

FOOD AND DRUG ADMINISTRATION
TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES
ADVISORY COMMITTEE

Holiday Inn
Versailles Ballrooms I & II
Bethesda, Maryland 20814
January 18 & 19, 2001

FIRST DAY, Thursday, January 18, 2001, OPEN SESSION

- 8:30 a.m. Opening
 P. Brown, M.D., Committee Chairman
- 8:35 a.m. Administrative Remarks,
 W. Freas, Ph.D., Executive Secretary
- 8:40 a.m. Presentation of Awards for Committee Service
 B. Schwetz, D.V.M., Ph.D.
 Acting Deputy Commissioner for Food and Drugs
 Senior Advisor for Science, FDA

TOPIC 1. Reconsideration of FDA policies on suitability of blood donors who have lived or traveled in France and other European Countries based on recent information concerning new-variant Creutzfeld-Jakob disease and bovine spongiform encephalopathy

- 8:50 a.m. Introduction, Charge and Questions
 D. Asher, M.D., OBRR, FDA

Updates on vCJD and Estimated Human Exposures to the BSE in the United Kingdom, France, and Other BSE Countries

- 9:00 a.m. United Kingdom
 R.G. Will, M.D.
 National Creutzfeldt-Jakob Disease Surveillance Unit,
 Western General Hospital,
 Edinburgh, Scotland, UK
- 9:20 a.m. France
 J-P. Deslys, M.D., Ph.D.
 Prion Research Group,
 Atomic Energy Commission,
 Fontenay-aux-Roses, France
- 9:40 a.m. Germany and other European Countries
 J. Loewer, M.D.
 Paul Erlich Institute, Germany

TSEAC AGENDA, JANUARY 18,2001 (continued)

- 10:00 a.m. Canadian Assessments and Policies Concerning Deferral of Blood Donors Who Resided or Traveled in Countries with BSE and vCJD
Antonio Giulivi, M.D., FRCPC
Health Canada
Ottawa, Canada
- 10:20 Break
- 10:40 Potential Dietary Exposures of US Service Personnel and Dependents to BSE Agent
Col. S.R. Severin, D.V.M.
DOD Vet Service Activity
Falls Church, VA
Col. M. Fitzpatrick, Ph.D.
Armed Services Blood Program Office
Falls Church, VA
- 11:00 Possible Effects of Recent Changes in FDA Blood-Donor Deferral Policies on US Blood Supply
P. McCurdy, M.D.
National Heart, Lung and Blood Institute, Consultant
Bethesda, MD
- 11:05 **Allan Williams, Ph.D.**
American Red Cross
Jerome H. Holland Laboratory
- 11:15 Open Public Hearing
- 11:40 Committee Discussion
- 12:30 Lunch

TSEAC AGENDA, JANUARY 18,2001 (continued)

Topic 2, The risks of Creutzfeldt-Jakob disease(CJD) and vCJD transmission by human cells, tissues, and cellular and tissue-based products intended for implantation, transplantation, infusion, or transfer that are currently or proposed to be regulated by FDA, and the possible deferral of donors who have resided in the United Kingdom.

- 1:30 p.m. Background on Current and Proposed Policies for Blood, Human Tissue and Dura Mater Regarding CJD and vCJD
R. Solomon, M.D., OBRR, FDA
- 1:50 Tissue Distribution of Infectivity in Human TSEs
C. J. Gibbs, Jr., Ph.D.
NINDS, NIH
- 2:00 Tissue Distribution of Infectivity in Animal TSEs
S. Priola, Ph.D.
Rocky Mountain Laboratories, Hamilton MT
- 2:20 CJD Transmission by Corneal Transplantation
R.N. Hogan, Ph.D., M.D.
U. of Texas Southwestern Medical Center
- 2:35 CJD Risk Among Cornea Donors
R.H. Kennedy, M.D.
Eye Bank Association of America
- 2:50 Comments:
R. Taffs, Ph.D., CBER, FDA
L. Schonberger, M.D., CDC
- 3:00 Legislative Consent: Safety and Supply of Corneal Transplants
David Glasser, M.D.
Medical Advisory Board
Eye Bank Association of America
- 3:10 BREAK
- 3:25 The Risk of nvCJD in Recipients of Hematopoietic Stem Cell Transplants and the Impact of Deferring Donors From the UK
D. Confer, M.D.
Chief Medical Officer
National Marrow Donor Program
- 3:40 Tissue and Organ Standards Process in Canada
P. Dubord, M.D.
Health Canada
Ottawa, Canada
- 3:55 Donor History Questionnaire/Rates of Donor Deferral
Duke Kasprisin, M.D.
American Association of Tissue Banks
- 4:05 Open Public Hearing
- 4:35 Committee Discussion
- 5:30 Closed Session (tentative)
- 5:40 Adjourn for the day

FOOD AND DRUG ADMINISTRATION

TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES ADVISORY COMMITTEE

SECOND DAY, Friday, January 19, 2001, OPEN SESSION

TOPIC 3. Discussion of issues related to deer and elk infected with or exposed to chronic wasting disease in the U.S. and potential for human exposure

- 8:30 a.m. FDA/CFSAN Regulatory Issues
R. Brackett, Ph.D., CFSAN, FDA
- 8:45 Background on Chronic Wasting Disease
Dr. M. Miller, D.V.M.
Colorado Division of Wildlife
- 9:15 a.m. Epidemiological Investigations of Young CJD Cases Exposed to Venison
E. Belay, M.D., CDC
- 9:35 Diagnostics (exact title to be determined)
K. O'Rourke, D.V.M.
- 9:55 Industry Perspective
G. Zebarth, D.V.M.
American Elk Breeders Assn.
- 10:15 Break
- 10:30 Open Public Hearing
- 11:00 Committee Discussion
- 12:00 Lunch

TOPIC 4. Discussion as to whether a history of possible exposure to various animal TSE agents should be considered by the FDA in determining suitability of blood donors.

- 1:00 p.m. Introduction, Charge and Questions
D.M. Asher, M.D., OBRR, FDA
- 1:10 Undifferentiated TSE in Flocks of Sheep in Vermont
L. Detwiler, D.V.M.
APHIS Emergency Programs USDA
- 1:30 Efforts to Initiate a Program to Eliminate CWD from Farmed Elk
L. Creekmore, D.V.M.
APHIS National Animal Health Programs Staff, USDA
- 1:50 Regulation of Ruminant Materials in US Dietary Supplements
R. Moore, Ph.D., CFSAN, FDA
- 2:30 Open Public Hearing
- 3:00 Committee Discussion
- 4:00 ADJOURN