

To: AARP's National Policy Council

From: Harriet Bartnick, AARP-NC Volunteer Health Specialist

Date: August 8, 2006

RE: Recommendations for *The Policy Book* – Procurement of Human Tissues

Introduction

This proposal is in response to Jill Finsen's memo of July 10th asking for input for *The Policy Book*. I appreciate the opportunity to make suggestions to AARP's public policy. I am on the national board of the Funeral Consumers Alliance (FCA) and am a volunteer with this area's organ and tissue procurement organization. These affiliations and my personal research in end-of-life matters have made me aware of serious problems involving the procurement and distribution of donated human tissues, problems that need corrective action.

The 'Tissue Issue,' as I will call it, is not limited to a discrete category. It is a public health issue when severe and/or non-curable diseases are transmitted, a personal and legal rights issue involving informed consent, an ethical issue when an altruistic gift is altered to a commodity for sale to the highest bidder. It is also a significant social and human relations issue when, at a time of great stress and grief, people are asked to make the decision to donate a loved one. Most importantly, this gift is a huge social benefit when recovered tissues, eyes and organs provide others with improved health, or even life itself.

Background

Organ and tissue transplants have saved or improved millions of lives. Over the last decade, the transplantation of human tissue such as bones, heart valves, ligaments and skin has grown exponentially. Donated tissue can be processed into different 'products' with ever-growing clinical uses. The use of human tissue products keeps expanding in oncology, sports medicine, spinal surgery and dentistry.

Technical innovation in the industry has been very rapid, leading to big changes in the organization and operation of tissue banks. Tissue procurement in America has become a booming industry containing for-profit and non-profit organizations that are often-interconnected. Although it shares many similarities with organ procurement, the tissue industry has gone through its rapid development with scant public exposure or scrutiny. In contrast, organ transplant is supervised with a national allocation system managed by the Organ Procurement and Transplant Network (OPTN)

Reports of unethical practices in the procurement and sale of human bodies and tissues are increasing in the media and in best-selling books. Earlier this year Annie Cheney published a compelling book, *Body Brokers: Inside America's Underground Trade*.¹ Mary Roach approaches the 'grave' subject with humor in *Stiff: The Curious Lives of Human Cadavers*.² Articles in the *Orange County Register*³ reported that some tissue processing and distribution companies were making undue profits and that their executives were drawing inappropriate salaries. The *Boston Herald*⁴ printed this quote from the chairman of the Health Law Department of

Boston University's School of Public Health, "*The market for body parts has become very lavish – skin, brain, and heart valves are not just used for research but are part of a for-profit industry now. People need to be informed of this.*"

Contributors to the scholarly publication *Transplanting Human Tissue*⁵ include physicians, academics, government agencies and procurement organizations who voice their concerns about the tissue industry and uniformly agree that better governance, legal regulation and public education are needed.

The growth in this new industry also raises important ethical and policy issues. Although federal law prohibits profiteering from organ and tissue sales, many people have become rich by working in the industry, even in the non-profits. Tissue banks can charge "reasonable fees" for the services they perform but these reasonable fees are not defined.

Tissue processing can be complex and is a large part of the cost that is passed on to the customer or insurance provider. In this unregulated industry, an increasing amount of the processing and distribution is done by for-profit companies. Since the viability of the tissue processing company depends on the profits they generated from the donated tissue, the 'products' it produces may or may not meet with greater needs of society.

Safety Concerns

Incidents of disease transfer have occurred in about a dozen transplant cases during the last 25 years. Current regulations do not require tissue to be tracked from donor to recipient; or reports to be filed in cases of infections and other adverse events occurring to the recipient. An average of 50-60 grafts can come from a single donor, thus many potential recipients may be at risk when a donor's communicable disease is not identified. Philosophically, it is hard to accept that human tissue is less regulated than metallic or synthetic implants. The public has a right to expect transplant products, including human tissue, to be safe.

Government Oversight

Government regulation has not kept up with the rapidly expanding field. Today, there are over 300 tissue banks in the US registered with the Food and Drug Administration (FDA). Federal regulation of tissue banks began in 1993. Then, as now, their main goal is to insure safety and prevent the spread of disease. Hampering their efforts to regulate this industry is that no reliable national data exist about the distribution and use of human tissue. In addition, there is limited federal and state law governing tissue transfers.

Industry Standards: Voluntary is Not Good Enough

The American Association of Tissue Banks (AATB) is the trade association for the industry. The AATB sets the 'Standards' and accredits tissue banks that pass inspection. Even though *the standards are voluntary*, less than one third of the 300+ tissue banks are members. The trade association is to be commended for its attempt to codify and regulate the industry, but there are too many organizations that are not operating by the AATB standards.

According to Jeffrey Prottas, Professor of Social Policy at Brandeis University and contributor to *Transplanting Human Tissue*, "The costs of processing are a large part of the costs of tissue and

are unregulated. The value of some tissue is high and profit in ‘manufacturing’ it for some uses is great. . . The complex mix of generally nonprofit tissue procuring banks, for-profit processors, unregulated pricing, and multiple and conflicting final tissue ‘products’ is a major cause of concerns about ethics in tissue banking and a major impediment to resolving concerns.”⁶

One of the recommendations made by Youngner et al in *Transplanting Human Tissue* is that “the tissue industry should adopt nationwide rules for the allocation and distribution of tissue, and provide for that system to be discussed and debated in public. Where voluntary action cannot rise to the occasion; government should step in – first to nudge, but if that fails, to enforce compliance.”⁷

The perception of wrong-doing and inequities in the distribution of tissue could mean that individuals might not receive the life-saving or life-enhancing organs and tissue to meet important medical needs. In addition, the perception could diminish the public’s inclination to donate and cause irreparable damage to the industry.

Allocation Standards

No agreed-upon criteria exist for the allocation of human tissue to recipients. Since tissue can be used for everything from saving the lives of burn victims, to saving limbs, to cosmetic enhancement, the choices faced in the production and distribution are far more complex than those facing the organ transplantation system. Adding to the problem is that hundreds of thousands more tissue transplants are done each year than organ transplants.

Professor Prottas states that “Neither the Association (AATB) or the FDA concerns itself with allocation issues or with the ethical conundrums that flow from them. Each local unit in the tissue banking system is free to set its own rules for the kinds of tissue it procures, how it deals with informed consent, and the final use to which its tissue is put. Not only is there no authoritative system-wide decision-making body . . . there is not even a permanent forum for the community to come together to discuss these matters.”⁸

The Funeral Consumers Alliance Takes a Stand

The Funeral Consumers Alliance strongly supports whole body, organ and tissue donation. However, it is concerned about abuses in “willed body” programs and with practices at certain cremation facilities. FCA is also troubled by reports of entrepreneurial profiteering in commerce of human tissue and failure to assure for fully informed consent. The public needs to be assured that the altruism motivating their gift, or the gift of a loved one’s body, doesn’t become raw material to enrich key people in the tissue industry. FCA has requested the National Conference of Commissioners on Uniform State Laws investigate these matters and FCA has also suggested amendments to the Uniform Anatomical Gift Act.⁹

AARP Endorsement Needed

The public is poorly informed about the range of possible uses of human cadaveric tissue, and the organization and financing of the industry. The term “informed consent” lacks meaning without the facts being known and uniform, enforceable standards. Organ and tissue donation can be the start of a healing process at the end of a loved one’s life or a very personal gift for the greater good at the end of one’s own life.

AARP is a leading voice for an aging America and the Tissue Issue is going to affect most of its members, either as recipients, a potential donors or surrogates. AARP and FCA's members, as well as the general public, rely on these organizations to provide factual, unbiased information and guidance on issues that affect their lives. AARP's research, support and advocacy can make a huge difference in educating the public and getting policies and regulations in place to protect the public.

I thank the National Policy Council for considering this request to look into The Tissue Issue and make a policy stand. Should any of the members or staff wish to reach me, I can be contacted at the mail address, e-mail address and phone number listed below.

Most sincerely,

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References

- ¹ *Body Brokers: Inside America's Underground Trade*, by Annie Cheney, Broadway Books, NY.
- ² *Stiff: The Curious Lives of Human Cadavers*, by Mary Roach. Norton, 2003.
- ³ **Orange County Register** published a series of articles in April 2000, entitled "The Body Brokers." On-line citation at <http://www.ocregister.com/features/body/>.
- ⁴ *Boston Herald*, May 19, 2003.
- ⁵ *Transplanting Human Tissue: Ethics, Policy, and Practice* by Youngner, Anderson, and Shapiro. Published by Oxford University Press, 2004
- ⁶ *Transplanting Human Tissue: Ethics, Policy, and Practice*, Chapter 9, "Ethics of Allocation: Lessons from Organ Procurement History," p. 129.
- ⁷ *Transplanting Human Tissue: Ethics, Policy, and Practice*, Chapter 13, "Concluding Thoughts and Recommendations," p. 188.
- ⁸ *Human Tissue: Ethics, Policy, and Practice*, Chapter 9, "Ethics of Allocation: Lessons from Organ Procurement History," p. 130
- ⁹ Letter written by FCA Executive Director and Chair of FCA's Legal Committee, to the National Conference of Commissioners on Uniform State Laws, dated July 1, 2003 can be found on the FCA website at: <http://www.funerals.org/UAGAWebLetter.htm>