

Food & Drug Administration
Transmissible Spongiform Encephalopathies
Advisory Committee
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Tissue Banks International (TBI)

- Non-profit Organization
- Network of 33 U.S. Eye & Tissue Bank locations
- International Membership of 41 Eye & Tissue Banks
- Main Office in Baltimore, Maryland

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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 <u>Donor</u>	Hospital Non ME <u>Donor</u>	Leg. Cons ME <u>Donor</u>
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

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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

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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.
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