

*Animal-Derived Dietary Supplement
Ingredients*

Robert J. Moore, Ph.D.
Office of Nutritional Products, Labeling and
Dietary Supplements
Division of Compliance and Enforcement
Food and Drug Administration

1

*Legal Basis for Animal-Derived
Ingredients*

- Dietary ingredients defined in 21 U.S.C. 321(ff)(1)
- Include "a dietary substance for use by man to supplement the diet by increasing the total dietary intake"

2

*Legal Basis for Animal-Derived
Ingredients*

- Also includes "a concentrate, metabolite, constituent, extract, or combination" of a defined ingredient
- Dietary substance = substance customarily used as human food or drink

3

Basic Regulatory Framework

- FDA can regulate dietary supplement ingredients
- Is, generally, a post-market regulatory scheme, except for “new dietary ingredients”
- No premarket review or approval by FDA

4

Basic Regulatory Framework

- Manufacturer is responsible for ensuring the safety of finished products and ingredients
- Does not have to share basis with FDA before marketing
- Government has authority and tools to remove unsafe products

5

Basic Regulatory Framework

- Manufacturer must:
 - Ensure that product is a dietary supplement
 - Ensure that the product is safe
 - Label the product using the common or usual name of all ingredients
 - Disclose any material facts necessary for the consumer to make an informed choice

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*Animal-Derived Dietary
Ingredients*

- Animal tissue
- Substances from animal tissue
- Animal products and their constituents
- Other

7

Animal Tissue Ingredients

- Examples
 - Glands (adrenal, pituitary)
 - Organs (Liver, brain, lung)
 - Tissues (antler, blood)
- Not limited to bovine-derived
- Not limited to mammals

8

*Tissue-Derived Dietary
Ingredients*

- Glucosamine (from bovine trachea)
- Numerous metabolites
- Blood proteins

9

How Has FDA Addressed The Use of These Ingredients

- Industry letters issued in 1992, 1993, 1994, 1996, and 2000
- Inspectional requirements in FDA Compliance Program
- Import Alert #17-04

10

What Information Do We Have?

- Inspectional evidence indicates most ingredients are US- or Aust/NZ-sourced
- Is some export and re-importation of US-derived bovine ingredients
- Most firms appear to have a plan in place to document source of dietary ingredients

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Can FDA Act?

- YES!
 - Import restrictions
 - Enforcement actions against adulterated bulk and finished products
 - Development of regulations
 - Consumer outreach and education

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Greater New York Hospital Association

555 West 57th Street / New York, N.Y. 10019 / (212) 246-7100 / FAX (212) 262-6350
Kenneth E. Raske, President

January
Sixteen
2001

Paul Brown, M.D.
Chairperson of Transmissible Spongiform Encephalopathies Advisory Committee to the U. S.
Food and Drug Administration

Dear Dr. Brown:

The greater New York area is currently suffering from a serious blood shortage. Despite increased local blood collections and regular purchases from other U.S. blood centers, the shortage remains critical and has increased our reliance on other sources of blood supply, most notably from Europe. As things stand now, the increasing demand for blood in our area cannot always be met, and we anticipate the situation will only get worse. Further restrictions on our ability to import Euroblood at this time will create an even greater crisis.

We are, of course, committed to the availability of a *safe* blood supply for residents of the greater New York area, but we ask that you weigh carefully the necessity of imposing regulations that would restrict the supply of blood further, based on what some experts believe may be a theoretical risk only. We therefore urge the Advisory Committee to consider the full, broad-reaching consequences of restricting our ability to import blood from Europe, an action that would worsen an already critical shortage in the New York area.

Thank you for your thoughtful consideration of these issues.

My best.

Sincerely,

Kenneth E. Raske
President

WRITTEN SUBMISSION
FOR OPCW PUBLIC COMMENT

Freas, William

From: Terry S. Singeltary Sr. [flounder@wt.net]
Sent: Monday, January 08, 2001 3:03 PM
To: freas@CBS5055530.CBER.FDA.GOV
Subject: CJD/BSE (aka madcow) Human/Animal TSE's--U.S.--Submission To Scientific Advisors and Consultants Staff January 2001 Meeting (short version)

Greetings again Dr. Freas and Committee Members,

I wish to submit the following information to the Scientific Advisors and Consultants Staff 2001 Advisory Committee (short version).

I understand the reason of having to shorten my submission, but only hope that you add it to a copy of the long version, for members to take and read at their pleasure, (if cost is problem, bill me, address below). So when they realize some time in the near future of the 'real' risks i speak of from human/animal TSEs and blood/surgical products. I cannot explain the 'real' risk of this in 5 or 10 minutes at some meeting, or on 2 or 3 pages, but will attempt here;

remember AIDS/HIV, 'no problem to heterosexuals in the U.S.? no need to go into that, you know of this blunder.

DO NOT make these same stupid mistakes again with human/animal TSE's aka MADCOW DISEASE. I lost my Mom to hvCJD, and my neighbor lost his Mother to sCJD as well (both cases confirmed). I have seen many deaths, from many diseases. I have never seen anything as CJD, I still see my Mom laying helpless, jerking tremendously, and screaming "God, what's wrong with me, why can't I stop this". I still see this, and will never forget. Approximately 10 weeks from 1st of symptoms to death. This is what drives me. I have learned more in 3 years about not only human/animal TSE's but the cattle/rendering/feeding industry/government than i ever wished to.

I think you are all aware of CJD vs vCJD, but i don't think you all know the facts of human/animal TSE's as a whole, they are all very very similar, and are all tied to the same thing, GREED and MAN.

I am beginning to think that the endless attempt to track down and ban, potential victims from known BSE Countries from giving blood will be futile. You would have to ban everyone on the Globe eventually? AS well, I think we MUST ACT SWIFTLY to find blood test for TSE's, whether it be blood test, urine test, eyelid test, anything at whatever cost, we need a test FAST.

DO NOT let the incubation time period of these TSEs fool you.

To think of Scrapie as the prime agent to compare CJD, but yet overlook the Louping-ill vaccine event in 1930's of which 1000's of sheep where infected by scrapie from a vaccine made of scrapie infected sheep brains, would be foolish. I acquired this full text version of the event which was recorded in the Annual Congress of 1946 National Vet. Med. Ass. of Great Britain and Ireland. from the BVA and the URL is posted in my (long version).

U.S.A. should make all human/animal TSE's notifiable at all ages, with requirements for a thorough surveillance and post-mortem

examinations free of charge, if you are serious about eradicating this horrible disease in man and animal.

There is histopathology reports describing "florid plaques" in CJD victims in the USA and some of these victims are getting younger. I have copies of such autopsies, there has to be more. PLUS, sub-clinical human TSE's will most definitely be a problem.

THEN think of vaccine CJD in children and the bovine tissues used in the manufacturing process, think of the FACT that this agent surviving 600°C.

PNAS -- Brown et al. 97 (7): 3418 scrapie agent live at 600°C

Then think of the CONFIDENTIAL documents of what was known of human/animal TSE and vaccines in the mid to late 80s, it was all about depletion of stock, to hell with the kids, BUT yet they knew. To think of the recall and worry of TSE's from the polio vaccine, (one taken orally i think?), but yet neglect to act on the other potential TSE vaccines (inoculations, the most effective mode to transmit TSEs) of which thousands of doses were kept and used, to deplete stockpile, again would be foolish.

--Oral polio; up to 1988, foetal calf serum was used from UK and New Zealand (pooled); since 1988 foetal calf serum only from New Zealand. Large stocks are held.

--Rubella; bulk was made before 1979 from foetal calf serum from UK and New Zealand. None has been made as there are some 15 years stock.

--Diphtheria; UK bovine beef muscle and ox heart is used but since the end of 1988 this has been sourced from Eire. There are 1,250 litres of stock.

--Tetanus; this involves bovine material from the UK mainly Scottish. There are 21,000 litres of stock.

--Pertussis; uses bovine material from the UK. There are 63,000 litres of stock.

--They consider that to switch to a non-UK source will take a minimum of 6-18 months and to switch to a non-bovine source will take a minimum of five years.

3. XXXXXXXXXXXX have measles, mumps, MMR, rubella vaccines. These are sourced from the USA and the company believes that US material only is used.

89/2.14/2.1

=====

BSE3/1 0251

4. XXXXXXXXXXXX have a measles vaccine using bovine serum from the UK. there are 440,000 units of stock. They have also got MMR using bovine serum from the UK.

5. XXXXXXXXXXXX have influenza, rubella, measles, MMR vaccines likely to be used in children. Of those they think that only MMR contains bovine material which is probably a French origin.

6. XXXXXXXXXXXX have diphtheria/tetanus and potasses on clinical trial. These use veal material, some of which has come from the UK and has been made by XXXXXXXXXXXX (see above).

I have documents of imports from known BSE Countries, of ferments, whole blood, antiallergenic preparations,

human blood plasma, normal human blood sera, human immune blood sera, fetal bovine serum, and other blood fractions not elsewhere specified or included, imported glands, catgut, vaccines for both human/animal, as late as 1998. Let us not forget about PITUITARY EXTRACT. This was used to help cows super ovulate. This tissue was considered to be of greatest risk of containing BSE and consequently transmitting the disease.

ANNEX 6

MEETING HELD ON 8 JUNE 1988 TO DISCUSS THE IMPLICATIONS OF BSE TO BIOLOGICAL PRODUCTS CONTAINING BOVINE - EXTRACTED MATERIAL

How much of this was used in the U.S.?

Please do not keep making the same mistakes;
'Absence of evidence is not evidence of absence'.

What are the U.S. rules for importing and manufacturing vaccines, medicines and medical devices?

Does the U.S.A. allow sourcing of raw material of ruminants from the U.S.A.?

U.S. cattle, what kind of guarantee can you give for serum or tissue donor herds?

The U.S. rendering system would easily amplify T.S.E.'s:

Have we increased the stability of the system (improved heat treatments) since the EU SSC report on the U.S.A. was published in July 2000?

What is done to avoid cross-contaminations in the U.S.A.?

How can the U.S. control absence of cross-contaminations of animal TSE's when pig and horse MBM and even deer and elk are allowed in ruminant feed, as well as bovine blood? I sadly think of the rendering and feeding policy before the Aug. 4, 1997 'partial' feed ban, where anything went, from the city police horse, to the circus elephant, I will not mention all the scrapie infected sheep. I am surprised that we have not included man 'aka soyent green'. It is a disgusting industry and nothing more than greed fuels it.

When will the U.S. start real surveillance of the U.S. bovine population (not passive, this will not work)?

When will U.S. start removing SRMs?

Have they stopped the use of pneumatic stunners in the U.S.?
If so, will we stop it in all U.S. abattoirs or only in those abattoirs exporting to Europe?
If not, WHY NOT?

same questions for removal of SRM in the U.S.A.,
or just for export?
If not, WHY NOT?

How do we now sterilize surgical/dental instruments in the U.S.A.?

Where have we been sourcing surgical catgut?
(I have copies of imports to U.S., and it would floor you)

When will re-usable surgical instruments be banned?

Unregulated "foods" such as 'nutritional supplements' containing various extracts from ruminants, whether imported or derived from

US cattle/sheep/cervids ("antler velvet" extracts!) should be forbidden or at least very seriously regulated. (neighbors Mom, whom also died from CJD, had been taking bovine based supplement, which contained brain, eye, and many other bovine/ovine tissues for years, 'IPLEX').

What is the use of banning blood or tissue donors from Germany, France, etc... when the U.S.A. continues exposing cattle, sheep and people to SRM, refuses to have a serious feed ban, refuses to do systematic BSE-surveillance?

The FDA should feel responsible for the safety of what people eat, prohibit the most dangerous foods, not only prohibit a few more donors - the FDA should be responsible for the safe sourcing of medical devices, not only rely on banning donors "from Europe", The 'real' risks are here in the U.S. as well, and have been for some time.

We must not forget the studies that have proven infectivity in blood from TSE's.

The Lancet, November 9, 1985

Sir,--Professor Manuelidis and his colleagues (Oct 19, p896) report transmission to animals of Creutzfeldt-Jakob disease (CJD) from the buffy coat from two patients. We also transmitted the disease from whole blood samples of a patient (and of mice) infected with CJD.1 Brain, Cornea, and urine from this patient were also infectious, and the clinicopathological findings2 are summarised as follows.

snip...

Samples were taken aseptically at necropsy. 10% crude homogenates of brain and cornea in saline, whole blood (after crushing a clot), and untreated CSF and urine were inoculated intracerebrally into CF1 strain mice (20 ul per animal). Some mice showed emaciation, bradykinesia, rigidity of the body and tail, and sometimes tremor after long incubation periods. Tissues obtained after the animal died (or was killed) were studied histologically (table). Animals infected by various inocula showed common pathological changes, consisting of severe spongiform changes, glial proliferation, and a moderate loss of nerve cells. A few mice inoculated with brain tissue or urine had the same amyloid plaques found in patients and animals with CJD.3

snip...

Department of Neuropathology,
Neurological Institute,
Faculty of Medicine,
Kyushu University,
Fukuoka812, Japan

JUN TATEISHI

(full text-long version)

and

CWD and transmission to man will be no different than other TSE's.

"Clearly, it is premature to draw firm conclusions about CWD passing naturally into humans, cattle and sheep, but the present results suggest that CWD transmissions to humans would be as limited by PrP incompatibility as transmissions of BSE or sheep scrapie to humans. Although there is no evidence that sheep scrapie has affected humans, it is likely that BSE has

caused variant CJD in 74 people (definite and probable variant CJD cases to date according to the UK CJD Surveillance Unit). Given the presumably large number of people exposed to BSE infectivity, the susceptibility of humans may still be very low compared with cattle, which would be consistent with the relatively inefficient conversion of human PrP-sen by PrPBSE. Nonetheless, since humans have apparently been infected by BSE, it would seem prudent to take reasonable measures to limit exposure of humans (as well as sheep and cattle) to CWD infectivity as has been recommended for other animal TSEs."

G.J. Raymond¹, A. Bossers², L.D. Raymond¹, K.I. O'Rourke³, L.E. McHolland⁴, P.K. Bryant III⁴, M.W. Miller⁵, E.S. Williams⁶, M. Smits² and B. Caughey^{1,7}

or more recently transmission of BSE to sheep via whole blood
Research letters Volume 356, Number 9234 16 September 2000

Transmission of BSE by blood transfusion in sheep

Lancet 2000; 356: 999 - 1000

F Houston, J D Foster, Angela Chong, N Hunter, C J Bostock

See Commentary

"We have shown that it is possible to transmit bovine spongiform encephalopathy (BSE) to a sheep by transfusion with whole blood taken from another sheep during the symptom-free phase of an experimental BSE infection. BSE and variant Creutzfeldt-Jakob disease (vCJD) in human beings are caused by the same infectious agent, and the sheep-BSE experimental model has a similar pathogenesis to that of human vCJD. Although UK blood transfusions are leucodepleted--a possible protective measure against any risk from blood transmission--this report suggests that blood donated by symptom-free vCJD-infected human beings may represent a risk of spread of vCJD infection among the human population of the UK."

"The demonstration that the new variant of Creutzfeldt-Jakob disease (vCJD) is caused by the same agent that causes bovine spongiform encephalopathy (BSE) in cattle has raised concerns that blood from human beings in the symptom-free stages of vCJD could transmit infection to recipients of blood transfusions (full text long version)"

and...

"The large number of cases (1040), temporal clustering of the outbreaks (15 in the first 6 months of 1997), the high in-flock incidence, and the exceptional involvement of goats (390 cases), suggested an accidental infection. The source of the epidemic might have been TSE-contaminated meat and bonemeal, but eight flocks had never been fed any commercial feedstuff. Infection might have arisen from the use of a formol-inactivated vaccine against contagious agalactia prepared by a single laboratory with brain and mammary gland homogenates of sheep infected with Mycoplasma agalactiae. Although clinical signs of TSE in the donor sheep have not been found, it is possible that one or more of them were harbouring the

infectious agent. Between 1995 and 1996, this vaccine was given subcutaneously to 15 of the affected flocks (to one flock in 1994); in these animals the disease appeared between 23 and 35 months after vaccination. No information is available for herd 13 because it was made up of stolen animals. Sheep from the remaining three flocks (1-3, figure) did not receive the vaccine, thus suggesting a naturally occurring disease." (again, full text long version).

IN SHORT, please do not underestimate this data and or human/animal TSE's including CWD in the U.S.A.

A few last words, please.

The cattle industry would love to have us turn our focus to CWD and forget about our own home grown TSE in Bovines. This would be easy to do. Marsh's work was from downer cattle feed, NOT downer deer/elk feed. This has been proven.

DO NOT MAKE THAT MISTAKE.

There should be NO LESS THAN 1,000,000 tests for BSE/TSE in 2001 for U.S.A. French are testing 20,000 a week. The tests are available. Why wait until we stumble across a case from passive surveillance, by then it is too late. IF we want the truth, this is a must???

United States Total Bovine Brain Submissions by State,

May 10, 1990 thru October 31, 2000

Total 11,700

FROM 1.5 BILLION HEAD OF CATTLE since 1990 ???

with same feeding and rendering practices as that of U.K. for years and years, same scrapie infected sheep used in feed, for years and years, 950 scrapie infect FLOCKS in the U.S. and over 20 different strains of scrapie known to date. (hmmmm, i am thinking why there is not a variant scrapie, that is totally different than all the rest)? just being sarcastic.

with only PARTIAL FEED BAN implemented on Aug. 4, 1997???
(you really need to reconsider that blood meal etc. 'TOTAL BAN')

<http://www.aphis.usda.gov/oa/bse/bseurvey.html#charts>

AND PLEASE FOR GODS SAKE, STOP saying vCJD victims are the only ones tied to this environmental death sentence. "PROVE IT". It's just not true. The 'CHOSEN ONES' are not the only ones dying because of this man-made death sentence. When making regulations for human health from human/animal TSEs, you had better include ALL human TSE's, not just vCJD. Do NOT underestimate sporadic CJD with the 'prehistoric' testing available to date. This could be a deadly mistake. Remember, sCJD kills much faster from 1st onset of symptoms to death, and hvCJD is the fastest. Could it just be a higher titre of infectivity, or route or source, or all three?

Last, but not least. The illegal/legal harvesting of body parts and tissues will come back to haunt you. Maybe not morally, but due to NO background checks and human TSEs, again it will continue to spread.

Stupidity, Ignorance and Greed is what fuels this disease. You must stop all of this, and ACT AT ONCE...

Thank You,

kind regards,
Terry S. Singeltary Sr.
P.O. Box 42
Bacliff, Texas USA 77518

Florham Park NJ 07932
Jan 16-2001

Dr William Fries
Center for Biologic Evaluation

VIA FAX 301-827-0294

Re Spongiform Encephalopathies

Protection of American citizens is what citizens expect from various government agencies, including USDA! We feel we have been "sold down the river" by this agency in favor of farmer greed and profits:

Eagles have spongiform.

- 2 -

Deer + Elk have spongiform.

It is in Italy, Spain, France and Germany! I do not believe humans are escaping it in U.S. The US govt. is afraid to admit it.

However, it is time to stop allowing all of the practices such as feeding chicken manure to cattle, feeding newsprint to cattle, feeding downed, sick, injured cattle to healthy cattle. You dont have to be

-3

a scientist to know you are spreading disease with such practices.

I blame USDA and U.S. government and state agricultural and FDA practices for the horror that is being caused by violating safe practices.

Yours truly
B Sachau

cc - Sen Torricelli
Sen Corzine
Rep Rodney Feltinghuesen



**America's Blood
Centers**

Statement

725 15th St., NW, Suite 700 ♦ Washington, DC 20005
PH: (202) 393-5725 ♦ FX: (202) 393-1282 ♦ Email: abc@americasblood.org
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STATEMENT TO THE TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY COMMITTEE

America's Blood Centers (ABC) represents 75 non-profit, community independent blood programs that together account for about half of the nation's volunteer donor blood supply.

ABC appreciates the fact that the FDA has, as a result of regular meetings of this committee, encouraged frequent review of the emerging information about the spongiform encephalopathies.

Against the background that there is still no evidence to demonstrate that new variant CJD is more than a theoretical risk for human blood transfusion recipients, ABC also appreciates FDA's commitment to requesting review of previous restrictions on donors for their continuing appropriateness.

At the same time, ABC recognizes that the spread of bovine spongiform encephalopathy to other European countries must prompt debate about possible modification of recent deferral criteria, which currently applies to donors previously visiting the United Kingdom.

In considering any need for additional precautionary measures, ABC asks the committee to balance new restrictions on donation against continuing deferral of donors. ABC recognizes that transfusion safety, which is of paramount importance, is a goal that must be linked to blood availability at a time when blood shortages are nearly chronic in nature and increasingly result in the cancellation of non-urgent surgeries.

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GIVEN BY: Dr. Merlyn Sayers, M.D., Ph.D.
Secretary, ABC

CONTACT: Melissa McMillan, Senior Director, Communications, ABC
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Transmissible Spongiform Encephalopathies Advisory Committee

Statement of Impact from the New York Blood Center January 18, 2001

Thank you for the opportunity to address the committee.

I am Dr. Robert Jones, President, of New York Blood Center. I am here to express grave concern about possible recommendations regarding the risk of transmission of spongiform encephalopathies via blood transfusion. I am not here to debate the scientific arguments regarding infectious risk to be addressed by your experts. We strongly support and participate in FDA's vigorous efforts to reduce risks associated with transfusion. As such, I am obliged to inform you of the medical crisis that is very likely with any significant reduction in availability of red blood cells for transfusion in the New York Metropolitan area.

The New York Blood Center is the major supplier of blood products for the entire New York – New Jersey metropolitan area with over 200 hospitals and major academic medical centers. Our distribution of nearly 1 million blood components a year is remarkably high due to the transfusion needs of our tertiary care centers that provide care to patients from all over the world. As with all blood programs, our most precious and scarce component is packed red blood cells (RBCs) derived from volunteer whole blood donations. Of our 600,000 RBC units distributed annually, 420,000 units come from donations made at NYBC, 30,000 units are purchased from US blood programs as surplus, and over 150,000 units (about 25 %), are imported under our Euroblood program. In April 2000, we experienced immediate drops in our collections when we introduced the UK deferral – we currently defer up to 1% of our donors at collection sites. More difficult to gauge is self-deferral of donors due this policy. However, we can accurately state the catastrophic impact on our RBC supply if a new guideline would restrict the importation of Euroblood. Also, any travel ban that extends to continental Europe will further erode our donor base of frequent international business travelers.

Euroblood was established some 30 years ago to deal with chronic shortages of blood that were particularly common in large urban areas such as New York City. It took almost a decade for the logistic, regulatory, political and financial details to be worked out. The RBCs were obtained as surplus over European transfusion needs from blood that was collected to obtain plasma for fractionation. Currently, blood centers in three countries participate – Germany, Switzerland, and Holland. The Euroblood Centers are FDA approved collection facilities for NYBC. They collect under the NYBC's FDA license, use approved SOPs and are routinely inspected by FDA staff. Thus, a unit of blood coming from these Euroblood centers fulfills the exact same criteria as a unit collected locally. Euroblood has provided as much as a third of our areas RBC needs.

With changes in demand for fractionated plasma and internal restructuring of blood programs, the availability of European red cells has declined over the past three years – dropping by about a third to its current level. We have compensated for this loss by increasing our collection rate over 20% during this period. Attempts to replace Euroblood with imports from US centers have been largely ineffective. Nationwide slow growth in collections vs. accelerating transfusion demand has created a chronically deficient red cell supply, most seriously in the now longer and more severe seasonal shortage periods. These shortages are leading to unsettling medical practices in our hospitals. These include delay of urgent or elective surgery, postponements or reductions of transfusions for cancer patients, and transfusion of Rh+ blood to Rh- recipients with its attendant risks. Emergency departments in our area have also reported having to close for admissions due to low blood availability.

A sudden, dramatic reduction or elimination of Euroblood will worsen these medical issues and have a catastrophic effect on the delivery of hospital care in our area. Replacement of this

resource with our own collections is our long-term goal. It cannot be achieved abruptly or without substantial planning and investments. Rapid replacement from other sources is also not realistic, given current global blood shortages. Therefore, any new policy that eliminates Euroblood will in effect reduce the availability of blood to our hospitals by 25% or put another way, approximately 1.5 to 2% of the nation's RBC supply. We feel it safe to say that this magnitude of blood shortage will likely produce a measurable increase in hospital mortality.

I reiterate our mutual concern about the safety of the blood supply. We support all regulations that have a clear impact on blood safety. However, we believe that there must be a balance between any theoretical risk and the measurable risk of a deficient blood supply. We respectfully request that in making your recommendations, you take into account the dire consequences of any action that would cause either additional donor deferrals or sudden elimination of the Euroblood program.

Thank you again for this opportunity. I welcome any questions that you may have.

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TBI Comments On:

- CJD Screening of Cornea Donors
 - Medical Examiner / Legislative Consent Programs
 - International Impact
 - Summary Statements
- ⋮

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CJD Screening of Cornea Donors

Applicable EBAA Standards Requires donor history from at least **one** of the following sources:

- Pathologist or Medical Examiner physical assessment of death report
 - police investigation report
 - medical examiner's investigative report
 - family interview
 - medical record or hospital chart
 - treating physician interview
- ⋮

CJD Screening of Cornea Donors

Eye Donor History Evaluation Profiles

	Non hospital Non ME Donor	Hospital Non ME Donor	Leg. Cons ME Donor
Autopsy Report			Always
Police Report			Often
ME Invest. Report			Always
Family Interview*	Always	Always	
Medical Records		Always	Often
Physician Interview	Often	Often	

* required by FDA except for legislative consent/ME donors

Medical Examiner / Legislative Consent Programs

- Medical Examiner or Coroner Cases
- Cause of Death: typically sudden & accidental; not disease related
- MEO may authorize cornea recovery
 - In autopsied cases
 - Unless next-of-kin objects

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Medical Examiner / Legislative Consent Programs

- First law in 1975 - State of Maryland
- Law exists in 19 states, D.C., Puerto Rico
- Utilized in Florida, Maryland, Texas & Puerto Rico
- Utilized by 7 Eye Banks (FL-1; MD-2; TX-3; PR-1)

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Medical Examiner / Legislative Consent Programs

- 2,200 corneas provided for transplant from these programs in the U.S.
- 5% of U.S. transplantable corneas **recovered**
- 7% of U.S. corneas transplanted
- Represents between 40% to 90% of corneas transplanted in the local service areas of those eye banks using these programs

Medical Examiner / Legislative Consent Programs

Background Information:

- CJD cases are typically not reported to the MEO
- CJD cases are typically not autopsied by the MEO
- Infectious disease cases are "off limits" to the eye bank
- CJD cases would be screened out **under current medical standards** as well as any case with unknown neurologic disorders

Medical Examiner / Legislative Consent Programs

Profile of Medical Examiners / Legislative Consent Program 1998 State of Maryland

	<u>Reported</u>	<u>Autopsied</u>
Medical Examiner Cases	8,003	3,184
All Nervous System Disease (NSD) cases	43	4
% of Total	0.5%	0.1%
Cornea donors after screening	125	125
% of Total	1.6%	3.9%
Cornea donors from NSD cases	0	0

* Office of the Chief Medical Examiner // 1998 Annual Statistics

** Medical Eye Bank of Maryland

International Impact

Outside of the United States, eye donor laws or systems are generally characterized as:

- “Opt In System” requiring donor or next-of-kin consent
- “Opt Out System” requiring donor or next-of-kin objection to donation; comparable to legislative consent
- Other than the U.S., countries that meet their needs for corneal tissue are Opt Out Systems

International Impact

European Association of Eye Banks - 1998

	<u>Opt Out</u>	<u>Opt In</u>	<u>Total</u>
Countries with EEBA Members	11	11	22
EEBA Members	23	44	67
Corneas Used for Transplant	5,200	10,900	16,100
% of total	32%	68%	100%

International Impact

TBI International Member Programs - 1999

	<u>Opt Out</u>	<u>Opt In</u>	<u>Total</u>
Countries with TBI Members	8	17	25
TBI Members	12	29	41
Corneas Used for Transplant	2,932	2,659	5,591
% of total	52%	48%	100%
Corneas per million population	10.9	1.0	1.9

International Impact Corneas Exported from U.S. Banks

- EBAA reports 12,745 corneas provided outside U.S.
- Used in countries where moderate to severe shortages persist
- Soft number: assumes surgical use frequently unconfirmed
- Most suitable corneas used in U.S.
- Legislative consent program-sourced corneas are typically not those exported

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International Impact

- U.S. eye banking standards and regulations generally recognized as the most extensive
 - Changes in U.S. Eye Banking generally influence changes worldwide
 - TBI, for example, promotes U.S. based standards our international outreach
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Summary Statements

- Successful screening for CJD for eye donors from medical examiner / legislative consent programs can co-exist with FDA regulations as presently performed for HIV & hepatitis.
 - Any loss of legislative consent for eye donors in the U.S. increases risk of CJD transmission in the remaining donor pool (due to higher average donor age and donor causes of death from illness and disease versus lower age and cause of death from trauma and accidents from ME cases).
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Summary Statements

- Loss of Legislative Consent eye donor programs will result in critical, local shortages in several large regions in the U.S.
 - Loss of Legislative Consent eye donors risk reduction of 2,000 surgical quality eye tissue. That means 2,000 patients who remain blind in the U.S. or abroad.
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Summary Statements

- Undoubtedly, elimination of “opt out” programs would eliminate eye banking and corneal transplants in some countries. Ten thousand transplantable corneas and the patients to whom they restore sight are at risk.
- • • • • • • •

(1)

The Advantages of a Medical Examiner Implied Consent Corneal Donor Law

Joseph H. Davis, M.D.

Medical Examiner, Miami, Florida

I am Dr Joseph H. Davis, I am Professor of Pathology Emeritus, University of Miami. I have been affiliated with the Medical Examiner Department for forty four years. My curriculum vitae is available.

Under a medical examiner corneal donor law the Eye Bank may harvest corneas from medical examiner cases. Permission is implied. The impetus for the law was the relief of blindness. Since the law was implemented maximum numbers of corneas have been obtained. Last year about 750 corneas were obtained in South Florida. Since 1962 about 33,000 have been obtained.

Medical examiner cases are unique in quality and quantity. The medical examiner donor material relies upon autopsy, investigation of medical and social data and acquisition of available medical records. All this data is correlated with Eye Bank personnel who follow strict protocols. The autopsy makes medical examiner cases outstanding in quality compared to donors where only history and laboratory tests are utilized.

(2)

Corneal retrieval has a narrow time zone, twelve hours after death. Timely harvesting under the medical examiner protocol assures improved quality.

The basis of the medical examiner donor law is to improve quantity and prevent blindness. Without the implied consent, which does not require tracing next of kin, available corneas would be cut by two thirds.

In summary the medical examiner protocol, which includes autopsy, assures a far greater quality assurance and protection against CJD transmission than those cases which depend upon contacting next of kin for history. Review of cases with corneal transmission of CJD reveal egregious violation of the quality assurance procedures that already exist for medical examiner cases.

Jack H. Davis M.D.
January 18, 2001



COUNCIL OF HOSPITAL BLOOD BANK DIRECTORS OF THE GREATER NEW YORK REGION, INC.

January 15, 2001

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Memorial Sloan Kettering Cancer Center
Tel. 212-639-2218

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Paul Brown, MD

Chairperson,

Transmissible Spongiform Encephalopathies Advisory Committee
FDA/CBER

Dear Dr. Brown:

I write to you on behalf of the Council of Hospital Blood Bank Directors of the Greater New York Region. We are concerned that the Transmissible Spongiform Encephalopathies Advisory Committee, in its deliberations about the risks to patients posed by the TSE's, understands the risk to patients posed by policy recommendations which could markedly and abruptly diminish the blood supply to our region. Our region could be much more adversely affected than other regions in the country.

We share with you the concerns of potential transmission of this fatal disorder by blood transfusion and agree that emerging information must be carefully monitored on an ongoing basis. However, the risk to the nation's blood supply in terms of loss of donors must be equally regarded in order to maintain sufficiently safe levels of inventory. Particularly, we feel compelled to respectfully point out certain germane facts unique to the NY Metropolitan area blood supply. Specifically, 25% of the NY Metropolitan area blood supply is provided by continental European blood centers on a daily basis through the New York Blood Center's "Euroblood" program. Abrupt discontinuation of this supply due to donor deferral policy changes would have an obvious substantial adverse impact and threaten our ability to support a full range of medical care in our region from life threatening emergencies to comprehensive care for acute and chronic medical and surgical illnesses.

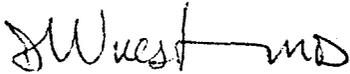
Currently, there is no other local or national source to replace this lost blood supply in the short term. Attempts to import blood from other regions of the country may not be possible due to the continuing national shortages we have been experiencing without compromising care in other geographic regions. A long term solution is to increase domestic collections. We propose that in the short term, a similar need exists.

Perhaps your Committee could find a way to recognize this potential calamity and suggest, for example, that there be a nationally funded initiative for an urgent campaign to increase the number of blood donors such as never has been seen in our country before.

We ask that during your deliberations you consider this clear and significant negative impact as a self-evident and major population risk with both local and national implications. As you evaluate the available information and decide whether or not to formulate recommendations that will necessarily result in such a major adverse effect on the national blood supply, please consider possible long and short term answers and solutions to be implemented to avoid these risks.

Thank you for your leadership and help in this matter of public safety.

Sincerely,

A handwritten signature in black ink that reads "D. Wuest MD". The signature is written in a cursive style with a horizontal line extending from the end.

David L. Wuest, MD

18 January 2001
Testimony before the
FDA Transmissible Spongiform Encephalopathies Advisory Committee
Bethesda, Maryland

Bess Beliveaux
Executive Director
Lions Eye Bank of Central Texas
Austin, Texas 78705
Telephone: (512) 457-0638
FAX: (512)457-0658

I am Bess Beliveaux, Executive Director for Lions Eye Bank of Central Texas, Austin, Texas. For more than twenty years, I have worked with and for medical examiner's offices and with and for donor programs. Throughout these years, I have spoken hundreds of times with family survivors in regards to the death of one or more family members. Though well intentioned, my experiences have proven that the majority of those interviewed are limited in their abilities to provide accurate medical and social information. What I have to share with you today is anecdotal; and, still, important for you to know.

Examples of medical and social history provided by "informed" family members include:

1. "The only time he's been sick is when he was born brain dead. . . but the doctors fixed him."
2. In a small Texas town, a 70-year-old Fire Chief collapsed during a fire fight and was transported to the local emergency department. All life saving measures failed and cause of death was listed as Myocardial Infarction. The decedent's wife wanted him to become a donor and provided medical and social information significant only for hypertension and heart disease. While performing the external body exam, eye bank technicians learned the decedent was wearing pink ladies underwear and had numerous, recent penile and scrotal piercings. The recent piercings being obvious contraindications to donation.
3. "When she was a child, she had screamin' mighty Jesus." – this is a colloquialism for spinal meningitis, though the correct medical diagnosis was unfamiliar to family members.
4. A father reported to an organ bank that his late-teens child had no tattoos, piercings, etc. After organ recovery, the external exam performed by the eye bank technician revealed the decedents back was nearly covered with fresh tattoos.

5. Family members told the staff at a local Emergency Department that their mother had a past medical history positive for some disease that began with an "H". The ER staff recorded this as hepatitis. Later conversation with the decedent's primary care physician revealed the "H" actually should have been recorded as hemorrhoids. Because the PCP was not readily available, corneal tissues were destroyed because we were unable to determine the validity of past medical history positive for hepatitis. Of note: all serology testing was non-reactive.
6. A father and mother reported their son, a suicide victim, had wished to be a donor and, reported no contraindicating medical or social history. Follow up with the medical examiner's office revealed the donor had an incarceration history recent enough and long enough to be a contraindication to donation.
7. In a face-to-face meeting with spouse and other family members, medical and social history provided for the deceased spouse/father was clear of contraindications. When the eye bank coordinator left the room, the spouse followed and stated that all was not well; and, that she had not wanted the children to know their father had engaged in promiscuous behavior with prostitutes. In many settings, the spouse may not have had an opportunity or inclination to make such confessions.

I am not implying all medical and social interviews are so blatantly misleading. For the most part, the misconceptions are very subtle and can easily be overlooked. Family members do not typically intend to provide misleading or incorrect information. Perhaps it is that our society has become far more mobile and far more distanced from the family nucleus than ever before that misleading or incorrect information can so easily be provided. Also, many family members simply are not savvy enough regarding medicine and/or social contraindications. It is my experience and belief that the medical/social interview is rarely, if ever, of true value in evaluating the usability of donor tissues. Especially, I am concerned that we are considering this source of information as a defining factor for determining the suitability of donated non-vascular corneal tissues. Additionally, I believe a donor that has the advantage of medical examiner investigation and forensic autopsy is one that comes with infinitely more accurate medical and social information.

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

Also, I am providing this committee with letters from corneal surgeons, a forensic pathologist and a neuropathologist regarding this matter of screening potential donors for transmissible spongiform encephalopathies and other prion diseases.

Thank you for your time and consideration.

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INFORMATION](#)[INVESTOR RELATIONS](#)**#2490: Creutzfeldt-Jakob Disease DetectR™****COMPONENTS**

Name	Method	Reference Range	Units
14-3-3 Beta Isoform	IB	Not detected	

SPECIMEN REQUIREMENTS

No	Type	Volume	Temperature
1	CSF	1.0 (0.5) mL	Frozen

GENERAL INFORMATION

Setup Schedule	Monday-Friday
Turn-Around Time	3-10 days
Fee	\$224.00
CPT Code	84182
Notes	Detects 14-3-3 Protein Beta-Isoform.

© 2001 Specialty Laboratories

For test information, please call *Specialty's* Client Services at 800-421-4449.site by [The Spider](#)

William F. McCormick, M.D.
120 Niles Wheelock Road
Jonesborough, Tennessee 37659
10-14-99

EBAA -- Medical Advisory Board
c/o Edward J. Holland, M.D.
University of Minnesota
Dept. of Ophthalmology
UHMC Box 493
420 Delaware Street, SE
Minneapolis, MN 55455

Dear Dr. Holland,

The idea behind the proposed new medical standard regarding corneal donation is good -- prevent direct transmission of prion (C-J) disease. However, it will have the "real" undesired VS "ideal" consequence of significantly decreasing available corneas far in excess of its potential to eliminate the very rare prion-diseased donor.

In forty-plus years of practice as a physician, pathologist, forensic pathologist, and neuropathologist, I have seen in my own autopsy material (more than 10,000), and in referred material, a half dozen cases of C-J (and other prion) disease(s). All of these cases were in clearly symptomatic hospitalized patients; none were in ambulatory, non-hospitalized "well" individuals who died as a result of violent death.

Even given its (their) rarity (1:1,000,000), the lethal nature of prion disease would warrant their absolute exclusion from the donor cornea population: (1) if it were possible, and (2) if we were still able to obtain corneas for the great (relative) number that need them. The proposed "interview" is impractical -- it will not work in the real world. The time required to find knowledgeable next of kin, relative, etc. is too great for transplant purposes. The key word here is knowledgeable.

The use of some markers such as 14-3-3 β -isoform would require the local hospital (laboratory) to be able to do the test accurately, in a timely fashion, and in a cost effective manner, with the second the greatest problem.

I would estimate that the use of laboratory tests and next of kin interviews would prevent cornea procurement in at least one half of the now-available donor population for the potential prevention of one-to-two cases of prion disease/year/USA. I would not require their (interview and labs) use in the vast majority of forensic pathology derived cases, but would urge medical examiners and forensic pathologists to exclude most debilitated and aged potential donors and obviously any with known dementia.

Sincerely,



William F. McCormick, M.D.
Deputy Chief Medical Examiner
State of Tennessee

I personally obtained authorization by telephone from William F. McCormick, MD, on 16 January 2001 at 7 p.m. CST, to provide copies of this letter to members of the FDA Transmissible Spongiform Encephalopathies Advisory Committee.



Bess Beliveaux
Executive Director
Lions Eye Bank of Central Texas
Austin, Texas 78705

Robert L. Rock, M.D.
H. Grady Rylander, M.D.
George C. Thorne, M.D.
Gary R. Rylander, M.D.



Janet A. Lindsey, M.D.
K. Randy Pierce, M.D.
Gregory L. Hemphill, M.D.
Mark A. Plunkett, M.D.

January 15, 2001

**Food and Drug Administration
Transmissible Spongiform Encephalopathies
Advisory Committee**

Dear Committee Members:

I have been a corneal surgeon in the state of Texas for twenty-one years and am distressed to hear that the Food and Drug Administration (FDA) will be adding a series of questions regarding Creutzfeldt-Jakob disease (CJD) to medical screening standards for all donor corneas. This requirement will significantly affect the number of tissues currently being obtained by legislative consent.

Texas and the US have greatly benefited by having available these young, healthy donor corneas recovered through the cooperative efforts of medical examiners. Medical examiner laws have been instrumental in helping to eliminate the waiting lists of patients in need of sight restoring corneal transplantation; and, has successfully and safely provided donor corneal tissues (in Texas) since 1977. This important legislation provides 50 - 60 % of the donor corneal tissues for our community.

I appreciate the position the FDA has taken to develop and maintain strict medical standards and screening devices to help ensure a safe supply of donor corneal tissues. However, with the annual incidence of CJD at one case per million population (with most cases being present in patients 60 years of age or older) and the calculated risk of a prion-infected corneal donor at .005%, imposing these screening steps which will terminate this important law is unnecessary.

I ask that you please consider the issues surrounding this important matter.

Sincerely,

A handwritten signature in cursive script that reads 'George C. Thorne, M.D.' The signature is written in dark ink and is positioned above the printed name.

George C. Thorne, M.D.

Robert L. Rock, M.D.
H. Grady Rylander, M.D.
George C. Thorne, M.D.
Gary R. Rylander, M.D.



Janet A. Lindsey, M.D.
K. Randy Pierce, M.D.
Gregory L. Hemphill, M.D.
Mark A. Plunkett, M.D.

January 16, 2001

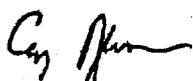
Food and Drug Administration
Transmissible Spongiform Encephalopathies
Advisory Committee

Dear Committee Members:

I have recently been informed about a potential new screening criteria for Creutzfeldt-Jakob disease, which could dramatically limit our access to young, healthy corneal tissue for corneal transplantation. If the information is accurate and the new screening process negates the effectiveness of our current medical examiner laws I would ask that you reconsider the situation. As a corneal surgeon I would hope to be able to use the healthiest donor material with the smallest risk of disease transmittance. The risk of disease transmittance via corneal transplantation will never be zero unless such a procedure is abandoned. The risk of transmittance of Creutzfeldt-Jakob disease via corneal transplantation is theoretically small enough that I and most of my patients can live with it in order to continue a readily available supply of young donor material.

Please reconsider the impact of the new screening criteria on our future availability of healthy young corneal donor material.

Sincerely,


Gary R. Rylander, MD

Subj: Re: FDA Hearing regarding TSE and CJD
Date: 1/15/2001 12:48:06 PM Central Standard Time
From: sfulcher@mailbox.sw.org (S.F. Fulcher)
BBeliveaux@aol.com

Dear Bess,

I hope the following helps:

To Whom it May Concern,

I am writing this letter in support of the use of corneal tissue obtained from Medical Examiner cases for corneal transplantation. In the State of Texas, the existence of Medical Examiner laws allowing for the use of such tissue has greatly enhanced the quality of life for countless individuals who have undergone corneal transplantation. These laws have significantly enhance the availability and quality of tissue for transplantation that would otherwise be wasted. I strongly support the continued use of such tissue, as the benefits far outweigh and exceed any risks associated with tissue transplantation, and therefore benefits society as a whole. I personally have NEVER encountered one single adverse event associated with donor tissue in the 12 years that I have performed corneal transplants. To change the regulations to prohibit the use of Medical Examiner approved tissue would seem to me to be over regulatory exuberance and overkill. Again, I urge those responsible to judiciously allow the continued use of Medical Examiner tissue for corneal transplantation in the interest of the overriding public benefit.

Sam Fulcher M.D.

Subj:
Date: 10/5/1999 3:28:59 PM Central Daylight Time
From: Stephen.Cina@59MDW.WHMC.AF.MIL (Cina, Stephen)
To: lebct@io.com (lebct@io.com)

Memorandum:

As we discussed on the telephone today, 10/5/99:

1. CJ is a highly infectious neurodegenerative disorder. Transplantation of any tissues from a known infected person would most likely be contraindicated.
2. Most patients dying of CJ would follow a clinical course that would suggest this diagnosis. It is possible that a person with very early CJ could die of trauma and be autopsied without knowledge of this infection.
3. I have performed 1000 autopsies and not encountered an occult CJ infection in a traumatic death.
4. I have been involved with 3000 other forensic autopsies. Of these, the diagnosis of CJ was suspected twice. I am not aware of a traumatic death in which CJ was diagnosed at autopsy.

I hope you find this information useful.

Stephen J. Cina, MD
Forensic Pathologist

----- Headers -----

Return-Path: <Stephen.Cina@59MDW.WHMC.AF.MIL>
Received: from rly-yd05.mx.aol.com (rly-yd05.mail.aol.com [172.18.150.5]) by air-yd05.mail.aol.com (vx) with ESMTP; Tue, 05 Oct 1999 16:28:59 -0400
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by mx2.io.com (8.9.1a/8.9.1a) with ESMTP id PAA30452
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id <S43B3VJT>; Tue, 5 Oct 1999 15:24:05 -0500
Message-ID: <86724839085AD211AB4E08002BE51EBD09D97D@59mdw.whmc.af.mil>
From: "Cina, Stephen" <Stephen.Cina@59MDW.WHMC.AF.MIL>
To: "lebct@io.com" <lebct@io.com>
Subject:
Date: Tue, 5 Oct 1999 15:24:04 -0500
MIME-Version: 1.0
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Content-Type: text/plain;
charset="iso-8859-1"



Monday, January 15, 2001

Food and Drug Administration
Transmissible Spongiform Encephalopathies
Advisory Committee

Dear Sirs,

I would like to respectfully submit to the Transmissible Spongiform Encephalopathies Advisory Committee an item to consider regarding issues and questions pertaining to Creutzfeldt-Jakob disease and other Transmissible Spongiform Encephalopathies.

Developing questions to ask a potential donor's family must meet several requirements. One of the first hazards is to avoid the use of terminology that is unfamiliar to the person answering questions (Spilker B, Schoenfelder J, Data Collection Forms in Clinical Trials. New York: Raven, 1991, page 27). Unfortunately, the questions pertaining to the symptomatology of CJD and other TSE's that have been proposed for widespread implementation greatly exceed the vocabulary of most individuals.

The validity of a medical-social interview must be based on the assumption that those being interviewed know the meanings of required medical terminology. Demographers often suggest that respondents chosen from the general population will answer most accurately if eighth graders can understand the questions (Aday LA, Designing and Conducting Health Surveys. San Francisco: Jossey-Bass, 1996, page 193). When the wording was tested to screen for CJD on software checks in a word processing program, the readability and grammar failed.

We feel that CJD-TSE interview questions are inappropriate and are above the educational level of most respondents. This could result in the unnecessary deferral of otherwise acceptable donors. We strongly recommend that the TSE Advisory Committee hire a consultant who is skilled in survey methodology and demography before implementing any interviewing screening criteria for Transmissible Spongiform Encephalopathies.

Respectfully,

Gary R. Warner OPA-C, CST
Chief Operating Officer
Lions Eye Bank of Central Texas

LIONS EYE BANK OF
CENTRAL TEXAS

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GARY R. WILANDER, MD
Corneal Consultant

BESS BELIVEAUX, CEBT
Executive Director

Certified Member



And member of the
Eye Bank Association of Texas



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Red Cross**

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Washington, DC 20006

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NEWS RELEASE

AMERICAN RED CROSS URGES TIGHTENED RESTRICTIONS ON BLOOD DONORS WHO RESIDED IN EUROPE

Red Cross President and CEO Describes Policy As "Prudent, Cautious"

WASHINGTON, January 18 – In its ongoing efforts to increase the safety of America's blood supply, the American Red Cross announced today it will encourage the Food and Drug Administration's (FDA) Transmissible Spongiform Encephalopathy (TSE) Advisory Committee to consider a further tightening of the current ban on blood donors who have traveled to or lived in the United Kingdom for a cumulative total of six months between 1980 and 1996. The Red Cross supports tightening the deferral period to less than six months in the U.K. and extending the exposure period to between 1980 and the present. Furthermore, the American Red Cross supports the logical expansion of the existing U.K. deferral to include France and Western Europe given the growing evidence of Bovine Spongiform Encephalopathy (BSE), also known as "mad cow" disease, in those countries.

"The safety of the blood supply is paramount," said Dr. Bernadine Healy, American Red Cross president and chief executive officer. "We must be prudent and cautious regarding TSE – a potential emerging threat to America's blood supply," she continued. "Any risk to the blood supply – real, or theoretical, such as TSE – must be taken seriously. While expanding the current ban will impact the supply of blood because more donors will be deferred, experience shows that in wars and disasters, the American public always responds."

Currently, according to FDA regulations, anyone who has spent a total of six months or more in the United Kingdom (England, Northern Ireland, Scotland, Wales, Isle of Man or the Channel Islands) between 1980 and 1996 is not eligible to donate blood.

Although there is no evidence of transmission of vCJD by blood in humans, evidence exists in animal models that TSE is transmissible through blood. Therefore, the Red Cross is urging caution to ensure the safety of America's blood supply for vulnerable patients.

-more-

AMERICAN RED CROSS – Add One

The American Red Cross is calling for expanded research to better understand TSE pathogens and to create a TSE-specific blood screening test. No such test currently exists. "It is reasonable to anticipate a TSE-specific test being developed in the next two or three years," Healy said. "With that test, we will have a means to assess the true risk, which will better inform our donor selection criteria."

The Red Cross estimates that expanding the deferral criteria will reduce the current number of blood donors in the range of 5 to 6 percent. It will be difficult for all blood centers to make up the shortfall. The Red Cross believes that it and others who share the mission of ensuring a safe, available blood supply should embark on a sustained national public awareness campaign to educate people on the importance of donating blood to save patients. Patients in need of blood transfusions are undergoing cancer treatment, transplants, routine surgeries and being treated for serious diseases such as sickle cell anemia and hemophilia.

"We know it will take a major investment of time, money and resources to attract new donors and retain current donors to meet the increasing needs of patients nationwide," Dr. Healy continued. "We are prepared to take on this added responsibility."

The Red Cross provides almost half of the nation's blood supply (collecting more than 6 million units a year from volunteer donors) to 3,000 hospitals through its national network of 36 Blood Services regions. Dr. Bernadine Healy is president and CEO of the American Red Cross.

--END--



American Red Cross

American Red Cross Position Statement to the Transmissible Spongiform Encephalopathy (TSE) Committee

The safety of the blood supply is paramount and is the American Red Cross's number one priority. The Red Cross and the Food and Drug Administration (FDA) believe it was a prudent step to ensure blood safety by deferring blood donors who have traveled to or lived in the United Kingdom based on the theoretical risk of vCJD and the lack of a blood screening test.

The current deferral is for people who have traveled to or resided in the United Kingdom (England, Northern Ireland, Scotland, Wales, Isle of Man or the Channel Islands) for 6 months or more between 1980 and 1996. The American Red Cross supports expanding this deferral to include France as well as all of Western Europe given the growing evidence of Bovine Spongiform Encephalopathy (BSE) in those countries. We believe the Transmissible Spongiform Encephalopathy (TSE) committee should consider a further tightening of the deferral period to less than six months in the U.K. We also believe the committee should examine extending the exposure period between 1980 to the present, instead of the current deferral between 1980 and 1996.

There is evidence in animal models that TSE is transmissible through blood. We must be cautious to ensure the safety of America's blood supply for vulnerable patients.

The American Red Cross calls for expanded research to better understand TSE pathogens and to create a TSE-specific blood screening test. We believe that if this is done, in the next two to three years we will have a means to assess the true risk, which will better inform our donor selection criteria.

We estimate that expanding the deferral criteria would reduce the current number of Red Cross blood donors in the range of 5 to 6 percent. Therefore, it is our shared obligation to embark on a sustained national campaign to educate the public to increase the number of American blood donors.

The American Red Cross knows it will take a major investment of time, money and resources to attract new donors and retain current donors to meet the increasing needs of patients nationwide. We are prepared to take on this public responsibility along with others who share our mission to ensure a safe and available blood supply.

The Red Cross is prepared to implement tightened donor criteria across our national system.



**AMERICAN
ASSOCIATION
OF BLOOD BANKS**

**CONTACT: Sara Foer
(301) 215-6557 office
(240) 603-1045 cell**

**Statement of the American Association of Blood Banks
before the
Transmissible Spongiform Encephalopathies Advisory Committee**

January 18, 2001

The American Association of Blood Banks (AABB) is the professional association for approximately 8,000 individuals and 2,000 institutions, including blood collection centers, hospital-based blood banks and transfusion services. AABB members are involved in all aspects of collection, processing and transfusion of blood, as well as hematopoietic progenitor cells (HPCs). Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in the United States. For more than 50 years, the AABB's highest priority has been to maintain and enhance the safety of the nation's blood supply.

The AABB appreciates the opportunity to comment on the potential deferral of certain donors of human cells and tissues due to the theoretical risk of transmitting Creutzfeldt-Jakob disease (CJD) and vCJD. As we have stated previously before this Committee, the AABB believes that patient welfare must be the utmost consideration when determining whether to implement any new donor deferral policies.

In deciding whether to adopt a policy to defer HPC or transplantable cell or tissue donors who have traveled to the United Kingdom or other countries, the Food and Drug Administration should carefully balance all relevant risks and benefits to patients. It should be noted that the treatment of patients through HPC transplants involves unique patient safety and product supply issues that are different from those involved in the context of blood collections.

HPCs are used in the treatment of patients battling life-threatening conditions, including several cancers and immune disorders. For many patients, HPC transplants represent their last hopes for survival. Successful treatment with HPCs depends on donor selection and appropriate HLA matching. Therefore, HPC donors are often donating their cells for particular individuals, who are frequently relatives. Choice of an HLA match can significantly affect the patient's chance of survival and avoidance of long-term, debilitating chronic graft versus host disease following transplant.

The importance of providing a well-matched HPC unit must be weighed against any potential risks associated with donor exposure to vCJD. Presently, this balancing of risks and benefits is left to the treating physician, in consultation with the patient. Information about UK and other potential deferrals is kept in the donor profile records to be considered by the transplant physician and his or her patient. Other deferral criteria

currently applied to blood donors do not necessarily automatically apply in the context of HPCs. For example, in certain instances patients are given bone marrow that tests positive for certain bacteria or pathogen markers. Transplant of such units is considered medically acceptable given extreme circumstances and the severity of the patient's underlying condition.

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

The AABB would welcome the opportunity to work with the Committee, the FDA, and others in the transplant community in addressing this important issue. Together, we must all strive to ensure that patients depending on HPC transplants receive the best possible care.