



DONOR ALLIANCE

Enhancing Lives Through Organ & Tissue Donation

2325 '02 JUL -1 A9:47

June 25, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear FDA Representative:

Regarding recommended donor eligibility criteria #2 on page 15 of **Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based products (HCT/Ps)**, I would like to see criteria more in keeping with actual risk.

For example, dementia per se would exclude tens of thousands of good potential donors with simple senile dementia. I think excluding dementias in younger donors (say 60 years old or younger), **with** rapid onset and progression of disease (say, within the last 12 months), would be a much more reasonable approach. This would cover the younger average age of onset of vCJD. For classic CJD, onset of dementia with rapid progression within the last 12 months would be adequate.

As a blood banker, the remainder of the eligibility criteria fits what we are already doing in that industry. This would make donor criteria, in general, consistent, even though the jury is still out regarding the scientific merits of the deferrals.

Please give these suggestions careful consideration. The demand for donated tissue continues to outstrip the supply. Given the excellent track record of tissue transplantation over the years, further regulations to mitigate classic CJD may not be necessary. My personal concern is vCJD, and I think the approach I have suggested satisfies that concern without overburdening the industry.

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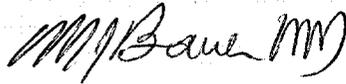
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You are doing a laudable job in protecting the safety of our patients. I appreciate very much the opportunity to communicate my concerns. If I may be of any assistance, please feel free to contact me personally.

Sincerely,

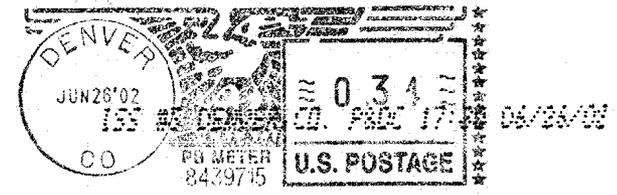
A handwritten signature in cursive script that reads "MJ Bauer MD". The signature is written in black ink and is positioned above the printed name.

Michael J. Bauer, M.D.
Medical Director



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