

1 [Slide]

2 The criteria in that appendix include the
3 following, persons with a diagnosis of CJD or a person with
4 a family history of CJD; persons with a history of dementia
5 or degenerative neurologic disorders of viral or unknown
6 etiology; persons who have received injections of human
7 pituitary growth hormone; and persons who are known to have
8 received transplants of human dura mater.

9 [Slide]

10 In addition to our standards and the appendix to
11 those standards, the AATB provides a uniform donor
12 assessment record, or questionnaire if you will, for its
13 members with an accompanying rationale that they can use.
14 Several of the questions on that questionnaire aim to
15 directly screen for CJD.

16 [Slide]

17 For example, on that questionnaire, since there is
18 always a risk of disease transmission when someone has
19 received an organ or tissue transplant we ask whether the
20 potential donor ever received organ or tissue transplants,
21 for example, bone, cornea, skin, heart, kidney or,
22 specifically, dura mater.

23 [Slide]

24 In addition, under our standards degenerative
25 neurological diseases and dementia are deferred from tissue

1 donation because we have found that many neurological
2 degenerative diseases are of unknown etiology and,
3 therefore, should be deferred as suspect for infectious
4 disease.

5 [Slide]

6 Because of that, we have a query whether the
7 potential donors suffer from any type of neurological or
8 brain disease such as Alzheimer's seizures, periods of
9 confusion or recent memory loss, history of brain tumor. Has
10 the potential donor or any of the donor's relatives had CJD?

11 [Slide]

12 In addition, our standards specify that receipt of
13 the human pituitary derived growth hormone results in
14 deferral of tissue donation because it has been associated
15 with transmission of CJD.

16 [Slide]

17 We ask and inquire whether the potential donor has
18 been given the human pituitary derived growth hormone.

19 [Slide]

20 We also have a question on our questionnaire that
21 deals with travel outside the United States, but up to this
22 point, quite frankly, that question has been aimed at
23 delineating malaria risk and determining donors who would be
24 deferred for that reason.

25 [Slide]

1 There are various spots in the donor screening
2 process where the individual can be deferred from the point
3 of self-deferral at the beginning of the process either by
4 the donor himself or the donor's family through the consent
5 process and the donor screening process, and these are
6 different points that I won't go into at this point.

7 [Slide]

8 Let me summarize very quickly by saying that we
9 first issued our standards in 1984, and since that time we
10 have had criteria in those standards for screening for CJD.
11 At the beginning, we listed in the deferral criteria history
12 of degenerative neurological disorders. Over the years those
13 criteria have been expanded with successive additions to our
14 standards. In 1989 we put in the deferral for the human
15 growth hormone, and we also put in a provision on the co-
16 mingling or pooling of tissues during processing and
17 packaging. This year we have added questions regarding
18 family history of CJD and we continue to assess these with
19 each successive addition to our standards. I thank you very
20 much for your time.

21 [Applause]

22 DR. FREAS: Thank you. Dr. Brown has asked that I
23 call the people who have requested to speak in the open
24 public hearing. Dr. Glasser who will not be here tomorrow.
25 Do committee members have questions for Dr. Glasser?

1 DR. BELAY: Dr. Glasser, how does your criteria
2 compare with the one that we just heard from the American
3 Association of Tissue Banks.

4 DR. GLASSER: It is not identical, and not being
5 an expert on the AATB's criteria, I am afraid I am not
6 really qualified to comment on that.

7 DR. BELAY: They are not identical?

8 DR. GLASSER: They are not identical.

9 DR. BURKE: You mentioned that there were some
10 cities with shortages of donors and I don't have a sense for
11 that. Currently, are there waiting lists? How long does a
12 person wait, and do people go without corneal transplants in
13 the United States today because of lack of donors?

14 DR. GLASSER: Currently there is not much of a
15 waiting list for corneal tissue. Most corneal transplant
16 surgery is done on a scheduled basis. That is a change from
17 probably 10 or 15 years ago when patients were on waiting
18 lists. It is more than simply an issue of patients waiting.
19 It is also an issue of quality of the team that is available
20 for the surgeon to do the surgery. When there are waiting
21 lists and the tissue becomes available, since the surgery
22 cannot be scheduled in a regular fashion with the OR, you
23 usually go in the evening after the normal patients are done
24 and you aren't likely to get the experienced ophthalmic team
25 to work with you unless you are working in a specific

1 dedicated eye OR. So, there are a number of other issues
2 besides simply how long the patient has to wait.

3 But to answer your question, currently those
4 cities that use a lot of tissue obtained via legislative
5 consent do not have long waiting lists. The concern is that
6 they would if the tissue were no longer available.

7 DR. BELAY: My understanding is that currently you
8 probably have a surplus of corneas and that you probably
9 export some of them outside the United States. Is that true?

10 DR. GLASSER: Yes, I think the estimate is that
11 approximately 10,000 corneas are exported to other
12 countries. It is not certain how many of those actually end
13 up being transplanted. I think, as I briefly referenced,
14 while all of this tissue meets EBAA and FDA standards, there
15 is an issue with education of U.S. surgeons in terms of
16 accepting tissue from older donors or where the death to
17 surgery time may be a little longer. Probably it is going to
18 require some education of surgeons to make this tissue more
19 easily placeable. I think probably what is going on is you
20 have the best of the best, the cream of the cream tissue
21 being used by U.S. surgeons.

22 DR. DETWILER: You mentioned there was a time
23 constraint on how long it can be from collection to the use.
24 What is that time? Because if you say they export it, it
25 must not be within an hour.

1 DR. GLASSER: Right. There are a couple of time
2 frames that are important. One is the time between death of
3 the donor and preservation of the tissue. Different banks
4 have different criteria and that is not specifically
5 addressed by the EBAA medical standards.. The shorter the
6 time from death to preservation, the better.

7 But the issue in terms of exported tissue versus
8 placing tissue is really the time between death and the time
9 of surgery. Most surgeons in the U.S. prefer to get that
10 tissue into their patient within four to five days. Now,
11 sometimes that time can be extended up to seven days or even
12 ten days. A lot of it will depend on the urgency of the
13 need. You are certainly going to be more inclined to use an
14 older cornea if you have someone who has a ruptured globe or
15 an infection and they are going to lose the eye if you don't
16 out a cornea in there right away. If nothing better is
17 available that cornea will be used. It is much harder to
18 place that cornea that is five or seven days old for a
19 normally scheduled transplant that is being done for
20 restoration of vision.

21 DR. SOLOMON: I did have a question but I think it
22 nas been answered, but I could just ask you to comment. I
23 believe EBAA keeps statistics yearly, and what do the trends
24 show in terms of overall cornea donation and exportation?

25 DR. GLASSER: I am afraid I don't have those

1 numbers in front of me. The total number of donors per year
2 and total number of transplants used per year have been
3 relatively stable. We have seen in the last two or three
4 years some decrease in the number of corneal transplants
5 done in the United States. I am not sure if this is related
6 to improvement in surgical technique for cataract surgery or
7 other factors, and I don't know if that is going to continue
8 to decline or not.

9 We face another issue in terms of corneal supply,
10 which is out there but hasn't been discussed, and that is
11 the explosion of population of refractive surgery. Currently
12 EBAA medical standards exclude the use of tissue from donors
13 that have undergone PRK or Lasik, RK or other refractive
14 surgery. That tissue can only be used in tectonic graft
15 cases where you are restoring the structural integrity of the
16 globe. It is not acceptable for use in the bulk of
17 transplants which are done for optical reasons.

18 DR. ROOS: I just want to make sure I understood
19 what your program of the legislative consent really
20 involves. There are only certain states, and most of these
21 cases are acute ones that may be sudden deaths perhaps. So,
22 what happens in all the other states to those corneas?

23 DR. GLASSER: There are legislative consent laws
24 in probably many more states than actually there are states
25 where they are being used. I think from the list of banks

1 you saw, primarily Florida and Texas and Maryland are the
2 three states where we see a substantial number of
3 transplantable corneas coming from legislative consent. But
4 what happens is most of these are sudden deaths -- gunshot
5 wounds, car accidents, things of that sort. This is where
6 the issue of time from death to preservation starts to
7 actually play a bigger role because there often is a delay
8 between the time of death and when the eye or tissue bank
9 gets notice of that. The difficulty in finding and
10 contacting a next of kin is believed by the banks that use a
11 lot of this tissue to create a barrier which would
12 eliminate, in their estimation, 90 percent of the tissue.
13 That is a very soft number. No one has tried it so they
14 don't know, but the banks that use a lot of this tissue tell
15 us that they believe that the vast majority of that tissue
16 would not be recoverable if they had to find an appropriate
17 person to do a donor medical history.

18 DR. NELSON: Can you clarify a little bit on the
19 age distribution, or median age, or whatever, of the corneal
20 recipients? The reason I ask this question is that the
21 previous comment, made by Dr. Schonberger, about the lack of
22 spontaneous CJD, I wondered are these mostly done on older
23 people or is there quite an age range?

24 DR. GLASSER: I am afraid I can't give you
25 specific numbers but I can tell you that there is probably

1 bimodal distribution. There is a subgroup of recipients that
2 are young adults, which tend to be trauma cases, patients
3 with keratoconus -- misshapen corneas, but they are probably
4 the smaller peak. The larger peak are people in their 60's
5 and 70's and beyond who are being transplanted because of
6 corneal edema, previous cataract surgery or Fuch's dystrophy
7 which causes the cornea to cloud over. Those are probably
8 the most common ones. There is a scattering of scars from
9 infection at any age, but I think we see probably a peak in
10 the younger group and then a much larger peak in the 60- and
11 70-year olds.

12 DR. NELSON: My understanding is that their CJD
13 increases up until the sixth or seventh decade and then
14 declines after that.

15 MS. FISHER: Transplantation is a voluntary
16 procedure. Is there disclosure to the recipient that there
17 is a theoretical risk of CJD?

18 DR. GLASSER: That is between the surgeon and the
19 patient. It is my belief that that issue is probably not
20 broached in the majority of cases because the risk is so low
21 based on what we know so far. There has been no case since
22 1975. Taking off my EBAA hat and putting on my corneal
23 surgeon hat, when I discuss the risk of surgery with my
24 patients I talk about the things that are likely to happen,
25 and then I lump in death, stroke, heart attack, going blind,

1 osing your eye as less than 1 in 1000 risk. So, that is how
2 describe it to my patients and I suspect that is how most
3 surgeons describe it without specific mention of CJD.

4 MS. FISHER: Rather than moving for restrictions,
5 ouldn't disclosure of theoretical risk be a compromise?

6 DR. GLASSER: Well, as Dr. Confer pointed out, I
7 think the last point on this slide was that he felt that the
8 best place to put the responsibility for this would be
9 between the surgeon and the patient, and I think it is my
10 personal belief that that is the appropriate place to put
11 that rather than in a regulatory sphere, given the fact that
12 the risk, as we know it now, appears to be so low.

13 DR. DETWILER: You had mentioned that the age of
14 the donor for legislative consent happens to be young. Is
15 that by happenstance because of sudden death or is it by
16 requirement?

17 DR. GLASSER: No, it is by happenstance. That just
18 happen to be the demographics of the population that comes
19 to legislative consent.

20 DR. FREAS: Last chance to question Dr. Glasser?
21 Thank you very much, Dr. Glasser. We appreciate it.

22 Now we are in the open public hearing and I will
23 call the speakers as I received the requests from our
24 announcement in the Federal Register. The first requester
25 was Mr. Jake Requard, managing director of Vision Share.

1 Open Public Hearing

2 MR. REQUARD: Thank you, Dr. Freas, for allowing
3 Vision Share to make public comment. Vision Share is a not-
4 for-profit eye bank consortium whose main purpose is to
5 coordinate the sharing of donor corneas for transplant.
6 Among our 13-member eye banks and with other United States-
7 based non-member eye banks and corneal surgeons, corneas are
8 distributed and shared on both the domestic and
9 international basis.

10 Based on the 1999 Eye Bank Association of
11 America's statistics, Vision Share accounts for
12 approximately 30 percent of the supply of transplanted
13 corneas generated in the United States. All Vision Share eye
14 banks are accredited members of the EBAA. From the 1999 EBAA
15 data, there were 45,765 donor corneas recovered for
16 transplant by U.S. eye banks. Almost 28 percent of this
17 volume, or over 12,000 corneas, were sent to users outside
18 the United States during this year. Many of these corneas
19 were from donors under age 65.

20 Vision Share supports the FDA's continuing efforts
21 to examine donor screening procedures to ensure that
22 recipients of transplanted human tissues and cells receive
23 donor materials that have normal risk of disease
24 transmission. In regard to the topic of this meeting, our
25 comments and observations are related to practical measures

1 that are routinely taken by our member eye banks, that can
2 be employed by all eye and tissue banks to screen for TSEs,
3 specifically CJD.

4 Section D1.120 of the EBAA medical standards list
5 Creutzfeldt-Jakob disease and family history of a blood
6 relative with Creutzfeldt-Jakob disease as a
7 contraindication to surgical use of donor tissue due to
8 possible transmission being threatening to the health of the
9 recipient. Most U.S. eye banks routinely include questions
10 about CJD and their next kin medical-social history
11 interview questionnaires, which are an essential part of the
12 donor screening process. Specific questions are asked about
13 the donor having a history or symptoms of CJD, or if a blood
14 relative has had this disease. In some cases, some eye banks
15 are using the panel of five quadrate prodrome questions
16 proposed by the EBAA medical advisory board to screen for
17 CJD, in June 1999.

18 It has not been our experience that this aspect of
19 donor screening has resulted in a significant decrease in
20 the number of corneal donors of transplant quality. However,
21 several eye banks have anecdotally reported obtaining
22 affirmative responses to questions about referred donors
23 having been diagnosed with CJD or having blood relatives
24 with CJD resulting in the donor corneas not being recovered
25 or used for transplantation.

1 One eye bank indicates that if any of the five
-2 questions are answered positively, additional investigations
3 are made using information from the donor's medical records
4 and through consultation with the attending physician to
5 rule out the possibility of CJD, along with consultation of
6 the eye bank's medical director. There have been no problems
7 reported by this eye bank using these screening questions,
8 whose age criteria for transplant corneas is 75 years.

9 It is also common for many eye banks to ask
10 families during the interview process about foreign travel
11 to screen for possible exposure to other infectious
12 diseases. Eye banks must also screen donors for previous
13 refractive surgery since the EBAA medical standards
14 currently only allows the use of these corneas for tectonic
15 corneal grafts to restore the structural integrity of the
16 patients eye. Obtaining information from the donor's family
17 is currently the only known effective way to screen for this
18 condition. A practical standard eyes method for detecting
19 such previous surgery in the donor cornea has not been
20 developed at this time.

21 From a cellular therapy perspective, this level of
22 screening should be required for any eye donor whose tissues
23 may in the future be used for retinal cell transplants to
24 treat various diseases in that part of the eye. Research has
25 been under way for several years using both fetal and adult

1 donor cells.

2 Vision Share is also currently working with a
3 pharmaceutical company to provide them with retinal pigment
4 epithelial cells from neonatal donors as a possible therapy
5 for Parkinson disease under an investigational new drug
6 regulation. These cells will be transplanted into the
7 substantia nigra region of the brain during upcoming planned
8 clinical trials. These neonatal donors are screened by
9 obtaining a maternal medical-social history by the source
10 eye bank in a manner that is consistent with procedures for
11 adult eye donors.

12 In conclusion, Vision Share recommends routine use
13 of medical-social history interviews, with informed next of
14 kin, along with consultation with attending physicians when
15 needed to screen tissue and cell donors for both CJD and
16 other medical contraindications in order to maximize the
17 biosafety of donor tissue and cells for recipients. Thank
18 you very much.

19 [Applause]

20 DR. FREAS: Thank you. The next speaker is Mr.
21 Gerald Cole, president and CEO of Tissue Banks
22 International.

23 MR. COLE: Thank you for the opportunity to
24 address the committee. I think there is a handout with a lot
25 more information but what I intended to is provide some

1 supplemental information.

2 [Slide]

3 My organization, Tissue Banks International, is a
4 non-profit organization. We operate 33 U.S. eye and tissue
5 bank locations in the United States. We also have an
6 international outreach program where we work with 41 eye and
7 tissue banks around the world. Our primary office is in
8 Baltimore, Maryland.

9 [Slide]

10 This is, I think, an important thing to understand
11 about different profiles of different donors. You have
12 hospital donors that are not medical examiner donors. You
13 have hospital donors. There are donors that don't go through
14 hospitals or medical examiner offices; some that go through
15 hospitals, not medical examiner offices; then you have the
16 profile of a legislative consent donor.

17 I just want to point out that sometimes all you
18 have is a family interview for those that don't go through
19 medical examiner or hospitals. But in the legislative
20 consent cases you always have an autopsy. You always have an
21 investigative report, and you often have additional
22 objective information.

23 [Slide]

24 There are 2200 corneas that were obtained from
25 programs around the country that use legislative consent

1 medical examiner programs. That represents 5 percent of all
2 the transplantable corneas recovered, 7 percent of all the
3 transplanted corneas in the United States, accounting for
4 the exports. But eye banks are largely community based. They
5 draw from and serve their communities and, depending on the
6 program, between 40 and 90 percent of those banks rely on
7 corneas from those sources.

a [Slide]

9 This is important too because for medical examiner
10 cases typically CJD cases are not reported to the medical
11 examiner's office. CJD cases are typically not autopsied by
12 the medical examiners' offices -- we spoke to a lot of the
13 pathologists and medical examiners that we work with -- nor
14 do they want to. If there is any infectious disease case, it
15 is off limits to the eye bank.

16 [Slide]

17 This is a profile of what the statistics we went
18 through in 1998 for the medical examiner's office for the
19 State of Maryland, and our own records from the Medical Eye
20 Bank of Maryland. There are over 8000 cases reported. Three
21 thousand were autopsied. Every year they issue an annual
22 report, the medical examiner's office does, and of all the
23 cases that were reported on autopsies, all nervous system
24 diseases of all sorts -- and this is where CJD type cases
25 would be classified -- amounted to 43 and 4 respectively on

1 the reported versus autopsied cases, representing the
2 percentages shown there. We had 125 cornea donors out of
3 that large denominator, and we had zero cases that we got
4 for cornea donations from the NSD cases, either reported or
5 autopsied. With the prevalence of CJD, you would think that
6 statistically we would have seen at least one or two cases.

7 [Slide]

8 I was asked to comment on the international
9 aspects too because corneal blindness in the world -- the
10 World Health Organization estimates there are 10 million
11 people corneally blind and we are lucky enough to have good
12 programs here, and we do provide tissue to other countries
13 in need. These other countries characterize themselves in
14 two ways, an Opt In System, which would be close to a
15 consent system, and an Opt Out System, which would be akin
16 to our legislative consent system.

6:00 p.m.

17 [Slide]

18 We have some of our own data to give you an idea
19 about what is happening there. We work with 25 countries
20 around the world. Eight of them have Opt Out Programs, 17
21 have Opt In Systems, and you see the number of banks. But
22 the one thing that we can say outside of the United States
23 is that we don't know of any other country in the world that
24 supplies their own needs for corneal tissue with an Opt In
25 System. So, opt Out Systems are very important to these

1 other banks, and the other eye banks, the global eye banking
2 community really looks to the United States to see what we
3 are doing in terms of standard setting.

4 [Slide]

5 I have some comments about corneal exports. I
6 think 12,745 was what was reported in the last year, 1999.
7 These are used in countries where moderate to severe
a shortages persist. Now, this is a soft number. In this
9 country we have a pretty good idea -- a very good idea
10 whether the cornea was used or not, and how the outcome came
11 about. In a lot of these other countries we are not sure if
12 the corneas were' actually used. It is frequently
13 unconfirmed. The highly rated corneas, as I think was
14 mentioned earlier, are used in the United States. The corneas
15 from legislative consent ME programs typically are not the
16 ones that are sent outside of the country.

17 I have some summary comments but I will just
1a mention the same one. I think that we have been operating
19 with this kind of exception criteria under the FDA
20 regulation for these programs for HIV. Safety doesn't seem
21 to be an ongoing issue, and I think that they can coexist
22 with the concerns about CJD. Thank you for your time.

23 [Applause]

24 DR. FREAS: Thank you, Mr. Cole. Our next speaker
25 is Dr. Joseph Davis, who is acting director of Miami-Dade

1 County Medical Office.

2 MR. COLE: He asked me to tell you that he had to
3 leave to catch a flight. I think he is going to provide some
4 written comments.

5 DR. FREAS: We look those written comments and we
6 are sorry that we are running so late. The next presenter is
7 Theresa Wiegmann, from the American Association of Blood
8 Banks, Office of General Counsel.

9 MS. WIEGMANN: Hello. My name is Theresa Wiegmann,
10 and I am general counsel and director of government affairs
11 for the American Association of Blood Banks. I will try to
12 keep my oral statement a little abbreviated today, given the
13 time and given the fact that earlier Dr. Confer made several
14 of the points that AABB would like to make.

15 The American Association of Blood Banks is the
16 professional association of approximately 8000 individuals
17 and 2000 institutions, including blood collection centers,
18 hospital-based blood banks and transfusion services. AABB's
19 members are involved in all aspects of the collection,
20 processing and transfusion of blood, as well as
21 hematopoietic progenitor cells, or HPCs.

22 The AABB appreciates the opportunity to comment on
23 the potential deferral of certain HPC donors due to the
24 potential risk of transmitting CJD or vCJD. As we have
25 stated before to this committee, the AABB believes that

1 patient welfare must be the utmost consideration when
2 determining to implement any new donor deferral policies.

3 In deciding whether to adopt a new deferral policy
4 relating to HPCs, the Food and Drug Administration should
5 carefully balance all relevant risks and benefits to the
6 patients. It should be noted and emphasized, we believe,
7 that the treatment of patients with HPCs involves unique
a patient safety and product supply issues that are different
9 from those involved in the context of blood transfusions.
10 HPCs are used in the treatment of patients battling life-
11 threatening conditions, including several cancers as well as
12 immune disorders. For many patients HPC transplants
13 represent their last hopes for survival.

14 As we have heard, HLA matching is particularly
15 important with hematopoietic progenitor cells, and because
16 of the importance of getting the right HLA match, many
17 patients needing these transplants do not have the ability
18 to turn to alternative donors. Presently, the balancing of
19 risks and benefits of HPC transplants is left to the
20 treating physician in consultation with his or her patient.
21 Information about U.K. and other potential deferrals is kept
22 in the donor profile records to be considered by the
23 transplant physician and the patient. Other deferral
24 criteria currently applied to blood donors do not
25 necessarily automatically apply in the context of HPCs. For

1 example, in certain instances patients are given bone marrow
2 that tests positive for certain bacteria or pathogen
3 markers.

4 Given the unique circumstances involving HPC
5 transplants, the AABB strongly believes that further inquiry
6 into the possible effects of a CJD-related deferral policy
7 should be undertaken before adopting a new policy for these
8 products. This inquiry should involve the advice and counsel
9 of the treating physicians, of patient advocates and of
10 medical ethicists, and should consider the unique range of
11 issues facing severely ill patients awaiting HPC
12 transplants.

13 The AABB would welcome the opportunity to work
14 with this committee, the FDA and others in the transplant
15 community in addressing this important issue. Together, we
16 must all strive to ensure that patients awaiting and
17 depending on HPC transplants receive the best possible care.
18 Thank you.

19 [Applause]

20 DR. FREAS: Thank you. Is Bess Beliveaux here, the
21 executive director of Lions Ocular Bank of Central Texas?
22 Yes?

23 MS. BELIVEAUX: I am Bess Beliveaux, executive
24 director for the Lions Eye Bank of Central Texas, in Austin,
25 Texas. For more than twenty years I have worked with and for

1 medical examiners' offices and with and for donor programs.
2 Throughout these years, I have spoken with hundreds of
3 families regarding the death of their loved ones. Though
4 well intentioned, my experiences have been that the majority
5 of those interviewed are limited in their abilities to
6 provide accurate medical and social information. What I have
7 to share with you today is anecdotal and I believe very
8 important for you to know. Some examples of conversations I
9 have had with families include this: "The only time he's
10 been sick is when he was born brain dead, but the doctors
11 fixed him."

12 Another very poignant example was when a 70-year
13 old fireman, chief of the fire department in a small Texas
14 town, died suddenly while fighting a fire. His wife very
15 much wanted to honor his wishes and have him become a donor.
16 She provided us with a medical and social interview that was
17 clear of all contraindications. He had hypertension and he
18 had a history of heart disease. When the eye bank technician
19 showed up at the hospital to recover the donor tissues and
20 began to do the external exam, they were most alarmed when
21 they found that the gentleman was wearing pink lady's
22 underwear and had numerous penile and scrotal piercings that
23 were fresh. It goes to show, I believe, that even the most
24 close next of kin does not always know of one's activities.

25 Another example is a colloquialism. I interviewed

1 a family about the death of a young girl, and the mother
2 said when she was a child she was sick. She had "screamin'
' 3 mighty Jesus." Had I not known that that was a colloquialism
4 for spinal meningitis I would have probably chalked it up as
5 just some cookie mom.

6 A farther reported that his son, in his late
7 teens, had a perfectly clean medical and social history --
8 no history of piercings, no history of tattoos. The organ
9 bank took the medical and social history and, after
10 recovering the organs, the eye bank came in to recover donor
11 corneas. At that time we performed a routine external body
12 exam and found that the young man's back was nearly covered
13 with fresh tattoos.

14 Family members told the staff at a local emergency
15 room, local to Austin, that their mother had a medical
16 history positive for some disease that started with "H." The
17 emergency room staff recorded this as hepatitis. Well,
18 because that was the only reference, we recovered the
19 tissues hoping that we could talk with this patient's
20 primary care physician and clear up the matter because there
21 was absolutely no other indication that this was the case.
22 Unfortunately, that physician was not readily available
23 until we had to destroy the tissues. Afterwards he called
24 and he said, oh, no. No. She had hemorrhoids. Her serologies
25 were non-reactive.

1 A father and a mother reported that their son, a
2 victim of suicide, had put on his driver's license that he
3 wanted to be a cornea donor. They were very patient and
4 provided a thorough medical and social history on the young
5 man. Because he was a suicide victim, he was taken to our
6 local medical examiner's office. At that time, the eye bank
7 technician easily discovered that the young man had a recent
8 and prolonged incarceration that did rule him out as a
9 potential donor.

10 My last example is one that is also, in my
11 opinion, very poignant, a mother and her children and
12 extended family sat in a family room of a local emergency
13 room and provided our eye bank coordinator with very
14 extensive, clean medical and social history on the father,
15 the spouse, who had died suddenly. When our eye bank
16 coordinator thanked the family and got up to walk out, the
17 wife got up and walked after her and said, "I didn't want my
18 children to know. He was very promiscuous with prostitutes."
19 How many times might this happen and they never come forward
20 and confess? How many situations exist when the opportunity
21 to confess might not be present?

22 I am not implying that all social and medical
23 histories are blatantly misleading, far from it. I believe
24 that everyone's intentions are very good. The other factor
25 to consider is that often misconceptions that arise can be

1 so subtle that without a confession we might never know.

2 Family members typically do not intend to provide
3 this misleading and incorrect information. Perhaps it is
4 that our society has become so mobile and we have been so
5 far removed from the family nucleus that accurate and
6 correct information isn't always available through this
7 interview.

8 Also, many family members simply are not savvy
9 enough regarding medicine and/or social contraindications.
10 It is my experience and belief that the medical-social
11 interview is rarely, if ever, of true value in evaluating
12 the usability of donor tissues. Especially, I am concerned
13 that we are considering this source of information as a
14 defining factor for determining the suitability of donated
15 non-vascular corneal tissues. Additionally, I believe a
16 donor that has the advantage of a medical examiner
17 investigation and forensic autopsy is one that comes with
18 infinitely more accurate medical and social information.

19 I appreciate your role to provide for public
20 health and safety. It is with this in mind, therefore, that
21 I ask this advisory committee' to explore options other than
22 medical-social interviews of a decedent's next of kin for
23 determining a potential donor's risk for transmitting
24 spongiform encephalopathy or any other prion disease.

25 Also, I have provided this committee with letters

1 from corneal surgeons, a forensic pathologist and a
2 neuropathologist regarding this matter of screening
3 potential donors for TSE and other prion diseases.

4 Before I conclude, I would like to let you know
5 that, yes, our eye bank does use the legislative consent to
6 recover corneas and loss of this ability to recover these
7 donor tissues in a timely manner could very easily mean the
8 loss of 400 to 600 very viable donor corneas that currently
9 are being used, in the majority, to serve our central Texas
10 36 counties that comprise our eye bank service area. I
11 appreciate what you do and I very much appreciate that you
12 all stayed so late to let us talk. Thank you.

13 [Applause]

14 DR. FREAS: Thank you. Is there anyone else in the
15 audience who at this time would like to address the
16 committee? Seeing none, Dr. Brown, I turn the microphone
17 over to you.

18 DR. BROWN: We will adjourn until 8:30 tomorrow
19 morning, at which time we will begin discussion and votes on
20 this issue, topic 2.

21 [Whereupon, at 6:15 p.m., the proceedings were
22 recessed, to resume on Friday, January 19, 2001 at 8:30
23 a.m.]