient stated would undergo treatment regardless;
3. Patient didn't want to know;
4. Consent was not possible; and
5. Full disclosure would have caused adverse effects.

North Carolina

§ 90-21.13(1976)

This statute is very similar to the Florida law with one addition - a clause is included which negates an assurance of results unless it is in writing and signed.

Ohio

§ 2317.54

This statute provides that written consent, which satisfies the following criteria, is presumed "valid and effective:"

1. sets out the nature and purpose of the procedure, what it is expected to do, the reasonably known risks and the name of the physician who shall perform it;

2. acknowledges disclosure of information and the answering of all questions; and

3. is signed by the relevant party.

A consent that complies with all of this can only be proved invalid by preponderance of the evidence of fraud.

Oregon

§ 677.097

This statute sets out what a doctor must do to obtain informed consent. He must explain:

1. the proposed treatment;

2. alternatives; and

3. risks.

The doctor must then ask the patient if more information is desired. If more information is wanted, the physician is required to supply it "in substantial detail."

The physician is required to consider the standards of practice of "same or similar community" in determining that full disclosure would be "detrimental."

Pennsylvania

40 § 1301.103

This statute is also included in Pennsylvania's insurance law. The physician is required to provide information on the "nature of the proposed procedure or treatment" and the risks and alternative treatments which would be "material to the decision whether or not to undergo treatment or diagnosis."

Informed consent is not required in an emergency or if, by preponderance of the evidence, it can be established that disclosure would have had adverse effects.

Rhode Island

§ 9-19-32

This statute is included as part of Rhode Island's law of evidence. It provides no standard, but states that issues of informed consent or disclosure are to be "initially considered by the court as preliminary questions of fact." These issues will only go to the jury if the judge (the court) finds that reasonable minds might differ.

Tennessee

§ 29.26-118.

Under Tennessee law, the plaintiff is required to provide proof that the defendant did not adhere to the recognized standard of care in the same or similar community.

Texas

Art. 4590i Subchapter F., §§ 6.01 *et seq.*

This statute establishes a Medical Disclosure Panel which is given the authority to determine procedures which do and do not require disclosure. The Panel has developed two lists - A and B. The procedures which require full disclosure are listed under A; whereas those which require no disclosure are listed under B.

If the required disclosure is not provided, a rebuttable presumption is created of a "negligent failure to conform to the duty of disclosure."

Vermont

T.12 § 1908

This statute provides a definition of informed consent which includes the risks and benefits of the proposed treatment and available alternative treatments. It appears to require a "same or similar standard" of care. Expert medical testimony is required to establish the scope of the information that should be provided. No disclosure is required in an emergency. The following situations are considered defenses against a complaint of lack of informed consent:

1. commonly known risk;

2. remote risk;

3. patient's intent to undergo treatment regardless;

4. patient's desire not to be informed;

5. consent was not possible;

6. a reasonable person, fully informed, would have undergone treatment; and

7. full disclosure would have adverse effects.

Utah

§ 78-14-5

In Utah, submission to treatment raises the presumption that the patient has consented. In order to recover for lack of consent, one must prove that:

1. a doctor-patient relationship existed;

2. care was rendered;

3. such care inherently implied possible risks of serious harm;

4. information of these risks were not provided;

5. consent would not have been given if information had been supplied; and

6. injury was suffered because of the unauthorized care.

The usual defenses are provided for the practitioner:

1. the risk was minor (remote);

2. the risk was commonly known;

3. the patient had expressed an intent to undergo treatment regardless or did not want to know;

4. full disclosure would have resulted in adverse effects; or

5. a written form which includes certain elements has been executed unless fraud was used to induce signing.

The statute also states that one may refuse treatment and provides for the classes of persons who may consent and for whom.

Washington

7.70.050

This statute sets out explicitly the elements of proof as follows:

1. lack of disclosure of a material fact or facts;

2. patient's consent without being aware of such material fact or facts;

3. reasonable person would not have consented if had known such material fact or facts;

4. injury resulted.

A material fact is defined as one a reasonable person would consider significant in making a decision on the proposed treatment. Expert testimony is required to establish certain material facts (medical facts). No consent is required in an emergency.

The contents of the consent form are set out in § 7.70.060. A consent form which describes in layman's language the following is prima facie evidence of informed consent:

1. the purpose of the proposed treatment;

2. the expected results;

3. alternative treatments;

4. serious risks, etc. of the proposed treatment and alternatives.

The patient may also elect not to be informed.

APPENDIX C

COMMONWEALTH OF VIRGINIA

EDWARD E. WILLEY
PRESIDENT PRO TEMPORE
10TH SENATORIAL DISTRICT
CITY OF RICHMOND.
WESTERN PART OF
4510 NEWPORT DRIVE
P. O. BOX 9138
RICHMOND, VIRGINIA 23227

SENATE

COMMITTEE ASSIGNMENTS:
FINANCE, CHAIRMAN
COMMERCE AND LABOR
EDUCATION AND HEALTH
LOCAL GOVERNMENT
RULES

December 1, 1983

Mrs. Norma E. Szakal
Staff Attorney
Division of Legislative Services
General Assembly Building
910 Capitol Street
Richmond, Virginia

Dear Mrs. Szakal:

I have, as have all of the Subcommittee members, great sympathy and understanding for the emotional and physical trauma suffered by any woman who undergoes a radical mastectomy or receives a diagnosis of breast cancer. I do not, however, believe that specific provisions for informed consent for breast cancer patients should be placed in statutory law.

Every patient has a right to participate in treatment decisions when there are viable alternatives available. The medical profession has an ethical and moral obligation to provide each patient with the relevant information on the risks and proposed treatment. Physicians also have an obligation to explain to a patient any other appropriate available treatments. However, the physician/patient relationship requires sensitive and delicate balancing and should, therefore, remain flexible. The scope of the information appropriate for one patient may not be the same as the scope of the information appropriate for another patient. In my opinion, control of the breadth of the information provided by a physician to a patient is not a subject amenable to legislative mandate.

Very truly yours,

Edward E. Willey

Edward E. Willey
Chairman, SJR 41
Joint Subcommittee Studying
Informed Consent for Breast Cancer

EEW:bb

BERNARD S. COHEN
221 S ALFRED STREET
ALEXANDRIA, VIRGINIA 22314

FORTY-SIXTH DISTRICT

COMMONWEALTH OF VIRGINIA
HOUSE OF DELEGATES
RICHMOND

December 2, 1983

COMMITTEE ASSIGNMENTS:
COURTS OF JUSTICE
HEALTH, WELFARE AND INSTITUTIONS
CONSERVATION AND NATURAL RESOURCES
CLAIMS

Norma E. Szakal, Staff Attorney
Division of Legislative Services
P.O. Box 3-AG
Richmond, VA 23208

Re: Informed Consent for Breast Cancer Treatment (SJR 41)

Dear Norma:

Enclosed is a proposed consent form. It ~~is~~ my recommendation that something along these lines be written into the law as a requirement prior to a woman having a biopsy for breast cancer. I would also consider a requirement that they acknowledge having received the pamphlet from the Virginia Medical Society. Perhaps we can even add a paragraph along the following lines:

> I have received a copy of a pamphlet prepared by the American Cancer Society, Virginia Division, and distributed in cooperation with the Medical Society of Virginia, entitled Breast Cancer Treatments: A Helpful Guide. I have had the opportunity to read the pamphlet and my physician has answered all of my questions to my satisfaction.

Perhaps the above language can be made the first part of paragraph two on the enclosed recommended consent form.

I have discussed this recommendation with Anita Rimler, and she concurs with my recommendation.

Very truly yours,

Bernie Cohen

BERNARD S. COHEN

BSC:ch
Enclosures
cc: Anita Rimler

CONSENT TO OPERATION AND ADMINISTRATION OF ANESTHESIA

Date: _____ Hospital: _____

1. I authorize the performance upon, _____

of the following procedure(s):

(a) biopsy with frozen section only;

OR

(b) biopsy--and if it is determined that I have a malignant tumor in my breast, then I authorize my physician or his associates to perform such operations or procedures (including breast removal) which they deem necessary.

(NOTE: PLEASE CROSS OUT THE PARAGRAPH WHICH YOU DO NOT WANT TO APPLY.)

2. The purpose and nature of the operation, possible alternative methods of treatment, the risks involved, and the possibility of complications have been explained to me. No guarantee or assurance has been given by anyone as to the results that may be obtained.

3. Physicians in the hospital training program may participate in these operations and procedures according to the instructions and under the supervision of the physician or physicians named above.

4. I consent to the administration of anesthesia and such anesthetics as may be considered necessary or advisable by the physician responsible for this service with the exception of _____.

Tissue Disposition:

5. I consent to the appropriate disposal of any body tissue removed during the above procedure(s) after the tissue has been examined by the Pathologists at Medical Center Hospitals.

Photographs:

6. I (do) (do not) consent to photographs/videotaping for teaching purposes and documentation.

7. I (do) (do not) authorize reproduction of said photos or video for publication or as part of a medical education program.

WITNESS: _____ SIGNED: _____

(Patient or person authorized to consent for patient)

The above procedures have been explained to the patient or persons authorized to consent for the patient.

_____

(Relationship to patient)

M.D.

December 13, 1983

Dear Mr. Chairman:

Please record me as being in favor of legislation which would make it impossible for a woman to lose her breast during surgery without prior consent.

Richard Saslaw

FROM: John C. Buchanan

TO: Norma Szakal, Staff Attorney

SUBJECT: Proposed legislation relating to Informed Consent for the Treatment of Breast Cancer

Although I do not think legislation is needed, this legislation appears innocuous and I will not oppose it.

JOHN C. BROWN
401 BELLEAIR LANE
BRISTOL, VIRGINIA 24201

SIXTH DISTRICT

COMMONWEALTH OF VIRGINIA
HOUSE OF DELEGATES
RICHMOND

COMMITTEE ASSIGNMENTS:
COUNTIES, CITIES AND TOWNS
HEALTH, WELFARE AND INSTITUTIONS
MINING AND MINERALS RESOURCES

December 6, 1983

To: Norma E. Szakal, Staff Attorney

From: Delegate J. Brown JB.

Re: Informed Consent for Breast Cancer

I believe that the evidence and testimony given before the meetings of this commission have stressed the need for better education among women concerning the treatment of Breast Cancer. Whether such education can be legislated is debatable. While some will argue that legislation already exists in common law, protecting women undergoing treatment for Breast Cancer, there seems to be additional protective legislation needed.

However, any legislation recommended by this commission I feel should be positive in nature. It should stress the need for a patient to be informed of the various alternative treatments available to her. In the explanation of the various treatments, a patient should be told of the advantages, disadvantages, consequences and risks of each type of treatment. The legislation should also guarantee that a patient could not undergo a radical mastectomy unless she has given permission for such treatment by signing a consent form.

While we as legislators cannot and should not legislate a certain treatment for a single illness or disease, we should seek to insure that a patient has the information and time needed to make the vital decisions affecting his/her life.

Delegates Phoebe M. Orebaugh and Julie L. Smith, and citizens members Elise Brookfield Heinz and Anita A. Rimler agree with Delegate Bernard S. Cohen's proposal.

PRACTICE LIMITED TO SURGERY

PHONE (703) 931-3300

ADESON, DEUTSCH & NIGRO, MD'S, LTD.
ROBERT L. ADESON, M.D., FACS
ALAN S. DEUTSCH, M.D., FACS
MICHAEL F. NIGRO, JR., M.D., FACS
SOUTHERN TOWERS
SHERWOOD BUILDING, #225
5001 SEMINARY ROAD
ALEXANDRIA, VIRGINIA 22311

December 7, 1983

Norma E. Szakal, Staff Attorney
Division of Legislative Services
P. O. Box 3-AG
Richmond, Virginia 23208

Re: Informed Consent for Treatment of Breast Cancer (SJR 41)

Dear Mrs. Szakal:

I. My initial instinct is that legislation is not the answer to the concerns that have been expressed to the Study Committee. The risks associated with legislating with respect to medical treatment of one disease entity are not insubstantial. I am especially concerned about starting a statutory laundry list of special requirements for different medical problems.

Notwithstanding the foregoing, I now believe that the Study Committee should consider recommending some legislation. Most of the women who have appeared before us continue to have one fundamental concern - namely, being subjected to a mastectomy without their knowledge or consent. None of these women had their treatment in the last five years, and to the best of my knowledge, I doubt that such a possibility exists today. One cannot deny, however, that some women do not accept this fact. Whether the problem truly exists, or is perceived to exist is a moot point; women are requesting strong assurance that no mastectomy be done without clearly expressed written consent.

Since I believe it is of utmost importance that physicians, especially surgeons like myself, make clear that we are sensitive to this issue, I will support a recommendation of this committee that the General Assembly enact legislation that states that a patient will not be deemed to have consented to a mastectomy unless a consent form has been executed that expressly authorizes a mastectomy.

PRACTICE LIMITED TO SURGERY

PHONE (703) 931-3300

ADESON, DEUTSCH & NIGRO, MD'S, LTD.
ROBERT L. ADESON, M.D., FACS
ALAN S. DEUTSCH, M.D., FACS
MICHAEL F. NIGRO, JR., M.D., FACS
SOUTHERN TOWERS
SHERWOOD BUILDING, #225
5001 SEMINARY ROAD
ALEXANDRIA, VIRGINIA 22311

II. The Study Committee should urge the Medical Society of Virginia and the Virginia Hospital Association to develop and distribute to their members improved model consent forms that will clarify the intent of the surgeon, and will serve to improve communication with patients.

III. I believe the Study Committee should encourage the Virginia Chapter of the American Cancer Society and the Cancer Committee of the Medical Society of Virginia to keep the brochure on treatment for breast cancer current and to continue to distribute the brochure throughout the state.

The state medical and surgical societies should be asked for their full cooperation to impress upon their members the importance of disseminating (at the very least) the appropriate information contained in the brochure.

These societies should also be urged to implement educational programs that will impress upon physicians the meaning and importance of informed consent to medical treatment.

IV. I believe the impact of legislation designed to improve the mechanism of consent will extend well beyond the form itself and will stimulate physician awareness and increase satisfactory patient-doctor communication. I would oppose any further legislative proposals as being neither necessary nor desirable.

Very truly yours,

R. L. Adeson

Robert L. Adeson, M.D.

RLA:pmb

December 13, 1983

Dear Mr. Chairman:

I am in favor of legislation to prevent radical surgery on women without informed consent.

Benjamin J. Lambert, III

December 13, 1983

Dear Mr. Chairman:

I am in favor of some form of legislation that would require the consent form to state specifically that alternative treatment is available.

Tapan Hazra, M.D.

A bill to amend the Code of Virginia by adding a section numbered 54-325.2:2 relating to informed consent for treatment of breast cancer.

Be it enacted that:

The Code of Virginia is amended by adding a section numbered 54-325.2:2 as follows:

§54-325.2:2. Informed consent for treatment of breast cancer; required form; distribution of pamphlet.-- A. Whenever a patient has a lesion in the breast which a physician believes presents a potential diagnosis of breast cancer and requires biopsy, the physician shall provide the patient with the form set forth below and a copy of the pamphlet prepared by the American Cancer Society, Virginia Division, entitled Breast Cancer Treatments: A Helpful Guide and shall discuss these materials with the patient.

B. The following consent form shall be required for biopsy or operation a lesion in the breast:

CONSENT TO OPERATION AND ADMINISTRATION OF ANESTHESIA FOR BREAST LESION

Date:_____ Hospital:_____

1. I authorize the performance upon, _____

of the following procedure(s):

(a) biopsy with frozen section only;

OR

(b) biopsy - and if it is determined that I have a malignant tumor in my breast, then I authorize my physician or his associates to perform such operations or procedures (including breast removal) which they deem necessary.

(NOTE: PLEASE CROSS OUT THE PARAGRAPH(S) WHICH YOU DO NOT WANT TO APPLY.)

2. I have received a copy of a pamphlet prepared by the American Cancer Society, Virginia Division, and distributed in cooperation with the Medical Society of Virginia, entitled Breast Cancer Treatments: A Helpful Guide. I have had the opportunity to read the pamphlet and my physician has answered all of my questions to my satisfaction.

3. The purpose and nature of the operation, possible alternative methods of treatment, the risks involved, and the possibility of complications have been explained to me. No guarantee or assurance has been given by anyone as to the results that may be obtained.

4. Physicians in the hospital training program may participate in these operations and procedures according to the instructions and under the supervision of the physician or physicians named above.

5. I consent to the administration of anesthesia and such anesthetics as may be considered necessary or advisable by the physician responsible for this service with the exception of _____ _____.

Tissue Disposition:

6. I consent to the appropriate disposal of any body tissue removed during the above procedure(s) after the tissue has been examined by the pathologists at Medical Center Hospitals.

Photographs:

7. I (do) (do not) consent to photographs/videotaping for teaching purposes and documentation.

8. I (do) (donot) authorize reproduction of said photos or video for publication or as part of a medical education program.

WITNESS:_____

SIGNED:_____
(Patient or person authorized to consent for patient)

_____
(Relationship to patient, if not signed by the patient)

The above procedures have been explained to the patient or persons authorized to consent for the patient.

_____M.D.

A bill to amend the Code of Virginia by adding a section numbered 54-325.2:2 relating to informed consent for treatment of breast cancer.

Be it enacted that:

The Code of Virginia is amended by adding a section numbered 54-325.2:2 as follows:

§54-325.2:2. Informed consent for treatment of breast cancer; waiver of right to two-step procedure.--Whenever a patient has a lesion in the breast which a physician believes presents a potential diagnosis of breast cancer and requires biopsy and possible breast removal, the patient shall have a right to elect the performance of the two-step procedure consisting of biopsy and a separate operation for incision or removal of the breast. In no case shall a physician perform a one-step procedure consisting of simultaneous biopsy and incision or breast removal unless the patient has specifically waived the right to the two-step procedure in writing.

LD1810132

SENATE BILL NO. 350

Offered January 24, 1984

A BILL to amend the Code of Virginia by adding a section numbered 54-325.2:2, relating to informed consent for treatment of breast cancer.

Patrons–Saslaw, Holland, E. M., Schewel, Gartlan, Russell, J. W., DuVal, and Colgan; Delegates: Cohen, Van Landingham, Plum, Keating, Brickley, Watts, Gordy, Cunningham, Harris, Callahan, Cody, Marshall, and Medico

---

Referred to the Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 54-325.2:2 as follows:

§ 54-325.2:2. Informed consent for treatment of breast cancer; paragraphs required in form.– Before a physician operates on a patient for a tumor of the breast, a consent form shall have been executed which includes the following:

''CONSENT FOR TREATMENT OF BREAST CANCER''

Sign option (a) or option (b), or option (a) and option (b).

(a).....Breast Biopsy
Side (right or left)

.....
Patient's Signature

(b) If it is determined that I have a malignant tumor in my breast or other breast abnormality requiring surgery, then I authorize Dr..... ..... to perform such operations or procedures, including breast removal, which are deemed necessary.

Procedure:

.....

.....

Patient's Signature

LD1810132

SENATE BILL NO. 350

Senate Amendments in [ ] - February 13, 1984

A BILL to amend the Code of Virginia by adding a section numbered 54-325.2:2, relating to informed consent for treatment of breast cancer.

Patrons–Saslaw, Holland, E. M., Schewel, Gartlan, Russell, J. W., DuVal, and Colgan; Delegates: Cohen, Van Landingham, Plum, Keating, Brickley, Watts, Gordy, Cunningham, Harris, Callahan, Cody, Marshall, and Medico

---

Referred to the Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 54-325.2:2 as follows:

§ 54-325.2:2. Informed consent for treatment of breast cancer; paragraphs required in form.– Before a physician operates on a patient for a tumor of the breast, a consent form shall have been executed which includes the following:

''CONSENT FOR TREATMENT OF BREAST CANCER''

Sign option (a) or option (b), or option (a) and option (b).

(a).....Breast Biopsy
Side (right or left)

.....
Patient's [or other authorized person's] Signature

(b) If it is determined that I have a malignant tumor in my breast or other breast abnormality requiring surgery, then I authorize Dr..... ..... to perform such operations or procedures, including breast removal, which are deemed necessary.

Procedure:

.....

.....

Patient's [or other authorized person's] Signature