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August 23, 2011

The Honorable Howard Koh, MD, MPH  
Assistant Secretary for Health  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Koh:

On behalf of the transplant community, the American Society of Transplant Surgeons (ASTS), the American Society of Transplantation (AST), the Association of Organ Procurement Organizations (AOPO) and NATCO, The Organization for Transplant Professionals are writing to express our concerns with the proposed “PHS Guideline for Reducing HIV/HBV/HCV Transmission,” along with the process used to develop it.<sup>1</sup> The process and document both fail to reflect the coordinated and cooperative approach toward transplantation that we had hoped would emerge as the result of the positive meeting that the ASTS and the AST had with you and your staff on April 27, 2011. The document has significant deficiencies, espousing firm recommendations that are impractical and not evidence-based. Most significantly, the proposed guideline has the potential to unnecessarily reduce the availability of organs for transplantation, an outcome inconsistent with HHS’ broader policy objectives and with the needs of our patients.

We support updating the 1994 PHS guideline for reducing the risks of transmission of blood borne pathogens, to more accurately reflect today’s clinical practice. For that reason, we were pleased to participate in the development of a new PHS guideline by appointing designated experts. However, the proposed guideline deviates so completely from the input provided by our expert representatives that most of them have withdrawn their names from the document. The experts’ serious concerns with the proposed guideline are set forth in greater depth in a separate letter from them to you and Dr. Frieden.<sup>2</sup>

While our organizations have serious concerns about the proposed guideline, our broader concern is that this document, like many that are issued by various divisions within HHS, appears to reflect the relatively

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<sup>1</sup> It is our understanding that this draft is to be published in the *Federal Register* in the near future.

<sup>2</sup> Summarizing, the proposed Guideline is based on weak evidence; is inconsistent with expert opinion provided during the guideline development process; directly contradicts the conclusions of the July 28, 2011 consensus panel sponsored by the AST, ASTS, UNOS, and NATCO; and purports to provide detailed proscriptive “instruction” for specimen preparation and handling which are supported by expert opinion or by clinical evidence.

narrow focus of the HHS division involved, and fails to reflect any coordination of policies related to transplantation at the departmental level. More specifically, the draft guideline reflects the CDC's focus on complete elimination of the risk of disease transmittal, without adequate consideration of the need to balance this objective against the need to increase the availability of organs for transplantation. In our view, if the guideline is finalized as proposed, organ wastage will increase and many of our patients will be unnecessarily deprived of life-saving transplants. Quite simply, as the consequence of a misguided effort to completely eliminate all risk of disease transmittal, more patients will die of organ failure than will be saved by avoiding donor-derived infection. Such a result would be inconsistent with the HHS' overall objective of increasing the availability of organs for transplantation: misguided from the standpoint of the transplant community and nothing less than tragic for those patients unnecessarily deprived of access to life-saving transplants, not to mention the significant increase in resource expenditure to accomplish these proposed guidelines.

Under these circumstances, we request that you consider revising the draft guideline prior to publication in the *Federal Register* or, at the very least, prior to publication in final form, to achieve a more reasonable balance of the need to prevent disease transmission against the need to maximize the availability of organs for transplantation. More broadly, we urge you to persevere with plans for inter-divisional coordination of transplant policy, knowing that the transplant community stands ready to assist you in this effort in any way we can.

Sincerely,



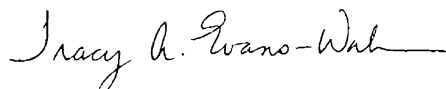
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