ASTS
American Society of Transplant Surgeons

September 28, 2012

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 American Society of Transplant Surgeons (ASTS), I am writing to inform you that we continue to remain extremely concerned about the draft *"Guideline for Reducing Transmission of HIV, HBV and HCV Through Organ Transplantation"* that has been shared with us (Draft Guideline), and to request that the agency refrain from publishing this document in final form.

We very much appreciate that the Draft Guideline was shared with us prior to its adoption in final form and that our views on the document were solicited. Our feedback was provided to Jim Berger by letter dated September 12, a copy of which is attached. In response to the serious concerns raised by ASTS and others, a meeting that included the Presidents of ASTS and the American Society of Transplantation, Dr. Valdiserri, Mr. Berger, Captain Kuehnert, and Dr. Cono (via phone) was held on September 19, 2012. We are very grateful for the opportunity to meet with them and to share our opinions and concerns regarding the Draft Guideline.

In that meeting, we were told that the basic recommendations included in the Draft Guideline would not change, but that the Public Health Service (PHS) would consider feedback and suggested edits on the tone of the narrative. We were offered ten days to provide such input, and even though this was a very short timeline, we were initially pleased for the chance to have one more opportunity to provide input. However, after significant discussion with our subject matter experts and society leadership, as well as considerable rounds of draft edits, we have concluded that mere wording changes in the tone of the narrative are inadequate. After nearly four years and immense effort by many, we still cannot understand why the Draft Guideline remains so different from that recommended by the Expert Panel and Review Committee, and includes many of the same deficiencies noted in our meeting with you last year.

This draft, like the version that was the subject of our prior meeting with you on this topic, appears to intermingle data relating to transmission of HIV, HBV, and HCV with data regarding transmission of other infectious diseases.

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This version, like the prior version, fails to make it clear how few donors "slipped through the cracks" of existing screening protocols and instead characterizes the risk of transmission of HBV, HCV and HIV as a "critical patient safety and public health issue." The language implies that there has been little effort focused on donor assessment and testing, and fails to acknowledge the role of OPTN policy in ensuring screening of deceased donors or efforts of the centers to screen live donors.

There is also no recognition that, from 2008-2011, over 113,000 organ transplants were performed in the United States, ans that, during this same period, over 29,000 people died waiting for an organ transplant and more than 14,000 people were removed because they became too sick to transplant. During this period, 50 deaths were attributed by the OPTN (DTAC) from unexpected disease transmission and only one of these was from HIV, HBV or HCV. We do not deny that unexpected disease transmissions (any infection or malignancy and not only HIV, HBV and HCV) is a tragedy and should be addressed, but the current document presents the problem completely out of context. The increasing risk that potential recipients will die while on the waitlist is a more pressing and critical issue than the risk of unexpected transmission of HBV, HCV or HIV through solid organ transplantation.

The Draft Guideline, like the prior version, has the potential to exacerbate this more pressing and critical issue: The document makes strong recommendations based on weak evidence and recommends the performance of NAT testing (for HCV) for <u>all</u> potential donors, without recognizing the potential impact of universal NAT testing on organ supply.[1] The proposed recommendations fail to address the issue of discordant and false positive results. This will result in community confusion, add more regulation and possibly result in negative outcomes for potential recipients awaiting transplants.

The Draft Guideline also continues to dictate medical practice and protocols with respect to post-transplant testing without sufficient evidence, and fails to fully recognize the role of the OPTN, CMS, state law and other authorities with regard to issues such as informed consent. By reiterating current CMS or OPTN policy, the Draft Guideline creates a scenario that will likely lead to discordant guidance since CMS and OPTN policy are likely to be changed or updated much sooner than the Draft Guideline would be once again revised. Preferably, any requirements that fall under the purview of OPTN or CMS should be removed from the document. At the very least, to the extent that the Draft Guideline makes recommendations based solely on OPTN, CMS or other requirements, this should be clearly disclosed. .

All of these issues and others are detailed in our September 12 letter to James Berger. It is our understanding that, despite these significant concerns – concerns voiced by the great majority of the practicing clinical transplant community, as represented by ASTS, AST, AOPO, and NATCO – the agency remains unwilling to make any substantive changes in the document. Under these circumstances, we do not believe that simple changes in tone will address our fundamental concerns.

We, as a transplant community, worry about disease transmission each and every day, and we are deeply committed to better defining the risks and reducing the possibility of unintended transmission of all donor-derived disease to our patients. However, we cannot approach this issue using a single-lens. Practicing clinicians also must worry about transmission of other

[1] While this version of the document recommends universal NAT testing only for HCV, since NAT testing is often performed as a panel, as a practical matter this recommendation likely will result in universal NAT testing for HBV and HIV as well.

diseases, organ availability, death on the waiting list, clinical outcomes, risk/benefit, and most importantly, how to accurately and reasonably inform our patients about these risks. Similarly, while the CDC is charged with addressing the single issue of HIV, HBV and HCV transmission, it is our understanding that PHS, as a whole, is charged with achieving a reasonable balance between this and other goals, including the goal of decreasing organ wastage and increasing organ availability. In our view, the Draft Guideline simply does not achieve that balance. We understand from the comments in our meeting last week that this was not meant to be a consensus document; however we would expect the guideline to provide and clear and objective description of the extent of unexpected transmission of HBV, HCV and HIV through solid organ transplantation, address the impact of the recommendations on organ availability, define how the community will track the impact of guideline implementation, justify the strong recommendations, and include data from the recent literature.

As we have previously stated, we understand and completely support the need to revise the 1994 guideline and recognize the need to "get it right" given the likelihood that the guideline may not be revised for another 15-20 years and will become a basis for policy for one or more regulatory agencies. Throughout this process, ASTS' goal has been to work collaboratively with PHS to develop an appropriate and realistic guideline that reflects the available clinical data, current clinical practice, and the risk/benefit equation unique to solid organ transplantation. We remain hopeful that this still can be achieved. We believe that, with additional time and additional input from the Expert Panel and society leadership, we could be successful at developing a better product for the public and the transplant community. We would support a one to two day meeting to develop a consensus that will accomplish the goals set forth by the PHS and address the needs of the transplant community and its patients, using the current draft as a framework.

Despite our extreme disappointment with the current draft, we reflect with optimism on the comments in your letter dated January 19, 2012 that "HHS will keep the PHS Guideline public comment review process and inclusive" as well as Dr. Cono's comments from the January 2012 conference call when she assured the professional societies that we would be happy with the final product. We remain hopeful that we can find a pathway forward, and we are committed to developing a final document that will truly serve the needs of the community and the public. We urge you not to release the draft guideline as currently written.

We wish to thank you for the opportunity to comment once again on this important document. If you have any questions or require additional information, please do not hesitate to contact medirectly. I welcome further dialogue.

Best Regards,

Kim M. Olthoff, MD
President

Enclosure

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