T&G **PLASMA-DERIVED PRODUCTS CONTAMINATED BY CJD CAN REMAIN ON MARKET.** FDA's Blood Products Advisory Committee recommended at its Dec. 15 meeting. The committee voted 10-3 with two abstentions that retrieval of plasma-derived products due to post-donation information revealing contamination by a donor with Creutzfeldt-Jakob disease is unnecessary as is notification to all consignees and recipients of such products. Committee member Kenneth Anderson, MD, Dana-Farber Cancer Institute, said that "to withdraw cellular components was supported by some animal data, but in the case of noncellular products, there hasn't been any evidence."

> The committee did recommend product retrieval of *blood* components contaminated by a donor with CJD and notification of consignees and recipients who have received the products. Committee members noted that although there is little risk of transmission, it is not zero risk.

¶ The committee was presented with data on the transmissibility of CJD through transfusion. "There has never been a reported case of transmission of CJD by the transfusion of blood or plasma products," Center for Biologics Evaluation & Research Division of Transfusion-Transmitted Diseases Director Paul Mied, PhD, said. Invited guest Lawrence Schoenberger, Centers for Disease Control & Prevention, added that "the existing data, although not definitive, indicate that the risk, if any, of transmission of CJD by blood products is extremely small and currently unmeasureable. Since CDC is unaware of documented cases of CJD caused by transfusion of contaminated blood products, we believe the risk appropriately can be described as theoretical."

¶ Mied also informed the committee that "plasma derivatives manufactured from a plasma pool would be expected to pose less of a risk to an individual recipient...than [blood] components due to the fact that first, they are prepared from the noncellular portion of the blood; second, any given plasma unit is greatly diluted — somewhere on the order of 4,000 to 30,000 units are combined in a plasma pool; and third, the dose of any material representing blood cells will be in much smaller quantity than a unit of a blood component."

➢ Committee members questioned whether shortages would occur if products were withdrawn. "I am concerned about the potential for a lack of availability of product. We can't wring our hands and say, well, we're not treating you, but we're giving you the safest nothing we have," committee member Edward Snyder, MD, Yale-New Haven Hospital, said. "We have to give [patients] the option of entering the decision with us with what we have on the shelf. Taking blood products is a risk that we should not deny them the right to assume," he asserted.

¶ The committee was convened to discuss this issue following the discovery by the American Red Cross that two of its donors were diagnosed *post-mortem* with Creutzfeldt-Jakob disease ("The Pink Sheet" Nov. 21, 1994, T&G-11). In October and November, 1994, the ARC initiated a voluntary withdrawal of in-date single donor blood components and placed on hold all plasma derivative products in its inventory. The ARC also withdrew certain lots of plasma derivatives. In November 1994 Miles, Baxter Healthcare and Sandoz all initiated voluntary withdrawals of plasma products manufactured from intermediates purchased from the ARC.