

July 1, 2003

National Conference of Commissioners on Uniform State Laws  
211 E. Ontario Street, Suite 1300  
Chicago, Illinois 60611

Dear Commissioners:

This letter is being written on behalf of the Board of Directors of the Funeral Consumers Alliance, the affiliates from Maine to Hawaii, and the more than 250,000 members of those organizations. The FCA is a nonprofit education and advocacy organization with more than 40 years of experience working on behalf of consumers of funeral goods and services.

Because of disturbing reports regarding commerce in human tissue that have recently come to our attention, we respectfully request that you conduct an investigation into this matter, with the intent of making any needed amendments to the Uniform Anatomical Gift Act (UAGA).

Since many of our members, as well as members of the general public, ask for and rely upon guidance from FCA regarding body donation as a method of "final disposition" of the body, we feel a vital interest in curbing the abuses which have occurred with human bodies in both "willed bodies" programs and cremations.

Much of this abuse stems from commerce in which tissues have been harvested without true informed consent.

According to a 2001 report from the Department of Health and Human Services, most of the American public believes that all body, organ and tissue donation is done with the humanitarian aim of helping the living and the critically injured. The report indicates that the disjuncture between this belief and the reality of contemporary tissue donation jeopardizes the public's trust in the system.

Because of the recent proliferation in the use of such tissue for both therapeutic and cosmetic purposes, the financial incentives and profits have risen dramatically. This new market in products has raised serious concerns about profits derived from body parts, transparency of the system to donors, the distribution of donated tissue, and the effect that "body brokering" is having on public perception of organ, body and tissue donation.

Some directors of willed body programs at medical schools are concerned that tissue banks are not subject to the same regulations or standards of ethical and nonprofit operation as organ donation agencies and university research departments.

The public's trust in medical school and organ donation agencies could be eroded by the behavior of unregulated tissue banks.

The UAGA prohibits the sale of body parts for transplantation or therapy, but the Act does not define what constitutes "reasonable payment" for procuring, processing and distributing tissue. This leaves a loophole allowing some tissue banks and for-profit companies to exchange large sums of money for processed skin, bones, tendons, heart valves and other body parts. They do so by referring to the transaction as the collection of "fees," rather than as an outright sale.

The authors of the UAGA could not have anticipated the explosion in biomedical technologies or the profits that are now made in the field.

Current biomedical technology has created far more uses for donated tissues and body parts than mere whole organ transplantation.

Donated tissue can be processed and formed into products far different from the tissue's original form. Consequently, some biomedical companies are making large profits on products derived from donated tissue, which seems to subvert the intent of the Act.

In addition, the sale of body parts for medical research was not addressed in the Act. While we wholeheartedly support the concept of donation to advance medical science, the prospect of middlemen reaping exorbitant profits from the sale of tissue from bodies donated to medical research facilities and companies is most troubling.

There is also no mandated system by which to allocate donated tissue and body parts to those in the great need.

Another report from the Department of Health and Human Services in 2001 found many burn centers difficulty obtaining skin for grafting in a timely manner. By contrast, newspaper and television investigations found many cosmetic or elective surgery clinics were able to obtain skin quickly and easily.

Standards for informed consent are also lacking. Government and private reports have found that the public considers donation an altruistic act that benefits those most in need. Yet the information given to donor families regarding the uses to which tissue is put often falls short of constituting real informed consent. In a May 19, 2003, *Boston Herald* article, the chairman of the Health Law Department of Boston University's School of Public Health said, "The market for body parts has become very lavish—skin, brain, heart valves are not just used for research but are part of a for-profit industry now. People need to be informed of this."

Such being the case, we respectfully suggest that the Commissioners consider the following questions and, if appropriate, revise the UAGA to include necessary safeguards:

1.  
Should there be a requirement that tissue banks be subject to the same ethical and nonprofit operating standards as organ procurement organizations?
2. Should the definition of what constitutes "valuable consideration" and "reasonable payment" for the removal, processing, disposal, preservation, quality control, storage, transportation or implantation of donated tissue and body parts be codified in the UAGA?
3.  
Should regulation of tissue commerce include a set of clear, comprehensive standards for what constitute informed consent and, if so, should such standards compel procurement agencies to prominently state to donors that donated tissue may be turned into a marketable product if that is the case? Should such standards also compel the procurement agencies to provide donors and families with specific information on the destination(s) of the donated tissue?
4.  
Should there be a requirement to establish a system by which donated tissue is allocated in order of medical priority?  
Such a system might allocate tissue in the following order: a) to those in danger of dying if they do not receive imminent treatment, b) to those in need of reconstructive surgery to correct such conditions: congenital birth defects or damage from disease (such as cancer) or injury, and finally c) to those desiring purely cosmetic surgery unrelated to a medical condition.

5. Should there be a prohibition against the sale of donated body parts and/or tissue for research?

The answers to these questions are likely to have an important effect upon capturing and maintaining the public's trust in biomedicine and, as a result of that, the availability of body and tissue donation for the foreseeable future.

We ask that the Commissioners begin a full and public inquiry at the earliest possible moment.

Respectfully submitted,

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FCA Board of Directors

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Funeral Consumers Alliance