

SEPTEMBER 12, 2006

RESOLUTION REGARDING ORGAN & TISSUE DONATION

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RESOLUTION

WHEREAS the NJSFDA membership adopted a resolution in September of 2000 to view organ/tissue donation as a gift of life and to work in a positive and supporting manner with donor families, to work with the local organ/tissue procurement center to identify the emotional needs of the survivors, and the funeral options they may wish to choose, and to work with medical personnel to ensure that bereaved families have the widest possible number of funeral options, **AND;**

WHEREAS the Organ & Tissue Committee was charged with examining the emerging issues in donation, **AND;**

WHEREAS the NJSFDA Organ & Tissue Committee was charged with defining suitable conduct for funeral director interaction with donor organizations, **NOW THEREFORE**

BE IT RESOLVED, that the NJSFDA Organ & Tissue Committee recommends the adoption of the following policies to the NJSFDA membership.



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FUNERAL DIRECTOR AND FUNERAL HOME CONDUCT

1. Procurement Activities at Funeral Homes

FINDINGS – The committee determined that there is no broad demand to perform recoveries for the purposes of transplantation within New Jersey funeral establishments. The Organ Procurement Organizations (OPOs) and their affiliates that serve New Jersey exclusively use hospital suites or their own facilities. The geographic proximity to health care facilities and donor facilities is a constant. There appears to be no need to utilize funeral homes at the current time with two exceptions reflecting ongoing activities of legitimate research projects and eye banks that may request the use of funeral home facilities for the convenience of families. Since funeral directors are not familiar with the many research projects being conducted across the United States, OPOs can serve as a resource for information.

POLICY RECOMMENDATIONS – Funeral homes should not function as recovery sites for organ and tissue recovery except upon the request of families to accommodate the recovery of research specimens for legitimate research projects and for cornea recovery by members of the Eye Bank Association of America. An example of a legitimate research project would include medical institutions in both Philadelphia and New York City which recover brain tissue for Alzheimer's research. OPOs can serve as a resource for information on such research projects. Funeral directors are advised that the recovery of tissue for research projects is not as well regulated as other areas of donation, and that different methods and levels of authorization exist within this area. Funeral directors should not make their facilities available unless, at a minimum, verbal consent has been obtained prior to the recovery, with a guaranty of written consent documentation to follow, if not immediately available, to be filed in funeral home records.

2. Funeral Directors Serving as Agents for Consent & Medical History Records

FINDINGS – National and state donor organizations do not support the concept of funeral directors obtaining family consent or medical histories. This committee concurs with that finding.

POLICY RECOMMENDATIONS – While nothing would preclude funeral directors from providing organ donation literature in their establishments, funeral directors should not solicit donation, execute family consent forms or take medical histories on behalf of donor organizations.

3. Qualified Donor Organizations

FINDINGS – The committee believes that a statutory prohibition on funeral home use is unnecessary in the effort to prevent criminal activity. Rather, the NJSFDA may assist funeral directors by identifying qualified donor organizations to help funeral directors recognize mainstream donor

organizations when responding to family inquiries. Such a resource is essential for funeral directors due to the diversity of donor organizations, the confusing regulatory environment and a growing number of unregulated whole body donation organizations not affiliated with medical institutions. The qualified donor organization list should be reviewed periodically for currency and completeness.

POLICY RECOMMENDATIONS – NJSFDA should maintain a list of qualified donor organizations as a resource for funeral directors. Recommendations should be reviewed on a periodic basis. When NJSFDA members or prospective donor families are contacted by organizations not reflected on this list, they should proceed with caution before establishing any relationship. The 2006 NJSFDA qualified donor organization list shall include the following:

- New Jersey's OPOs and their affiliates (The New Jersey Organ & Tissue Sharing Network and The Gift of Life program),
- Eye banks which hold membership in the Eye Bank Association of America, and
- Whole body donation programs at University of Medicine and Dentistry of New Jersey UMDNJ-Robert Wood Johnson Medical School and Mercer County Community College.

PRACTICE ISSUES

1. Funeral Director Compensation

FINDINGS – Funeral directors can accept reimbursement from qualified donor organizations for additional time spent in restoring donor remains for public viewing due to the additional labor and equipment costs associated with such work. Funeral directors can be compensated for funeral home use and transportation by disease research organizations recovering research specimens or eye banks recovering corneas.

POLICY RECOMMENDATIONS – NJSFDA will continue to work with donor organizations to set appropriate reimbursement rates for restoration of donor remains, reimbursement for transportation services when needed and facility use for obtaining research specimens or corneas.

2. Donor Organization Interaction with Funeral Directors

FINDINGS – Donor organizations recognize the need for consistent execution of restorative policies, scheduling and structured funeral director communications.

POLICY RECOMMENDATIONS – NJSFDA will continue to work with qualified donor organizations to improve the coordination of work between the organizations, families and funeral directors.

3. Funeral Directors Promoting/Supporting Donation

FINDINGS – Funeral directors are a source of information for their communities and can share information about organ and tissue donation with families. Recent events and liability concerns require that funeral directors be more explicit with families about the donation process, use of recovered materials, and the resulting condition of remains without creating an environment that will discourage donation. Information shared should include the varied use of donated materials for transplantation, research and product development and the impossibility of predicting its final disposition.

POLICY RECOMMENDATIONS – NJSFDA members should support donor families and promote donation to the general public, be educated on the complexities of donation and share such information with families when appropriate.

LEGAL/REGULATORY CONCERNS

1. Support Aggressive Prosecution

FINDINGS – The alleged activities of the parties in the Biomedical Tissue Services case have harmed the goodwill of donor organizations and the funeral industry, violated public trust and triggered public health alerts. Actions not only were criminal but have the potential to harm donation rates and affect the health and welfare of tissue recipients.

POLICY RECOMMENDATIONS – Support a no tolerance policy by the aggressive prosecution of individuals involved in illegal activities.

2. Regulatory Structure of OPOs, Tissue Banks and Funeral Homes

FINDINGS – OPOs are non-profit organizations. They are federally designated to procure solid organs and tissue for transplantation and follow standards set by the Uniform Anatomical Gift Act (UAGA), which allows organs to be donated, and the National Organ Transplant Act (NOTA),

which specifies that organs cannot be “sold.” The activities of OPOs are regulated by the Department of Health and Human Services, Medicare Program.

Overseen by the Food & Drug Administration (FDA), tissue banks procure tissue for both transplantation and non-transplant purposes. Many are members of the American Association of Tissue Banks (AATB), a trade association which manages a voluntary accreditation program for member tissue banks. OPOs as well as tissue banks can be reimbursed for “reasonable payments” associated with recovering, processing and distributing tissue but cannot pay families for consenting to donation. Legislation introduced by United States Senator Charles Schumer (D-NY) in April 2006 would require audits of tissue banks, the development of model consent forms, accreditation and determination of “reasonable payments.” No laws or regulations define the funeral industry’s role in donation outside of permitting recovery in morgues and medical examiner facilities. At this time, no additional legislation needs to be initiated to define the funeral director’s role in donation because there are no proposals to expand their role in the recovery process.

POLICY RECOMMENDATIONS – While donor organizations may feel existing industry regulations and AATB accreditation are sufficient, the NJSFDA supports the federal legislation to create improved supervision over tissue bank activities as a matter of sound public policy.

3. New Jersey Criminal Penalty Legislation

FINDINGS – Donor organizations and the NJSFDA support stronger penalties for the theft of human remains, falsification of medical history documents and failure to obtain proper family consent. Two bills currently in the New Jersey Assembly address these concerns.

POLICY RECOMMENDATIONS – The NJSFDA supports improved laws that will clarify and impose stronger sanctions for the unlawful procuring of organs and tissue.

BACKGROUND INFORMATION

The 2006 indictment of Biomedical Tissue Services (BTS), its owner Michael Mastromarino, and New York funeral director Joseph Nicelli, for the alleged unlawful procurement and distribution of human tissue and bone for transplant purposes, created the need to reappraise the funeral director’s role in the organ and tissue donation process. While BTS prevailed upon a small number of New Jersey funeral homes to secure consent from families and to allow recovery to occur on their premises, and while those funeral homes have not as of this date been identified as being party to the fraudulent actions alleged against BTS and Nicelli, their participation begs the question: “What should the scope of funeral home participation be in promoting and recovering human bone and tissue from cadavers?”

Additionally, the rapid development in the variety of biomedical products derived from donated tissue and bone, and the changes in their transplant and research uses, suggests that funeral directors and families require more information with respect to the uses to which donations will be applied, many of which may differ from the understanding most people have of solid organ donation. Accordingly, the NJSFDA developed a task force to explore the pertinent issues and to make policy recommendations on donation to the NJSFDA membership.