REPORT OF THE
JOINT SUBCOMMITTEE STUDYING

ISSUES REGARDING INFORMED CONSENT TO MEDICAL PROCEDURES AND TREATMENT

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

SENATE DOCUMENT NO. 4

COMMONWEALTH OF VIRGINIA
RICHMOND
1997

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To
The Governor
and
the General Assembly of Virginia

Richmond, Virginia

I. BACKGROUND

A. Authority and Scope

At the 1995 Regular Session, the General Assembly passed Senate Joint Resolution No. 313 (Appendix A), which established a joint subcommittee to study issues regarding informed consent to medical procedures and treatment. The resolution directed the subcommittee to examine several key issues including (i) the availability and adequacy of education and training for Virginia practitioners on informed consent practices and protocols; (ii) whether language, cultural barriers, and disabilities affect the ability of health care professionals to obtain informed consent, and the need to overcome these problems; and (iii) the effectiveness in improving the informed consent process through explicit legislative or regulatory requirements and the criminal and civil penalties for failure to comply.

B. Members

Serving on the joint subcommittee were Senators Jane H. Woods of Fairfax (chairman), Warren E. Barry of Fairfax, and Richard L. Saslaw of Springfield; Delegates L. Karen Darner of Arlington (vice chairman), Bernard S. Cohen of Alexandria, Jay W. DeBoer of Petersburg, Barnes L. Kidd of Tazewell, and Samuel A. Nixon, Jr., of Chesterfield; Margaret J. Borwhat; F. Roosevelt Gilliam III, M.D.; J. Shelton Horsley III, M.D.; Norris J. Johnson, M.D.; Carolyn C. Lavecchia, Esq.; M. Pierce Rucker, Esq.; and E. Armistead Talman, M.D.

C. Development of the Informed Consent Doctrine

Prior to World War II, the role of the patient in health care decision-making was almost nonexistent. Patients followed their doctors' orders without question because they believed that their doctors knew best. As news spread about the inhumane medical experimentation in Nazi concentration camps, patient advocate groups argued for greater protection for human subjects involved in medical research. In 1947, the International Military Tribunal adopted protocols for conducting medical research on human subjects that required researchers to inform participants about the objectives and risks of the proposed research prior to obtaining their voluntary consent.[1]

Informed consent practices also spread to clinical settings, but these practices varied depending upon the treatment prescribed or the procedure to be conducted. For less intrusive procedures and diagnostic tests, health care professionals depended on the patient's conduct to infer consent, e.g., when a patient rolls up his sleeve for a blood test. For invasive procedures, obtaining the patient's express written consent became the customary practice. However, in many cases, health professionals could not agree whether a particular procedure was invasive enough to require the more explicit form of consent.[2]

Most medical scholars agree that in order to have informed consent, the following events must have taken place: disclosure by the health care professional of the nature, benefits, and risks of, and alternatives to the recommended course of treatment; comprehension by the patient of the information conveyed by the health care professional; and express consent given voluntarily by the patient who has the capacity to weigh and evaluate information and alternative treatments. Within these parameters, health care professionals develop their own personal styles for communicating information. What the health care professional says to the patient is shaped by many external factors including the patient's personal medical history, education, religious or cultural beliefs, and prior medical consultations. In discussing experimental or research-oriented treatment and procedures, health care professionals may offer different medical opinions regarding the benefits and risks. A patient's reaction to the information conveyed by the practitioner is influenced by these same factors and may affect the patient's comprehension.[3]

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[1] Smith, Deborah L., JoAnn C. Cutting, Robert O. Riggs, Ensuring Subjects' Understanding of Informed Consent, Research Management Review, p. 2.

[2] Rozovsky, Fay A. Consent To Treatment, 2nd ed. pp. 4 and 5.

[3] Smith, Cutting, and Riggs, pp. 3 and 4.

D. Informed Consent and the Law

1. Common Law

The first legal recourse available to patients subjected to unauthorized medical treatment was to bring a cause of action for assault and battery. To prove that a medical assault or battery had occurred, the plaintiff has to show that he was subjected to an examination or treatment for which there was no express or implied consent and that the physician intentionally departed from the form of care agreed to. Because the assault and battery law did not provide a remedy in cases in which the patient relying upon incomplete or misleading information consented to treatment, a separate legal redress based upon a theory of negligence was developed. To prove medical negligence, the plaintiff has to show that the health care provider did not meet the applicable standard of disclosure and that the patient consented to and underwent a procedure based upon the provider's inadequate disclosure. The plaintiff must show that, as a reasonably foreseeable consequence of the inadequate information, he was injured. Finally, the patient must be able to prove that if he had been given all the relevant, significant information, he would not have agreed to the procedure. [4]

Two standards evolved from case law to govern what the physician must disclose to the patient. The traditional standard of disclosure, adopted by the majority of the states including Virginia, looks at the customary practice in the medical community and what a reasonably prudent physician is likely to disclose to the patient under similar circumstances. The patient-need standard, or modern approach, relies upon what a reasonable person in the patient's position would want to know under the same or similar circumstances. In addition to these common law standards, many states have enacted legislative standards governing disclosure to ensure that health care professionals inform their patients about certain benefits, risks, and alternatives inherent to a recommended course of treatment. [5]

2. Virginia's Statutory Law

a. Disclosure Requirements

The subcommittee found that Virginia regulates informed consent practices (i) by requiring health care professionals to make, in a limited number of cases, disclosures to patients about proposed treatments and (ii) by authorizing

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[4] Rozovsky, pp. 6-11.

[5] Ibid., pp. 59-62.

substituted consent for persons deemed incapable of giving their informed consent, e.g., minors and mental incompetents. What a health care professional should disclose legally to his patient depends more often upon the prevailing practice in the medical community. Virginia courts have ruled that the failure to obtain informed consent in accordance with the prevailing practice is malpractice under Virginia's Medical Malpractice Act (§ 8.01-581.1 et seq. of the Code of Virginia[6]). Under this Act, the plaintiff or the defendant in a civil action has the right to request from a medical review panel an opinion that may be used as nonconclusive evidence in the lawsuit. The request for the opinion can be submitted at any time within 30 days after the filing of the responsive pleading.

Some of the provisions of Virginia law that have preempted the common law and provided specific disclosure requirements include:

- *Infertility Procedures* -- The health care provider must disclose rates of success in correcting infertility problems at the clinic or hospital where the procedure is to be performed. The information must include the total number of live births, the number of live births as a percentage of completed retrieval cycles, and the rates for clinical pregnancy and delivery per completed retrieval cycle bracketed by age groups consisting of women under 30 years of age, women aged 30 through 34 years, women aged 35 through 39 years, and women aged 40 years or older. In addition, the patient must be informed about the safety in testing protocols used to ensure safe donor specimens. (See § 54.1-2971.1.)

- *Abortion* -- The physician must inform the pregnant woman of the nature of the proposed procedure to be utilized and the risks, if any in her particular case, to her health in terminating or continuing the pregnancy. (See § 18.2-76.)

- *HIV Testing* -- Prior to performing the test, the subject must be given an oral or written explanation of the meaning of the test. A subject may be deemed to have consented to the test when (i) he seeks the services of a facility offering anonymous testing, (ii) his blood was obtained during a routine diagnostic purpose and was tested for HIV as part of a confidential seroprevalence study on the virus, or (iii) he donates or sells his blood. (See § 32.1-37.2.)

- *Human Research* -- Prior to conducting the research, the subject must be told about (i) the purposes of the research, (ii) the expected duration of his participation, (iii) any experimental procedures, (iv) any reasonably anticipated discomforts and/or risks, (iv) the expected benefits, (v) any alternative procedures, (vi) the confidentiality rules regarding information and records, (vii) the available medical treatments for adverse effects, (viii) the opportunity to ask questions concerning the procedures, and (ix) the right to withdraw consent and

[6] Subsequent citations are to the Code of Virginia unless otherwise indicated.

discontinue participation in the treatment or study at any time without prejudice. (See § 32.1-162.18.)

- *Sexual Sterilization* -- The patient must receive a reasonable and comprehensive medical explanation of the meaning and consequences of the procedure and alternative methods of birth control. If a person does not have any natural or adopted children, the procedure may not be performed prior to 30 days from the date of the written request. (See § 54.1-2974.)

- *Breast Biopsy and Subsequent Treatment including Breast Removal* -- A specific consent form must be used which includes the authorization for the surgeon to perform a breast biopsy and specifies the course of treatment elected by the patient if the biopsy reveals a malignant tumor. (See § 54.1-2971.)

b. Capacity to Consent

Under common law, minors and mental incompetents are not legally capable of consenting to medical procedures and treatment. By statute, Virginia recognizes a minor's ability to consent to certain medical procedures and treatment, particularly those relating to sexual privacy. In other statutes, the role of parentis loci has been extended to the courts, which may authorize the performance of certain medical procedures and treatment for minors and mental incompetents.

The following statutory provisions are representative of substituted consent statutes that provide mechanisms for minors and mental incompetents to gain access to certain health care services:

- *Emancipated minors* -- Emancipated minors may consent to medical, dental, or psychiatric care, without parental consent, knowledge, or liability. (See § 16.1-334.)

- *Minor deemed an adult for certain procedures and treatments* -- A minor is considered an adult for and may consent to (i) testing or treatment of a venereal disease or any infectious or contagious disease which the State Board of Health requires to be reported; (ii) medical services required in case of birth control, pregnancy or family planning except sexual sterilization; (iii) treatment or rehabilitation of substance abuse; and (iv) outpatient care, treatment or rehabilitation of emotional disturbance. Seventeen-year-old minors may also consent to donating blood if the procurer is a nonprofit, voluntary organization and no payment is given to the minor. (See § 54.1-2969.)

- *Minor's commitment to a mental health facility* -- Minors 14 years of age may be admitted to a willing mental health facility upon the joint application and consent of the minor and the minor's parent. (See § 16.1-338.)

- *Sexual sterilization of minors and mental incompetents* -- Sexual sterilization of a minor may be performed on a minor between the ages of 14 and 18, 30 or more days after a court order authorizing a qualified physician to perform the sterilization has been entered. At the hearing before the judge, the minor and his/her parents or guardian must be informed of the meaning, consequences and risks of the sterilization procedure, and the judge must hear the child's interests and/or desires. Similar procedures are required for an adult who has previously been found by a court to be incompetent or legally incapacitated to give consent. (See §§ 54.1-2975 and 54.1-2976.)

- *Emergency medical treatment for certain persons incompetent to give informed consent* -- Mental patients in facilities operated by the Department of Mental Health, Mental Retardation and Substance Abuse Services may render emergency care if no guardian or legal representative is available, two physicians state in writing that they have explained the treatment to the incompetent, and the incompetent has not objected. (See § 54.1-2970.)

  Emergency treatment of minors is permitted if no person authorized to give consent is available within a reasonable time. However the consent of a minor 14 or older who is physically capable of giving consent must be obtained. (See § 54.1-2969.)

E. Common Professional Practices

The subcommittee reviewed three professional practices within the medical community which (i) provide education and training on informed consent issues; (ii) minimize or remove language problems, cultural barriers and other disabilities that hinder the informed consent process; and (iii) devise legally sufficient informed consent forms that enhance a patient's ability to make informed health care decisions. Information about these practices was obtained through telephone interviews with representatives from Virginia's medical schools, medical ethics review committees, and health care systems' risk management and legal teams.

1. Medical Education and Training

Most health care professionals learn about informed consent practices as care-givers. Beginning as medical students and residents, physicians acquire valuable communication skills by observing and imitating how other physicians

interact with their patients. Ethical issues that arise during the informed consent process are often covered in medical ethics courses offered by medical schools. However, except for the University of Virginia Medical School, which requires a medical ethics course as part of its first-year curriculum, medical schools in Virginia do not currently require classroom instruction on medical ethics.

Practicing physicians receive additional education and training in a number of ways. First, many medical facilities have established medical ethics review committees which consider ethical questions and problems raised by health care professionals, patients, and family members of patients. These committees are comprised primarily of health care practitioners, attorneys, risk managers, social workers, and clergy and act in an advisory capacity. Second, many health care systems offer special topical seminars on medical ethics as a means to provide continuing education for health care professionals.

Growing interest in medical ethics and informed consent practices has also led to the creation of a national study. In 1995, the Center for Bioethics of the University of Pennsylvania initiated a two-year comprehensive study program to determine how certain dynamic forces in medicine and society -- increased patient autonomy, expanded managed care emphasis on cost containment and quality outcome measures, and advanced sophistication of medical research -- interplay with the informed consent process. The study focuses on what economic, legal, institutional, cultural, religious and interpersonal factors and variables influence what a patient needs and wants to know concerning his treatment and prognosis. At the time the joint subcommittee completed its work, the national study had not released its final findings and recommendations.

2. Removing and Minimizing Language and Cultural Differences

Language and cultural differences present other challenges in obtaining informed consent. Most medical facilities handle language differences by soliciting assistance from their bilingual staff and the family and friends of the patient. Also, many hospitals utilize the AT&T language translation service that operates 24 hours a day and offers telephone translators for approximately 140 languages and dialects. The cost of this commercial telephone service varies depending on the language requested and the time of day the service is used. Health care professionals agree that the success of translation programs depends on the quality of the translators. Translators should be more than just proficient in a foreign language; they should also be familiar with medical terminology and confidentiality requirements and demonstrate the ability to translate without editing information or interjecting their own opinions.

3. Use of Informed Consent Forms

Many health care institutions develop their own informed consent forms. General admission forms authorize the health care professional to perform necessary health care services during the duration of the patient's stay. Separate forms cover specific surgical procedures and diagnostic tests, including blood transfusion. Some health care professionals also use medical charts and patient records to document consultations with the patient. Although the informed consent form was seen as a necessary part of the informed consent process, speakers at the subcommittee's hearings objected to increasing the form's importance above the informal communication between health care professionals and their patients. The speakers recommended that informed consent forms be written in a language and style that could be easily understood by a majority of patients.

II. SUBCOMMITTEE'S FINDINGS AND CONCLUSIONS

The subcommittee held two meetings and received testimony and comments from health care professionals, members of medical ethics review committees and health care risk managers. After examining some of the professional practices governing informed consent, the subcommittee reported the following findings and conclusions:

- Informed consent practices serve two purposes: to meet the legal requirements for obtaining informed consent in order to minimize the health care professional's exposure to malpractice suits and to open a channel for communication between the health care professional and the patient to explore the patient's objectives, expectations, and concerns.

- The main goal of the communication process should be to increase a patient's understanding regarding his health care situation and choices. A patient who has a greater understanding about his health care situation will be able to make a health care decision with confidence. Health care professionals should undertake efforts to confirm that their patients comprehend the information conveyed, such as asking patients to recite in their own words what the health care professional has explained.

- A patient's personal medical history, cultural and religious beliefs, personal experiences and prior medical consultations will affect what the health care professional should reveal to the patient to raise the patient's understanding to an appropriate level. Health care professionals must tailor their informed consent practices to meet the informational needs of each patient.

- Advances in medicine occur everyday and can substantially change medical opinions regarding the benefits, risks, and alternatives of a recommended course treatment. Any attempt to regulate the disclosure of these factors may lead to requirements that conflict with the need to provide the patient with the latest medical information.

- Many medical facilities draw upon a pool of language interpreters, including members of its staff, family members and friends of the patient and representatives from commercial services such as the AT&T interpreter service. Interpreters should be familiar with medical terminology and confidentiality requirements and demonstrate the ability to translate without editing information or interjecting their own opinions.

- To the extent that informed consent forms are used during the communication process, the forms should be written at a reading level achieved by most people.

- Health care professionals should consider using pictures to illustrate medical procedures whenever a patient's understanding would be enhanced.

- Health care professionals learn about informed consent practices as care-givers. To the extent practicable, medical schools and professional organizations should continue and expand their present efforts to educate health care professionals about informed consent practices. Foreign-educated professionals may need additional training, depending upon their exposure to these practices.

- Discourse among health care professionals should be encouraged because health care professionals learn about informed consent practices and issues as care-givers.

III. RECOMMENDATIONS

After careful consideration, the subcommittee unanimously elected not to recommend any new legislative requirements to regulate the informed consent process at this time. In support of this decision, the subcommittee offered these reasons: (i) the lack of complaints about the current informed consent process brought to the subcommittee's attention; (ii) the need for flexibility in the informed consent process to meet the different informational needs of patients; and (iii) the advisability of waiting until the findings and recommendations of the national study are released later this year. However, the unsystematic way in which health care professionals learn about informed consent practices and issues concerned the subcommittee. For this reason, the subcommittee decided to request by letter that the Virginia Board of Medicine initiate discussions among health care professionals

to determine the need for the publication of guidelines on basic informed consent practices and the changing role of the informed consent process in clinical and research settings. [See request letter from Chairman Woods (Appendix B).] As a starting point for these discussions, the subcommittee suggested that the Board review the issues raised in the subcommittee's findings and conclusions and examine any recommendations offered by the national study.

Respectfully submitted,

Senator Jane H. Woods, Chairman
Delegate L. Karen Darner, Vice Chairman
Senator Warren E. Barry
Senator Richard L. Saslaw
Delegate Bernard S. Cohen
Delegate Jay W. DeBoer
Delegate Barnes L. Kidd
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Margaret J. Borwhat*
Dr. F. Roosevelt Gilliam III
Dr. J. Shelton Horsley III
Dr. Norris J. Johnson
Carolyn C. Lavecchia
M. Pierce Rucker
Dr. E. Armistead Talman

*Dissenting Opinion of Margaret J. Borwhat (Submitted August 26, 1996)

I disapprove of the final report of the Joint Subcommittee Studying Issues Relating to Informed Consent to Medical Procedures and Treatment pursuant to Senate Joint Resolutions No. 313 (1995) for the following reasons:

There is a considerable regional variation between mastectomy and breast-conserving surgery, lumpectomy, being practiced today. Some studies have shown that Virginia is in a region of the country where the rate of breast-conserving surgery is below that of other areas. (See references 1 and 2.)

Scientific research reported in peer-reviewed journals since 1992 have consistently found no difference in long-term survival based upon these two treatments. (See reference 3.) Research also indicates that women show better psychosocial adjustment to the diagnosis and treatment of breast cancer when they

are given a choice between mastectomy or breast-conserving surgery regardless of their choice. (See references 4, 5, and 6.)

Requiring physicians to present women with written communications explaining the options for the treatment of breast cancer has been adopted in other states. (See reference 7.) The Virginia legislative report states that such an approach is not viable because of rapidly changing treatment approaches. However, surgical techniques for the treatment of breast cancer can be handled by a periodic review of the written communications provided to women. Such written information will also serve to provide updated information to clinicians working with women diagnosed with breast cancer.

Legislation is needed to ensure that the women of Virginia are given information about the surgical options for the treatment of breast cancer. This legislation should require that:

1. The communication be written, periodically reviewed, and updated to reflect advances in treatment;

2. The written communication (a brochure) be understandable by the lay person and be provided in languages other than English when needed;

3. The availability of the brochure be widely communicated, including notices on mammography machines; and

4. Nondisclosure of all viable breast cancer treatment options be a violation of law.

Providing written information of treatment options to women facing the diagnosis and treatment of breast cancer has not been shown to interfere with the physician-patient relationship. (See references 8 and 9.)

Women who buy new cars get more information and documentation on options and performance than those going under a surgeon's knife (and there are new models every year necessitating updates of sales and marketing materials). Should women who are getting ready to experience body-disfiguring treatment for a life-threatening disease be expected to be satisfied with any less information on which to make their decisions? In Virginia, there is a consumer protection law for major purchases --- you can reverse them without consequence within 72 hours of the purchase. A woman who has lost her breast doesn't have the option for a full refund!

For the above reasons, legislation requiring clinicians to present women with information on treatment options for breast cancer will enhance the quality of women's health care being practiced in the Commonwealth of Virginia.

References

1. Osteen R.T., Steele G.D., Menck H.R., Winchester, D.P., "Regional Differences in Surgical Management of Breast Cancer." *Cancer J Clinicians* 41 (1992): 39-43.

2. Farrow D.C., Hunt W.C., Samet J.M., "Geographic Variation in the Treatment of Localized Breast Cancer." *N Engl J Med* 326 (1992): 1097-1101.

3. Fisher B., Anderson S., Redmond C.K., et al. Reanalysis and Results after 12 Years of Follow-up in a Randomized Clinical Trial Comparing Total Mastectomy With Lumpectomy With or Without Irradiation in the Treatment of Breast Cancer. *N Engl J Med* 333 (1995): 1455-1461.

4. Wolberg W.H., Romsaas E.P., Tanner M.A., et al. "Psychosexual Adaptation to Breast Cancer Surgery." *Cancer* 63 (1989): 1645-1655.

5. Ashcroft J.J., Leinster S.J., Slade P.D. "Breast Cancer - Patient Choice of Treatment: Preliminary Communication." *JR Soc Med* 78 (1985): 43-46.

6. Morris J., Ingham R. Choice of Surgery for Early Breast Cancer: Psychological Consideration. *Soc Sci Med* 27 (1988): 1257-1262.

7. Nayfield S.G., Bongiovanni G.C., Alciati M.H., et al. "Statutory Requirements for Disclosure of Breast Cancer Treatment Alternatives." *J Natl Cancer Inst* 86 (1994): 1202-1208.

8. Harris J.R., Hellman S., Kinne D.W. "Limited Surgery and Radiotherapy for Early Breast Cancer." *N Engl J Med* 313 (1985): 1365-1368.

9. National Institutes of Health: National Institutes of Health Consensus Development Conference Statement: Treatment of Early Breast Cancer. Bethesda, MD. *NIH* (1990): July 14-16.

IV. APPENDICES

SENATE JOINT RESOLUTION NO. 313

Establishing a joint subcommittee to study issues regarding informed consent to medical procedures and treatment.

Agreed to by the Senate, February 23, 1995
Agreed to by the House of Delegates, February 22, 1995

WHEREAS, the Commonwealth has an interest in ensuring that citizens receiving medical care make well-informed choices about care based on accurate and complete medical information; and

WHEREAS, current state statutes regarding informed consent for medical procedures impose different standards and requirements for different procedures; and

WHEREAS, language, cultural barriers or disabilities may make it difficult to communicate effectively with some patients, thereby discouraging patients from seeking care or understanding the choices about care that must be made; and

WHEREAS, consistent with standard medical practice, informed consent should be tailored specifically to the needs of each patient; and

WHEREAS, the Commonwealth must be sensitive to free speech rights of those in the medical profession; and

WHEREAS, any regulation of informed consent should have a positive effect on the provision of medical services, the doctor-patient relationship, and the well-being of patients; now, therefore, be it

RESOLVED by the Senate, the House of Delegates concurring, That a joint subcommittee be established to study issues regarding informed consent to medical procedures and treatment. The joint subcommittee shall be composed of 15 members to be appointed as follows: three members of the Senate, to be appointed by the Senate Committee on Privileges and Elections; five members of the House of Delegates, to be appointed by the Speaker; one physician recommended by the Medical Society of Virginia, one individual recommended by the Virginia Breast Cancer Foundation, and one attorney recommended by the Virginia Trial Lawyers Association, all to be appointed by the Senate Committee on Privileges and Elections; and one physician recommended by the Old Dominion Medical Society, one individual recommended by the American Heart Association, Virginia Affiliate, one individual recommended by the American Cancer Society, Virginia Division, and one individual recommended by the Virginia Defense Attorneys Association, all to be appointed by the Speaker.

The joint subcommittee shall study the current law and professional practices in the Commonwealth regarding informed consent, including, but not limited to, statutes, regulations and court decisions; current practices by health care practitioners in obtaining informed consent; the impact on the health and well-being of patients of any mandatory delays in the treatment process mandated by informed consent requirements; the effectiveness in improving informed consent of explicit legislative or regulatory requirements and criminal and civil penalties for failure to comply; the availability of, and attendance by Virginia practitioners at, continuing medical education courses on the topic of informed consent generally, or on specific procedures or courses of treatment; current practices within medical schools and other institutions providing advanced degrees for medical professionals within the Commonwealth relating to the instruction and the teaching of practical skills for obtaining informed consent; whether language, cultural barriers, or disabilities currently affect the ability of health care professionals to obtain informed consent in some circumstances, and the need for training to overcome these problems; and the fiscal impact, if any, in those states that require the development and distribution of written materials, videos, or telephonic information as part of the informed consent process for certain procedures.

The direct costs of this study shall not exceed $9,500.

The Division of Legislative Services shall provide staff support for the study. All agencies of the Commonwealth shall provide assistance to the joint subcommittee, upon request.

The joint subcommittee shall complete its work in time to submit its findings and recommendations to the Governor and the 1996 Session of the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents.

Implementation of this resolution is subject to subsequent approval and certification by the Joint Rules Committee. The Committee may withhold expenditures or delay the period for the conduct of the study.

Commonwealth of Virginia

GENERAL ASSEMBLY
RICHMOND

August 21, 1996

Dr. Warren S. Koontz
Director, Virginia Board of Medicine
6606 West Broad Street, 4th Floor
Richmond, Virginia 23230

Dear Dr. Koontz:

At the last meeting of the Joint Subcommittee Studying Issues Relating to Informed Consent to Medical Procedures and Treatment pursuant to Senate Joint Resolution No. 313 (1995), the members of the subcommittee voted unanimously to share its findings and conclusions with the Virginia Board of Medicine and to request the Board to initiate discussions among health care professionals to determine the need for the publication of guidelines on basic informed consent practices and the changing role of informed consent in clinical and research settings.

The joint subcommittee was charged under Senate Joint Resolution No. 313 to examine several issues including (i) the availability and adequacy of education and training for Virginia practitioners on informed consent practices and protocols; (ii) whether language, cultural barriers, and disabilities affect the ability of health care professionals to obtain informed consent, and the need to overcome these problems; and (iii) the effectiveness in improving the informed consent process through explicit legislative or regulatory requirements and the criminal and civil penalties for failure to comply. In carrying out its charge, the subcommittee reviewed the current law, including applicable statutes, regulations, and court decisions, and solicited comments about professional practices in the Commonwealth. In addition, the subcommittee tracked the progress of a two-year comprehensive national study on informed consent begun in 1995 by the Center for Bioethics at the University of Pennsylvania.

The subcommittee found that Virginia law regulates informed consent practices: (i) by requiring health care professionals to make, in a limited

number of cases, certain disclosures to patients about proposed treatments and (ii) by authorizing substituted consent for persons deemed incapable of giving their informed consent, e.g., minors and mental incompetents. However, informed consent to most medical procedures and treatments are governed by professional practices that may not be uniformly known or accepted. The subcommittee examined some of these practices in-depth and reported the following findings and conclusions:

- Informed consent practices serve two purposes: to meet the legal requirements for obtaining informed consent in order to minimize the health care professional's exposure to malpractice suits and to open a channel for communication between the health care professional and the patient to explore the patient's objectives, expectations, and concerns.

- The main goal of the communication process should be to increase a patient's understanding regarding his health care situation and choices. A patient who has a greater understanding about his health care situation will be able to make a health care decision with confidence. Health care professionals should undertake efforts to confirm that their patients comprehend the information conveyed, such as asking patients to recite in their own words what the health care professional has explained.

- A patient's personal medical history, cultural and religious beliefs, personal experiences and prior medical consultations will affect what the health care professional should reveal to the patient to raise the patient's understanding to an appropriate level. Health care professionals must tailor their informed consent practices to meet the informational needs of each patient.

- Advances in medicine occur everyday and can substantially change medical opinions regarding the benefits, risks, and alternatives of a recommended course treatment. Any attempt to regulate the disclosure of these factors may lead to requirements that conflict with the need to provide the patient with the latest medical information.

- Many medical facilities draw upon a pool of language interpreters, including members of its staff, family members and friends of the patient and representatives from commercial services such as the AT&T interpreter service. Interpreters should be familiar with medical terminology and confidentiality requirements and demonstrate the ability to translate without editing information or interjecting their own opinions.

- To the extent that informed consent forms are used during the communication process, the forms should be written at a reading level achieved by most people.

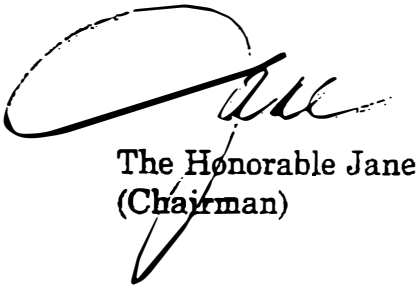
- Health care professionals should consider using pictures to illustrate medical procedures whenever a patient's understanding would be enhanced.

- Health care professionals learn about informed consent practices as care-givers. To the extent practicable, medical schools and professional organizations should continue and expand their present efforts to educate health care professionals about informed consent practices. Foreign-educated professionals may need additional training, depending upon their exposure to these practices.

- Discourse among health care professionals should be encouraged because health care professionals learn about informed consent practices and issues as care-givers.

After careful consideration, the subcommittee elected not to recommend any new legislative requirements to regulate the informed consent process at this time. In support of this decision, the subcommittee offered these reasons: (i) the lack of complaints about the current informed consent process brought to the subcommittee's attention; (ii) the need for flexibility in the informed consent process to meet the different informational needs of patients; and (iii) the advisability of waiting until the findings and recommendations of the national study are released later this year. However, the unsystematic way in which health care professionals learn about informed consent practices and issues concerned the subcommittee. For this reason, the subcommittee requests the Board of Medicine to initiate discussion among health care professionals to determine the need for the publication of guidelines on basic informed consent practices and the changing role of the informed consent process in clinical and research settings. As a starting point for these discussions, the subcommittee suggests reviewing the issues it raised in its findings and conclusions and examining any recommendations offered by the national study. On behalf of the subcommittee, I would like to thank you in advance for your attention to this matter.

Yours Truly,



The Honorable Jane H. Woods
(Chairman)