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Re: Docket 2004D-0193

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The National Marrow Donor Program (NMDP) appreciates the opportunity to comment on the Draft Guidance - *Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)*, docket number 2004D-0193. The NMDP welcomes the opportunity to discuss our concerns related to the physical exam requirements directly with the FDA. I can be reached at 612-362-3425.

Sincerely,

Dennis L. Confer D.R.

Dennis L. Confer
Chief Medical Officer

enclosure

2004D-0193

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National Marrow Donor Program® Comments
Draft Guidance, Docket Number 2004D-0193
*Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and
Tissue-Based Products (HCT/Ps)*

II.H The Donor-Eligibility Determination

What do I do with the HCT/Ps before the donor-eligibility determination has been completed?

Quarantine means the storage or identification of an HCT/P, to prevent improper release, in a physically separate area clearly identified for such use, or through use of other procedures, such as automated designation.

The NMDP interprets the implementation of processes *to prevent improper release* to include not only physical processes, as provided in the example of *such as automated designation*, but also standard operating procedures that define a controlled release process. The NMDP suggests additional clarity in regard to this requirement.

III.G Donor Screening (§ 1271.75)

What physical evidence do I look for?

- 1. Physical evidence for risk of sexually transmitted diseases such as genital ulcerative disease, herpes simplex, syphilis, chancroid;*
- 2. For a male donor, physical evidence of anal intercourse including perianal condyloma;*

For the purposes of Donor Screening, living donors of cord blood, peripheral blood stem cells and donor lymphocytes should not be expected to have an examination of the genital and anal areas. Blood donors are not subjected to this humiliation and neither should be the hematopoietic cell donor. Routine genital and anal examinations would be highly intrusive, minimally useful and ill-advised.

These living donors are directly and repeatedly questioned about risk behaviors related to the relevant exposures. This direct questioning produces a behavioral history that is superior to that obtained in the non-living donor setting. Furthermore, the living donor's blood is tested with FDA-licensed, approved or cleared test kits specifically developed to detect evidence of exposure to the relevant infectious diseases. This dual approach of controlled questioning and validated testing is unlikely to be improved by the addition of an ill-defined, uncontrolled examination/inspection of the genitalia and anus.

There are no physical findings that positively establish prior anal intercourse. Condylomata acuminata, which FDA suggests is pathognomonic of anal intercourse, may be initiated by numerous alternative exposures. How are such non-specific physical findings to be weighed when the questioning and testing of the donor is negative for risk? Similarly, what is the value

or utility of discovering genital herpes? Especially when one considers that serologic testing for the virus is not required.

FDA must restrict the routine physical examination of the living donor to the head, trunk and extremities. Examination of the genital and anal areas in this donor population is unacceptable. The National Marrow Donor Program supports recommendations of the American Association of Blood Banks Technical Manual, which requires the following components within the physical examination:

- General appearance
- Weight
- Pulse
- Blood Pressure
- Skin lesions (arms).