

President Barack Obama
The White House
1600 Pennsylvania Avenue NW
Washington DC 20500

February 26, 2009

2009 Legislation

Additional regulation to ensure enforcement of Medical Directives

Dear President Obama,

My daughter, Robyn Libitsky, passed away from Ewing's sarcoma (rare form of pediatric bone cancer) on February 15, 2005 at age 29 at Kaiser Permanente Hospital in Woodland Hills California. What made this tragic situation unbearable was Kaiser Hospitalist Shahab Attarchi blatantly ignoring Robyn's instructions in her Medical Directive and requesting her corneas for donation by an unauthorized individual. The Medical Directive, in which she spent \$1000 to prepare by an Attorney, made specific her request not to be a donor as well as designating the individuals responsible for making those decisions.

For example, when physicians and staff refuse to adhere to Medical Directives, patient's families find it impossible to seek help through the probate court system, as it is costly and slow to act, further punishing the dying patient and their family. Medical Directive violations, regarding organ donation, occurring in a hospital, always involve the dying, recently deceased and their organs, requiring a timeframe of one hour to make a decision, the window in which organs remain viable.

Currently, hospitals such as Kaiser, disregard these laws, to keep them out of the organ procurement organization's radar ensuring their financial gain, as they are acutely aware, options are limited to prosecute them.

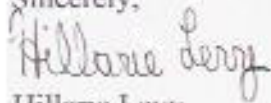
Enclosed please find correspondence from the Eye Bank Association of America and One Legacy in addition to a magazine article, all in response to the clear and convincing evidence presented to them regarding this violation.

Please be aware, had the unauthorized individual given permission for Robyn's unsuitable corneas to be donated, the implications for the recipient would have been deadly!

I am not asking you to solve my own issue, rather I am presenting you with documents as examples for the need of this legislation. The Congressman in my district, Elton Gallegly, has no interest in issues concerning medical or military, only environmental.

Medical Directives serve an important function in the organ transplant arena and although expensive to obtain, most wish to ensure their dying wishes are followed. Extending additional regulation and fines will provide a more effective way to ensure compliance of Medical Directives and safety in organ donation.

Sincerely,



Hillarie Levy
2958 Chippewa Avenue
Simi Valley, CA 93063
805-522-5188
Hillarie643@aol.com



Subj: **Letter to EBAA**
Date: 5/24/2007 7:32:07 A.M. Pacific Daylight Time
From: patricia@restoresight.org
To: Hillary643@aol.com
CC: acochran@onelegacy.org

May 24, 2007

Dear Mrs. Levy:

Your letter of May 23rd was on my desk this morning; please excuse the informal nature of this response, but I consider it the most expedient way to reach you.

First, please accept my sincere condolence on the death of Hillarie. The accompanying biographical sketch you provided described a lovely, vital and vivacious woman. Thank you for including this information on Hillarie. Any death is too soon, especially one whose life is ahead of her (many years ago, my 23 year old sister died of kidney disease).

Your description of the actions and behavior of medical personnel immediately following your daughter's death, is indeed, troubling, and it warrants a thorough investigation.

EBAA member banks are all charitable institutions whose mission is to provide corneas safe for transplantation; they have been recovering tissue for over 60 years. Medical standards are in place to set requirements that are scientifically based and that support the mission. Not all cancers are contraindications for corneal transplant, but it is distressing that customary standards of care and accepted procedures may have been violated. This response to you is copied to appropriate personnel at One Legacy.

Please keep me informed of the outcome of the process you have instigated, and in the meantime, I grieve with you over your tragic loss.

Sincerely
Patricia Aiken O'Neill
President and CEO
Eye Bank Association of America (EBAA)



October 5, 2007

Ms. Hillarie Levy
2958 Chippewa Avenue
Simi Valley, CA 93063

Dear Ms Levy:

Thank you so much for calling and sending me your information regarding your daughter's hospital experience. On behalf of all the staff at OneLegacy, we would like to express our deepest sympathy on the death of your daughter, Robyn. Our thoughts are with you and your family during this difficult time. I am so sorry for the terrible loss you must be feeling for your daughter, coupled with the difficulties of the inappropriate approach for corneas.

Although I can't speak for Kaiser's action, the normal procedure prior to speaking to someone concerning their loved one's death would be to read the chart and be sure of any advance directives that would help guide them in their conversation. If any indications of opposition to donation were noted in the chart, the hospital would call OneLegacy and report the death, along with advance directive information. We would then accordingly follow the directives.

I am so sorry this was not the procedure the hospital followed in your case, as you explain it. OneLegacy is dedicated to achieving the donation of life saving and life enhancing organs and tissues for those in need of transplants and to providing a sense of purpose and comfort to those families we serve. We take great pride in adhering to this mission, and whenever we hear from our donor families that we were unable to meet their needs, we know that we must try to prevent this from happening again. I have personally contacted Kaiser Woodland Hills Medical Center about this. They are providing additional training to their staff about advance directives prior to discussing end of life decisions with families and prior to calling OneLegacy.

I hope that knowing we care and that your persistence in bringing this to our attention so that others will not suffer undue stress at such a difficult and painful time will bring some comfort to you. We understand that words cannot eliminate the pain that you and your family may feel. Again, please accept our sincerest apologies.

Sincerely,



Jeff Fleming
Family Services Director

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four, CA 90010
20-6500
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Letters to the Editor

EDITORIALS & OPINIONS

Enforceable Regulations with Penalties Needed For Overseeing Tissue/Cornea Transplant Materials



by Vickie Travis

A few stories ago we learned in the *KaiserPapers* that an attending physician had attempted to obtain the cornea of a deceased patient by discreetly obtaining permission from the family. He had intentionally bypassed his hospital's contractually obligated and federally mandated organ procurement process.

This caused concern for the family mentioned above as they were aware that the patient had signed an advance directive forbidding any harvesting of organs or tissue/cornea.

Federal regulations state that a federally designated non-profit organization is responsible for coordinating organ donation and transplantation. They are also responsible for determining the viability and safety of the organs or tissues for transplant [1].

The State of California code states that the attending physician may have no part in this process and that advance directives must be respected [2, 3].

Unfortunately, there is no enforcement capability in existence nor is there any actual punishment for knowingly violating these regulations.

The criteria for cornea transplants are such that there are absolute exclusions - HIV positive, active cancer and systemic infections. The patient had died of a cancer that had spread into her bone marrow. If this harvesting had been allowed it is possible that the patient's dis-

ease would have spread to the recipient. Transmission of donor malignancy to the recipient could be one of the most serious complications of corneal grafting [4].

We asked for an opinion of a cornea specialist regarding the probable danger of the spread of disease under these circumstances. He did not think that there was much danger because of the lack of blood vessels in cornea. We later provided him the evidence that proved the risk is great enough that the patient should be informed and given the opportunity to make their own decision on using the potentially diseased donor tissue. Some of the diseases that can be transmitted through cornea transplant are known to often take months or years to develop and there is often no way to track their source.

It seems rather cruel if a child receives a diseased cornea that manifests into a life threatening disease years down the road that he or his parents had no say in the matter, even if the odds were considered low when the transplant was done. If that happens it still has happened, low odds or not and his life is shortened. If a person in their 70s or 80s wishes to take the risk of disease being spread years down the road that is another matter and one in which the risk is more realistic to take. Currently, there is little choice of patients having the opportunity to make these types of decisions.

We also did a quick, non-scientific survey to see, in general, how informed people in the medical field and private sector are on this topic. We also contacted the agencies that we were advised were regulating these issues to ask the same questions.

What we found is that no one cares. They do not know the facts and simply do not think that it is either possible to spread disease through the cornea or do not think that the risk is great enough for concern. There are numerous

studies that show how diseases can spread through cornea transplants. Yet, many people in positions of authority do not recognize or acknowledge the inherent dangers of these issues when obtaining cornea from bodies recognized as having potentially transferable disease.

We also wondered why any physician or their hospital or medical group would condone such a dangerous practice.

We found that in the United States you may not purchase a tissue or organ for transplant purposes. There is a processing fee however, that is charged by the contacting Organ Procurement Organization. The cornea processing fee costs around \$2,000.00. Synthetic cornea which do not carry the risk of disease run around \$7,000.00 [5].

We noticed that a facility that routinely performs cornea transplants and does harvesting at the same location could save some money by bypassing the Organ Procurement Organization. We also checked with the Organ Procurement Organization that should have been involved in this matter and found that their primary concern was the contract violation. It sounded as if their concern would have been the money they missed out on if the family would have allowed the harvesting of the cornea.

The most common transplanted organ/tissue in the United States is the cornea. In 2005 based on information provided to the U.S. Census Bureau by Organ Procurement Organizations and transplant centers there were 71,324 cornea grafts [7]. According to the National Eye Institute - the cost of the operation itself runs around \$5,000.00 [6].

We also found out that there really is no law protecting anyone, although the Organ Procurement Organizations lead people to believe that there is legal protection.

There is a Federal regulation instructing the Joint

Commission to oversee these issues but at best their recommendation, if they so choose to issue one, is that Medicare funding could be withdrawn. The Joint Commission on Accreditation of Health Care Organizations (JCAHO) sets donor standards and requires hospital policies and procedures for organ and tissue procurement. In a perfect world this could be a good system but it is not.

Perhaps this is a case of good intention not having proper follow through. In any event with what took place with the deceased and her family mentioned in this editorial, good intention is not good enough.

Sources:

1. (US Federal Code 42CFR482.45 also known as the Routine Death Notification Legislation re Facilities, Sec. 482.45)
2. Health and Safety Code Health 7154(b) (transplant protocol -listing organs from patients)
3. California Probate Code 771.5(a) (living patients wishes in their Medical Directive, a legal document) is also supposed to cover these issues. The attending physician may have no part in this process according to regulation.
4. *BOYS*, April 2006, Vol. 47 No. 4 Experimental Study of the Survival of Metastatic Cancer Cells in Corneal Organ Culture
5. Wikipedia - I found so many different upwards errors cited that Wikipedia seemed a moderate and reasonable source to cite. http://en.wikipedia.org/wiki/Corneal_transplantation#Risks
6. http://www.census.gov/comprod/health/health_instructions/
7. www.nia.nih.gov/newsroom/releases/101462.asp

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