

Ronald Wade
Acting FEO President
Director, State Anatomy Board
655 W. Baltimore St. Rm. B-024
Baltimore, MD 21201-1559
V: 410-706-3313
F: 410-706-8107
E: rwade@som.umaryland.edu

Melissa Johnson Williams, CFSP
Acting FEO Secretary
6109 N. Francisco St.
Chicago, IL 60659
V: 800-303-1017
E: MjohnsonCFSP@aol.com

David Zinner
Acting FEO Treasurer
Kavod v'Nichum
8112 Sea Water Path
Columbia, MD 21045
www.Jewish-funerals.org
V: 410-799-8070
E: davidzinner@comcast.net

Barbara Bouton
Director, Community Hospices
Vice-Chair, NCHPP, Bereavement
Section Leader
2120 Newburg Rd., Ste. 200
Louisville, KY 40205
V: 502-719-8925
E: bbouton@hospices.org

Mike Brannon
Brannon Monuments
1310 White St.
Dubuque, IA 52001
V: 563-583-6318
E: brannon@MWCL.net

Malin Byington
Rocky Mt. Pre-cast
P.O. Box 2062
Idaho Falls, ID 83403-2062
V: 208-542-5161
E: malin@onewest.net

Hari Close II CFSP
Hari P. Close Funeral Service
709 Tessier St.
Baltimore, MD 21201
V: 410-327-3100
E: HPCloseF@bellatlantic.net

Graham Cook
Homesteaders Life
P.O. Box 1756
Des Moines, IA 50306
V: 515-235-0415
E: gcook@homesteaderslife.com

John Eadie
Public Policy Special Advocate
NY Statewide Senior Action Council
275 State St.
Albany, NY 12210-2101
W: NYSenior.org
V: 518-436-1006
E: JohnLEadie@aol.com

Jim Eaton
President, Newmark of Colorado
14101 E. 33rd Pl., Ste. E
Aurora, CO 80011
V: 800-634-4137
E: jeaton1029@aol.com

The Funeral Ethics Organization
P.O. Box 10
Hinesburg, VT 05461
www.funeralethics.org
866-866-5411



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Carl Lisman
Commission Uniform State Laws
84 Pine St.
Burlington, VT 05401

Dear Mr. Lisman:

Enclosed is documentation to support our request for a revision of the Uniform Anatomical Gift Act. We hope that the following provisions can be addressed:

- that the acquisition and harvesting of cadavers and human cadaveric tissues be done only by nonprofit entities;
- that a state license and regulate such entities, to include setting standards for what is a "reasonable cost" for the work of harvesting various body parts (reasonable cost is to include any repair to the body that is required for an open-casket funeral when only limited tissue is harvested) and that those costs be made available as public information;
- that anyone acquiring cadaver tissue for research or medical technology do so only through a duly licensed facility (it should be a crime to purchase elsewhere);
- that harvesting facilities be required to work with a regional or national system for monitoring and establishing priority of use to meet the critical needs for the living before tissue is allocated for other uses;
- that harvesting facilities be required to meet the FDA requirements for testing tissue to assure that the tissue is not infectious and that the facilities themselves meet certain standards;
- that standards be set by the state for the disposition of body parts after study, research, or testing;
- that donors be given informed consent.

Many of us are troubled by the increasing number of for-profit (as well as the highly-paid "nonprofit") companies in the body parts business. The current Uniform Anatomical Gift Act did not anticipate the growth in medical technology that would create a demand for more body donation.

Ron A. Hast
Abbott & Hast Publications
4 Saint Lucia Pl.
Tiburon, CA 94920
V: 800-Ron-Hast
E: RonAHast@aol.com

Erda Hillmann
Funeral Consumers Alliance of
Houston
5200 Fannin St.
Houston, TX 77004-5899
V: 713-869-1076
E: erda@swbell.net

Randy Singer
Forever Enterprises
1921 Hunting Lake Ct.
Kirkwood, MO 63122
Cell: 314-239-1105
E: rsinger@forevernetwork.com

Jack Springer
Executive Director
Cremation Assoc. of N. America
401 N. Michigan Ave.
Chicago, IL 60611-4204
V: 312-644-6610
E: jspringer@sba.com

Z. G. Standing Bear, Ph.D.
514 Hopi Cir.
Divide, CO 80814
V: 719-687-8087
E: MGSpikers@aol.com

Jacque Taylor
Executive Director
New England Institute at Mt. Ida
College
777 Dedham St.
Newton Centre, MA 02459-3323
V: 617-928-4711
E: jstaylor@mountida.edu

Rudy Thomas
Executive Director
Arizona State Funeral Board
1400 Washington St.
Phoenix, AZ 85007
V: 602-576-2458
E:
Rudy.Thomas@funeralbd.state.az.us

Staff

Lisa Carlson
Executive Director

Only if a company harvesting body parts is required to be nonprofit will the finances be available for public inspection, per IRS requirements. Furthermore, by setting standards for what is a "reasonable cost" for the harvesting procedure there will be some cap on medical inflation at the initial stage of any such commerce. It will be important to establish what transactions are deemed criminal in an effort to thwart the black market retrieval of cadaver parts.

Informed consent must include a signed acknowledgment that the entire body may be dismembered when that is the case; that tissue may be shipped out of the state and out of the country; that some portions may be fabricated into transplantable tissue for reconstructive surgery on the living; that other portions, after medical study, will be cremated as medical waste and disposed of according to state law, or will be returned to the family, when that is the case.

Clearly, we will need to work with the FDA on setting up a system for monitoring priority needs for the living and for testing tissue for infectious or communicable diseases. By eliminating the for-profit motive at the primary level, such standards should be easier to enforce and meet.

Only Florida and New York states attempt to regulate tissue donation. The enclosed statutes may give you a beginning framework to consider. But even those laws don't go far enough, with New York licensing for-profit entities. Improved regulation of the harvesting of cadaver tissue should elevate consumer confidence and participation, as well as making the medical uses safer and more timely.

If you have any questions, please don't hesitate to call.

Sincerely,

Lisa Carlson
Executive Director

Attachments #1: Series of articles by the Orange County Register
Attachments#2: Articles from other states
Attachments#3: financial report for Regeneration Technology
showing the close ties with "nonprofit" SETA
Attachments #4: Ethical considerations; informed consent; laws from
Florida, California, and New York