

July 22, 2012

From: Frank H. Arlinghaus, Jr., MD, FACP, FCCP

To: The Honorable Frank Pallone, Jr.  
Member of Congress, House of Representatives

Subj: Food and Drug Administration Hearings Re: Reuse of Pacemakers

#### Background

1. In 1995 the FDA last reviewed and ruled on the reuse of cardiac pacemakers from potential donors. Due to the limited technology of assessing transmissible infectious disease risk such as HIV and Hepatitis C, the ruling discouraged such practices.
2. Since that time assessment of infectious disease risk has improved dramatically.

#### Current developments

1. At this time Dr. Kim Eagle and Dr. Tom Crawford of the Michigan Cardiovascular Institute are working on protocols for the reuse of pacemakers that are being offered as donated organ-equivalents. At the present time very expensive pacemakers that outlive their original hosts may not be transported across state lines due to the FDA regulation.
2. Associates of Drs. Eagle and Crawford include Dr. Kris Oswald of the Community Services Foundation, a NGO of 75 to 100 years of service to developing countries. They (CSF) are developing computer based mapping software to follow areas of the world where pacemaker need is the greatest including India and South America.
3. The CSF New York representative Dr. Chris Dickey is in close collaboration with UNICEF and UNDP for adoption and expansion of these endeavors.

#### Network collaboration

1. This endeavor was brought to my attention (at a recent family memorial gathering for my late brother) by my cousins Dr. Sandra Arlinghaus and Dr. William Arlinghaus, retired Mathematics Professors of the University of Michigan and collaborators with both Drs. Eagle and Crawford and Dr. Oswald. They are unaware of how to approach the FDA successfully.
2. At the gathering was also my other political physician associate Dr. Wellington Tichenor who assisted in the gathering in NYC two years ago. Dr. Tichenor has been in touch with Nancy Anne DeParle, Deputy Chief of Staff at the White House, with a special portfolio of medical care policy.

Desired Action:

1. Dr. Crawford and Dr. Dickey as well as myself, Dr. Tichenor and a member of the Tissue Sharing Network of NJ, would like to give a presentation to you and hopefully we would be joined by Ms. DeParle. Drs. Crawford and Dickey would like to present the compelling nature of a re-evaluation by the FDA of the current restriction on interstate and re-use of donated organ equivalent pacemakers. The Tissue Sharing Network of NJ will be there as a subject matter expert on donated organs. Dr. Tichenor who has had correspondence with Ms. DeParle on other matters would be her host.

**2. The desired outcome would be a request by you and the White House to the FDA to hold hearings with the goal in mind to update the regulation and, it is hoped, allow the interstate shipment of pre used pacemaker, both here and abroad.**

3. Are you able to travel to NYC in the August recess for such a presentation, or would the campaign and travel schedule make it better to do this locally. We would also wish to note that the CSF has extensive projects in India including clean water as well as potentially supporting use of donated pacemakers which many developing countries cannot afford.

4. As we are coordinating the travel of Drs Crawford from Michigan, Dr. Dickey in NYC, and the legal policy official of the Tissue Sharing Network, not to mention the possible attendance of Ms. DeParle, can you commit to a time and location?

5. Personal best regards!