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JALBCA's 2010 ANNUAL SYMPOSIUM- "Who Owns Your DNA: Property, Privacy and the Cancer Battle"



(Left to right) Larry Norton, MD, Ellen Moskowitz, Esq., Elsa Reich MS CGC, Minna Elias, Esq., Hon. Judith S. Kaye, Hon. Sondra Miller, Hon. Karla Moskowitz, Hon. William C. Thompson

Introduction

The Fifteenth Annual Ellen P. Hermanson Memorial Symposium was held at Memorial Sloan-Kettering Cancer Center on November 10. The following panelists took part: Minna R. Elias, Esq. (NY Chief of Staff, Congresswoman Carolyn Maloney), Ellen Moskowitz, Esq. (Senior Counsel, Proskauer Rose LLP), Larry Norton, MD (Head, Division of Solid Tumor Oncology, MSKCC), and Elsa Reich, MS (Professor of Pediatrics, Genetic Counselor, NYU Medical School).

Dr. Larry Norton opened the program with a description of his current thinking concerning tumor growth. He explained that a cancer is a biological entity with three components: tumor, invasion (involving destruction of normal tissue) and metastasis

(where the tumor recapitulates its biology at a different organ).

Dr. Norton explained that our understanding of the growth pattern of human breast cancer has its genesis in the work of the 19th century mathematician, Benjamin Gompertz. Dr. Norton showed the audience how researchers use microarray analysis to determine the genes in a cell and whether normal or cancer cells are involved. He explained the self-seeding hypothesis of cancer metastasis, published in December 2009. Under that hypothesis, cancer cells spread to the primary tumor as well as other sites and can go from a metastasis site back to the primary site. This, he stated, follows Gompertzian growth patterns.

The goal of Dr. Norton's current research is to find drugs that block tumor

seeding. This requires the identification of the genes involved in seeding and testing for drugs that block them. Thus, the following must be done: define the genes; identify the proteins coded by the genes; create a drug that inactivates these proteins; conduct appropriate clinical trials; and then match the therapy to the disease. Dr. Norton acknowledged the need for researchers to be respectful of the rights of participants and to guard against the perception of discrimination in the research process. However, he pointed out the burdens faced by physicians and/or researchers in finding each tissue contributor and obtaining consent. In this way, Dr. Norton introduced the Symposium topic for the evening, *i.e.*, who owns the DNA used in cancer research.

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Program

Attorney Ellen Moskowitz began by describing the law relating to the protection of donors' rights. She referenced the seminal case of Moore v. The Regents of The Univ. Of Cal., 51 Cal 3d 120 (1990). The Moore court rejected the notion of a donor's ownership interest or property rights to donated tissue and dealt with the donation pursuant to a medical model. Moore, therefore, held the donor had no cause of action for conversion. Rather, the court held that the physician who took Mr. Moore's tissue had a fiduciary obligation to fully inform Mr. Moore of his research and pecuniary interests before obtaining Mr. Moore's consent. The court further rejected Mr. Moore's privacy right claims. In making its decisions, the court relied upon state statutes dealing with tissue disposal, the Anatomical Gift Act and public policy reasoning.

Ms. Moskowitz explained that under Federal and State laws governing human subjects research, informed consent and institutional review boards (IRB's) assure that subjects are participating in research that is ethical. Most of these laws make the sale of tissue a crime, similar to the sale of organs. She raised the issue of whether, in this context, a donor can even be involved in an arrangement where s/he receives payment for tissue and receives a portion of future profits.

Attorney Minna Elias then discussed a case involving American Indians, where researchers used the tissue for a variety of purposes other than the original, stated research purpose (explaining high levels of diabetes in the population concerned). The case was settled prior to resolution in the courts, the research was halted and the research results were destroyed. Use of the tissue for these broader purposes, even though a broad consent form had been signed by the participants, had resulted in unanticipated cultural disruption of the group concerned. The practical result, as noted by Judge Thompson, was the loss of research results and disincentive to study the group for clues to their high level of diabetes incidence.

Ms. Moskowitz reiterated that tissue donors are entitled to substantial protections as human subjects and there are professional standards in place that are supposed to assure that this occurs. Dr. Norton noted that people do not read informed consent forms or show them to their attorneys. They sign

them, basically, because they trust their doctors so that fine-tuning the subtle language of an informed consent form is not an answer to the problems concerning use of donated tissue. Elsa Reich opined that when research goes beyond the original intent of the researchers, the donors should be re-approached for their consent, discounting the argument that simply because researcher do not know where their research will ultimately lead researchers have a right to rely on the original consent form.

Ms. Moskowitz mentioned The Common Rule – Title 45 Part 46 of the Code of Federal Regulations – which sets forth the requirements for research on human subjects when the research is funded, in whole or in part, with Federal monies. In this case, the FDA would not permit marketing of a drug if it is based on unethical research in violation of the consent of the involved human subjects. Ms. Moskowitz noted that the chain of custody of tissue is evidenced by a contract (*i.e.*, a Cooperative Research & Development Agreement (“CRADA”)), which typically requires law compliance and that it would be unusual for an academic institution to seek to be involved with the violation of human subjects' rights. However, private commercial companies down the chain of custody might not have concerns about The Common Rule.

Ms. Elias reported on relevant hearings that took place in the Energy and Commerce Committee of the House of Representatives during March 2010. The Committee members heard about a physician at the National Institute of Mental Health who was involved in Alzheimer research but also had outside contracts with the pharmaceutical industry. The physician/researcher took tissue that had been donated to the Federal government and sent it to the company, from which he had received compensation over the years for projects and speaking engagements. The Congressional Committee took an interest in protocols for sharing materials and tissue, and Ms. Elias reported that HHS will make changes in its protocol based on what was learned during the hearings.

This led to Dr. Norton pointing to the interest of society in pursuing research and the unintended consequence of inhibiting people from pursuing research because of issues relating to human subject protection. He questioned who was harmed under some

of the scenarios discussed by the panel. Ms. Reich, however, objected to an analysis based on the common good. She argued that people should not be deceived into thinking their tissue would remain at the National Institute of Mental Health if this is not the case, and that donors may not have voluntarily provided their tissue if they were aware that it would be shared with private companies who would profit from the marketing of drugs that are developed based on use of their tissue. Ms. Moskowitz, however, noted that sample consent forms for tissue donation generally list “commercial” purposes. She remarked that even though there are issues of custody and control over tissue – issues between the Federal agency and the pharmaceutical company that ended up with it – once tissue is out of the body, the person cannot sell it. As noted by Moore, the tissue is waste under the law and the donor has no use or ownership rights in the tissue. Judge Moskowitz agreed that the tissue donor had no right to return of the tissue. While consent can be withdrawn under an informed consent form, consent cannot be withdrawn once the tissue has been used. Ms. Elias offered the taxpayer perspective – taxpayers covered the expense of taking the material and yet received none of the benefits, since it was the pharmaceutical company that profited.

The question was raised as to whether there should be a national policy on the subject. Ms. Elias reminded the audience that Congress does not like to legislate in a vacuum. Also, some of the discussion on these issues may be caught up in the issue of stem cell research, which is a controversial subject with most members of Congress. Ms. Moskowitz felt that existing laws address the parties' rights and merely need to be enforced – Federal laws protect donors' tissue for research and many states also have tissue banking laws, *e.g.*, New York laws cover record-keeping, inspections, banking and transfer of tissue. It was acknowledged that the privacy rights of donors have strengthened over time, *e.g.*, HIPAA and state laws with regard to individually identified information. Ms. Reich offered a dose of reality – donors are not always in the best situation, because of their compromised health, to make these kinds of decisions and, therefore, oversight is still required notwithstanding an existing body of laws.

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Ms. Moskowitz suggested that, at a certain point, if a tissue is manipulated – “more than minimally manipulated” – it no longer is tissue that is illegal to sell but becomes a pharmaceutical that can be bought and sold. Obviously, the transformation occurs within a legal framework.¹ The FDA has a regulatory scheme applicable to human tissue.

Finally, the panel turned to an update on the Myriad Genetics case (which involved patent eligibility for genes, the subject of JALBCA’s 2009 annual Symposium). Dr. Norton remarked that there are several arguably undesirable consequences to consider with restrictions on patenting- there will be even less money available for research and people will keep their ideas as trade secrets. Ms. Reich (who disclosed that she is a co-plaintiff in the Myriad case) noted that the gene causing cystic fibrosis was patented but it was done in a way – unlike how the BRCA1 and BRCA2 exclusive licensing was handled by Myriad Genetics – where it could be widely licensed across the country, with different labs performing the test in different ways. She challenged Myriad, not as a laboratory, but with regard to its philosophy. Ms. Elias acknowledged the limited amount that is spent on research in the United States and the criticism of some that we are walking away from one of the country’s best assets by not investing more in medical research.

Summary

In the absence of legislation to define public policy, courts have tried to sort out the putative rights of donors of cells or tissue used to further medical research, who have sued those who profited (or stood to profit) from commercialization of the research. These courts have labored against the backdrop of property rights, informed consent and anatomical gift statutes. The resulting case law, for the most part, has upheld the property rights of commercial enterprises to enjoy the fruits of their research and product development. However, the rights of a patient, and to a lesser degree a donor to research, are deemed protected by case law, statutory law and ethical obligations bearing on the requirement of informed consent and, in some cases, a doctor’s fiduciary duties to his/her patient. Absent legislation creating affirmative property rights in donated cells or tissue, the courts look to property rights, informed consent, statutes, ethical codes and policy.

In evaluating the issues for public policy purposes, issues for tissue providers are generally as follows: (1) a reluctance to provide cells and genetic materials if it will be used for research they find morally objectionable (or violative of cultural or religious beliefs) or about which they are not informed; (2) a desire to share in profits from the commercialization of their cells and genetic material or a disinterest in others profiting from such commercialization; and (3) adverse impacts

from a breach of confidentiality or unanticipated disclosure of their genetic information, e.g., their inability or that of their close genetic relatives to obtain insurance coverage, employment or other opportunities, or appropriate medical treatment, and the potential for emotional distress or embarrassment.

Balanced against these interests are those of researchers and society. These interests can be generally described as follows: (1) the desire to advance science and medicine with as few restrictions on human tissue research as possible; (2) a concern that permitting tissue providers to share in the profits of commercialization; and dictate the use to which their tissue can be put, will cause a diversion of cells from worthwhile research and a disincentive for research funders to invest in research and development; (3) the desire of researchers, biotechnology companies, and pharmaceutical or medical device makers to be financially rewarded for their research investment; and (4) the administrative and related burdens that ensue from the need to track the ownership and transfer of tissue, indefinitely, through research banks from one research project to another, possibly over many years, and the effect of consent withdrawal on research.

1. Minimal manipulation means: (1) For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue’s utility for reconstruction, repair, or replacement; and (2) For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues. 21 CFR 1271.3(f)

UPCOMING PROGRAMS REPORTING ON THE SAN ANTONIO BREAST CANCER SYMPOSIUM

SHARE PROGRAM: Metastatic Breast Cancer Update: News from the San Antonio Breast Cancer Symposium

Medical experts and patient advocates will report on research and treatment updates. Presenters will also share information regarding resources and ways to cope with the psychosocial aspects of this disease.

DATE: January 11, 2010

TIME: 6 PM

PLACE: NYU Langone Medical Center
550 First Ave. (at 31st St.)
Alumni Hall B
Manhattan, NY

PRESENTERS: Kathy Hynes-Kadish, Metastatic Breast Cancer Survivor, SHARE Hotline Volunteer and Facilitator;

Diane Palmieri, PhD, Staff Scientist, National Cancer Institute; Lisa Sevanick, LCSW, Supportive Services Program, NYU Clinical Cancer Center; Amy Tiersten, MD, Associate Professor, Department of Medicine (Oncology), NYU

MODERATORS: Deborah Axelrod, MD, Associate Professor, Department of Surgery, NYU, and Ilene Winkler, Director of Metastatic Programs at SHARE.

SHARE/AMERICAN CANCER SOCIETY PROGRAM: Advocates Report Back from San Antonio

Hear medical and advocacy perspectives on the latest breast cancer research, clinical trials, and treatment strategies presented at the annual San Antonio confer-

ence. Dr. Rick Michaelson, Chief Medical Officer for Oncology, Cancer Center of Saint Barnabas Hospital, and SHARE advocates, will interpret the findings, answer questions and discuss the meaning of the research results. *SHARE in collaboration with ACS.*

DATE: January 19, 2010

TIME: 6 PM

PLACE: Hope Lodge,
American Cancer Society
132 West 32nd St., 4th Fl.,
Conference Room
Manhattan, NY

For the SHARE programs, please rsvp@sharecancersupport.org or call 212.719.2943, ext. 338 to register.

CALENDAR/CONTACTS

ADELPHI NY STATEWIDE BREAST CANCER

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www.breastcancerhotline@adelphi.edu

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c/o Jennifer Fiorentino

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