Dr. Ramón M. Suárez Calderón
Cardiovascular Center
of Puerto Rico and the Caribbean
AT THE RYTHM OF YOUR HEART

0811 '00 FEB 24 A10:11

February 1, 2000

Mrs. Paula McKeever
Docket No. 97N-4B4S
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, Md 20852

Dear Mrs. McKeever:

It was recently received in our offices a request for comments on the proposed rule for "Suitability Determination for Donors of Human Cellular and Tissue-Based Products".

The Cardiovascular Center of Puerto Rico and the Caribbean is a 192-bed hospital that provides cardiovascular care including cardio-thoracic surgery and invasive and non-invasive procedures. Since December 1998, we developed a heart transplant program and have performed six heart transplants. We keep an agreement with Lifelink of Puerto Rico to both receive and donate organs. Even, when we do not do any cell or tissue transplants, we are interested in the new rules for suitability because we understand cells and tissues should be deeply tested.

After a review of the proposed rule, we understand it is highly recommended to pursue all the screening and testing you are proposing. First, we believe that this new regulation will help patients gain confidence towards the process of transplantation. As long as people know all the screening the cells and tissues were exposed to, they will promote the transplantation.

97N-4845

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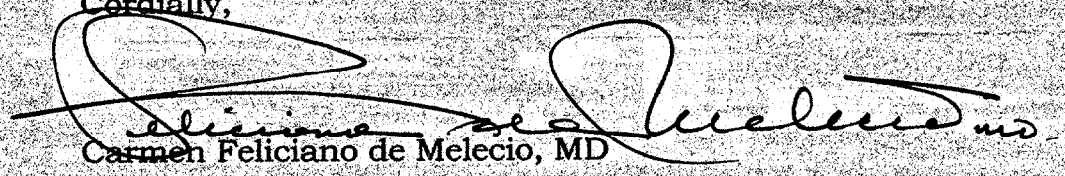
Second, we understand that it will lower the chance to acquire a transmissible disease through implantation of diseased cells or tissues. The potential risks of acquiring a transmission disease are very high if the appropriate tests are not conducted.

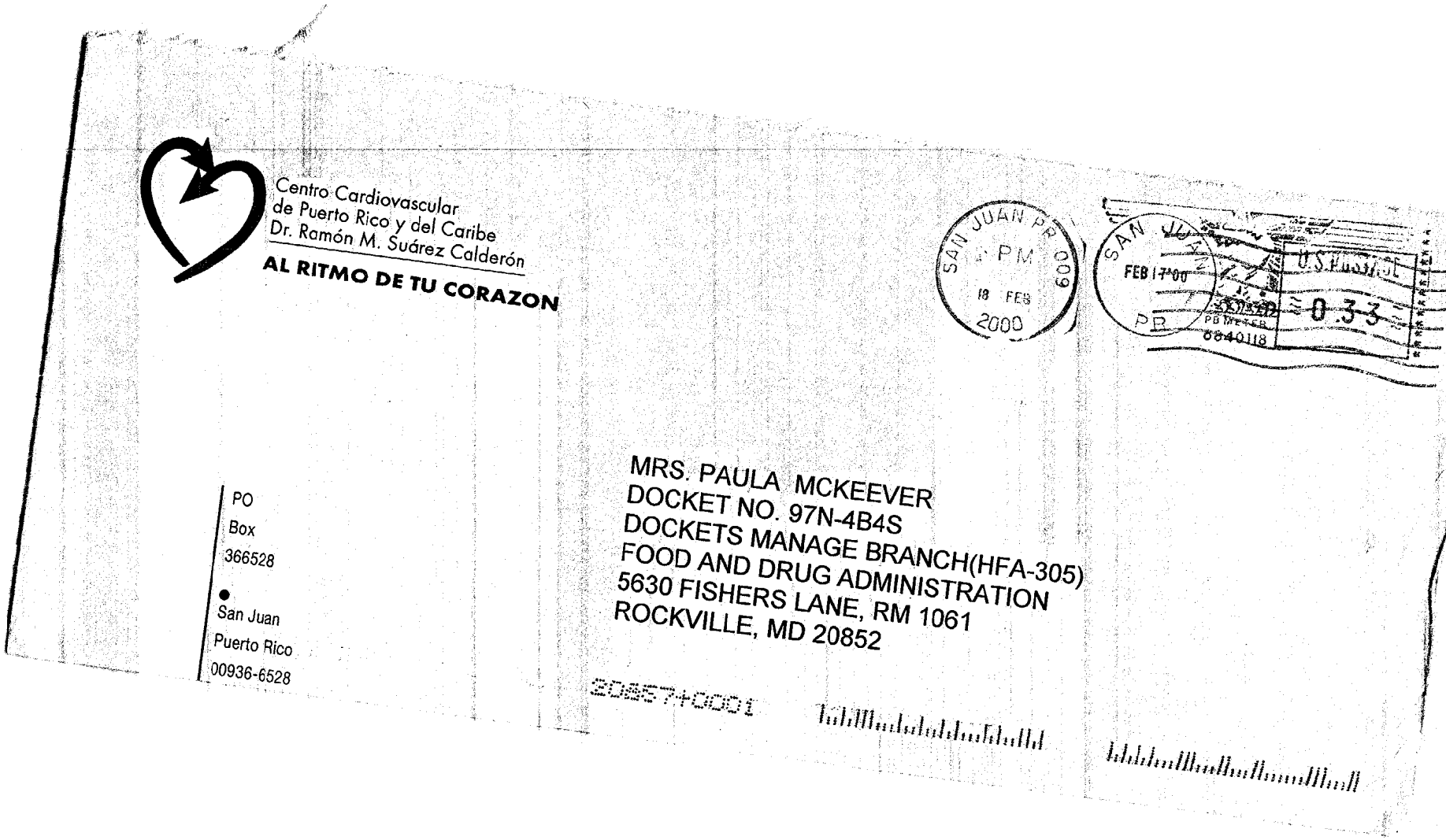
Another important issue is the fact that the new regulation covers the aspect of confidentiality by not providing the suitability document with the donor's name. This aspect is very important to us, especially since we deal with potential recipients.

We appreciate the opportunity given to expose our comments on this matter.

Cordially,



Carmen Feliciano de Melecio, MD
President
Board of Directors
(Secretary of Health)



Centro Cardiovascular
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Dr. Ramón M. Suárez Calderón

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