



Food and Drug Administration
Rockville MD 20857

AUG 15 2000 12 78 03 AM '00

The Honorable Rick Santorum
United States Senate
Washington, D.C. 20510-3804

Dear Senator Santorum:

Thank you for the letter of January 11, 2000, on behalf of your constituent, Abraham K. Munabi, M.D., Medical Director, Reproductive Science Institute of Suburban Philadelphia, P.C., who is concerned about the Food and Drug Administration's (FDA or the Agency) September 30, 1999, proposed rule titled, "Suitability Determination for Donors of Human Cellular and Tissue-Based Products." We apologize for the delay in responding.

You enclosed Dr. Munabi's letter, which was sent to FDA's Docket Management Branch. Please assure Dr. Munabi that all letters FDA has received under this docket will undergo appropriate consideration.

FDA has proposed this rule in order to provide more appropriate oversight for the wide spectrum of human cellular and tissue-based products that are marketed now or may be marketed in the future. We believe the Agency's action would improve protection of the public health and increase public confidence in new technologies, while permitting significant innovation and keeping regulatory burden to a minimum.

FDA is proposing to issue these new regulations under the authority of section 361 of the Public Health Service Act. Under that section, FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or from foreign countries into the States. Certain diseases are transmissible through the implantation, transplantation, infusion, or transfer of human cellular or tissue-based products derived from donors infected with those diseases. In order to prevent the introduction, transmission, and spread of such diseases, FDA considers it

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necessary to take appropriate measures to prevent the use of cells or tissues from infected donors.

FDA now proposes to require manufacturers of certain human cellular and tissue-based products to screen and test the donors of cells and tissues used in those products for risk factors for and clinical evidence of relevant communicable disease agents and diseases. The proposed regulations are intended as safeguards to prevent the transmission of communicable diseases that may occur with the use of cells and tissues from infected donors.

In acting to increase the safety of the nation's supply of human cellular and tissue-based products, FDA is also seeking to avoid unnecessary regulation. Thus, consistent with the proposed approach document, the Agency has tailored the proposed testing and screening requirements to the degree of communicable disease risk associated with the various types of human cellular and tissue-based products. The testing and screening for donors of cells and tissues that pose a high degree of communicable disease risk will be more extensive than for donors of cells and tissues with lesser risk. Where the risk is quite low (e.g., cells or tissues used autologously) FDA will recommend testing and screening, but will not require them; however, certain labeling will be required.

As part of this regulatory action, the Agency is proposing to amend the current good manufacturing practice regulations that apply to human cellular and tissue-based products regulated as drugs, medical devices, and/or biological products to incorporate the new donor-suitability procedures into existing good manufacturing practice regulations.

Proposed § 1271.75(a)(1) states that the relevant medical records for a cell or tissue donor shall be reviewed for risk factors for and clinical evidence of infection due to relevant communicable disease agents and diseases. This section also specifically lists HIV, HBV, HCV, and TSE as relevant communicable disease agents and diseases for which such screening is required. These four disease agents and diseases are listed as the "minimum" for which screening would be required; should a new relevant communicable disease arise or be identified, the Agency would consider manufacturers to be

required, under this section of the proposed rule, to screen for the new disease as well.

Special concerns arise with respect to donors of reproductive cells or tissue, when those cells or tissue are recovered through methods that could lead to the transmission of sexually transmitted and genitourinary diseases. Accordingly, under proposed § 1271.75(b), if those methods are used, donor screening would be required for risk factors for and clinical evidence of infection due to sexually transmitted and genitourinary diseases. Certain methods of recovery (e.g., laparoscopy to recover oocytes) are not directly connected with the transmission of sexually transmitted and genitourinary diseases, and would not trigger this requirement.

Proposed § 1271.90(a) identifies two situations in which a determination of donor suitability would not be required. In the case of banked cells and tissues for autologous use, cells and tissues are removed from a patient and stored for later use in the same patient. Because the risk of the patient contracting a new communicable disease from cells or tissues taken from his or her own body is extremely low, FDA is not requiring communicable disease testing or screening. (Any handling and storage requirements for such cells or tissue may be addressed later, in the proposed good tissue practices regulation.) However, as a general safety measure, FDA recommends that autologous donors be subjected to the same testing and screening as proposed under §§ 1271.75, 1271.85, and 1271.90 for allogeneic donors of comparable human cellular or tissue-based products.

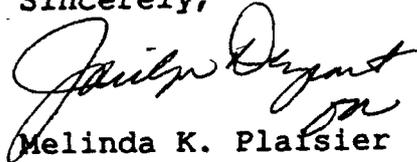
The second situation in which FDA is recommending, but not requiring, testing is for reproductive cells or tissue donated by a sexually intimate partner of the recipient. In this case, the recipient will likely have been routinely exposed to the donor's semen or other body fluids. Although some screening and testing of the donor and recipient may be appropriate, FDA believes that this should be the responsibility of the attending physician and the donor and the recipient.

Please be assured that FDA will consider all comments submitted in response to the proposed rule. FDA will then make appropriate modifications to the proposed rule and issue a final rule that incorporates these changes.

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Thanks again for contacting us regarding this matter. If you have further questions, please let us know.

Sincerely,

A handwritten signature in cursive script, appearing to read "Melinda K. Plaisier".

Melinda K. Plaisier
Associate Commissioner
for Legislation

cc: Dockets Management Branch
(Docket Number 97N-484S)