ASTS
American Society of Transplant Surgeons

November 11, 2011

The Honorable Thomas Frieden, MD, MHP
Director, Centers for Disease Control and Prevention
1600 Clifton Rd, N.E.
Mailstop A-07
Atlanta, Georgia, 30329

**Re: Docket No. CDC-2011-0011: Public Health Service Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) through Solid Organ Transplantation**

Dear Dr. Frieden,

The American Society of Transplant Surgeons (ASTS) is pleased to have this opportunity to comment on the draft "PHS Guidelines for Reducing the Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Solid Organ Transplantation," hereafter referred to "the Draft Guidelines". The ASTS is comprised of over 1900 transplant surgeons, physicians, scientists, advanced transplant providers and allied health professionals dedicated to excellence in transplant surgery through education and research with respect to all aspects of organ donation and transplantation so as to save lives and enhance the quality of life of patients with end stage organ failure.

The ASTS has always welcomed the opportunity to work collaboratively with federal agencies to develop meaningful guidelines for improving solid organ transplantation. In keeping with this commitment, we were pleased to provide representatives to serve on the Expert Panel and Review Committee to update the current guidelines for reducing HIV and hepatitis transmission through solid organ transplantation. However, we are deeply disappointed that our representatives, along with most of their fellow expert panel and review committee members, felt compelled to withdraw from participating because of lack of a collaborative process, resulting in a deeply flawed and misleading document. Its release to the public was far too premature; its recommendations do not reflect the evidence or consensus expert opinion; it reflects an institutional bias on the part of the Public Health Service (PHS) that fails to weigh the risk of disease transmission appropriately vis-à-vis other risks to prospective transplant recipients; and it has a real potential to mislead the public regarding the risks of disease transmission through solid organ transplantation.



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In the spirit of providing what we hope will be constructive feedback, we will summarize our concerns by addressing the *process*, the *content*, and the *potential public reaction* that we anticipate from this document in the sections below.

Preliminarily, however, we note that the National Organ Transplantation Act (1984 Pub.L. 98-507), which governs most aspects of organ transplantation in the United States, specifically requires the Secretary of the Department of Health and Human Services to contract with an Organ Procurement and Transplantation Network (OPTN) which, among other things, is required to:

> **adopt** and use standards of quality for the acquisition and transportation of donated organs, including **standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome.**

(Emphasis added.) The Draft Guidelines were drafted by the PHS independent of input from the OPTN. and, in fact, it is our understanding that leaders of the United Network for Organ Sharing (UNOS), which currently holds the contract as the OPTN, have filed comments strongly objecting to the Draft Guidelines. In light of NOTA's clear in delegation of a role for the OPTN in the adoption of standards in this area, it is inconsistent with Congressional intent for the CDC to fail to consult with the OPTN in formulating the Draft Guidelines.

**PROCESS**

The expert panel and review committee provided input into the development of this document in 2009 and 2010, prior to interagency review. After interagency review, in the summer of 2011, the document was returned to the expert panel and review committee. The document had been dramatically altered by the interagency review process, with the addition of new recommendations, numerous instances of rewording and strengthening of recommendations, and reinterpretation of the data. **Virtually all of the external expert reviewers indicated that the changes made during the course of the interagency review were not consistent with the little evidence that is available, and that the document, as modified, did not represent their expert opinion.**

After reviewing the Draft Guidelines that emerged from interagency review, our representatives and most of their colleagues from the other transplantation stakeholder organizations recommended that the Draft Guidelines be revised again before being published for public comment: While the current guidelines are outdated, there is no compelling need for immediate revision of the current guidelines to avert a public health hazard, nor is there any other identifiable need for precipitous action. Despite this recommendation, and despite the fact that PHS representatives knew that the Draft Guidelines no longer reflect expert consensus, the Draft Guidelines were published for public comment and the expert panel disbanded in protest, precluding the possibility of adoption a of much better, more relevant and more useful set of guidelines.

Under these circumstances, we take exception to those portions of the document that suggest or imply that the Guidelines are based on "expert consensus." In fact, the "Expert Panel" named in the Draft Guidelines does not include a single expert in the field of transplantation, but rather includes solely specialists in laboratory sciences and epidemiology employed by the CDC. The Review Committee

includes only one external member who is a physician expert in transplantation. The original Expert Panel and Review Committee included 14 physicians and surgeons from throughout the US and Canada with expertise in the field of transplantation, all of whom requested that their names not be listed in the Draft Guidelines.

Under these circumstances, we believe that it is extremely misleading to state that any of the recommendations are supported by "expert consensus." Yet, in describing "Expert Opinion", the Draft Guidelines state:

> These recommendations were agreed upon by expert consensus and are designated either IB if they represent a strong recommendation based on accepted practices or IIB if they are a weak recommendation. (Emphasis added)

In light of the circumstances surrounding development of the Draft Guidelines, such statements are highly misleading. We strongly urge that if the Draft Guidelines are finalized without expert input and consensus development that it be made crystal clear that these recommendations are, in fact, inconsistent with the consensus opinion of the experts in the field of transplantation and that they do not represent the expert opinion of the group initially named to the Expert Panel and Review Committee.

Because little solid data is available regarding the critical questions addressed by the guidelines, expert opinion is particularly critical. Frequently in this document however, guideline statements are supported by little (if any) hard data and are inconsistent with the consensus of expert opinion. These assertions should not be characterized as a "strong" recommendations. Yet, the Draft Guidelines include a significant number of "strong" recommendations that are supported by neither hard evidence nor expert opinion, and many are not consistent with accepted practices. The inclusion in the Draft Guidelines of "strong" recommendations implies some level of credible scientific evidence or, at the very least, a strong consensus of expert opinion neither of which are present here, and, for this reason, the inclusion of "strong" recommendations in this document is misleading to both the public and the professional community.

**CONTENT**

***Title***

The ASTS has long advocated for effectively informing potential transplant recipients about all of the potential risks of donor organs and of transplantation generally. We strongly support efforts to better define these risks through cost-effective testing of donor organs. But we strongly disagree with the premise, as implied by the title of this document, that the risk of transmission of these viruses poses so fundamental a threat to public health that reducing that risk necessarily outweighs other clinical and public health considerations, regardless of the cost and regardless of the consequences to potential recipients. Framing the issue in this way fails to recognize that the false positive rate for behavioral history or blood screening is not well defined and could potentially exclude many more donor organs than necessary. Isolating and elevating the risk of disease transmission over all of the other potential risks involved in transplantation—many of which carry consequences that are far more severe for

potential recipients--reflects an institutional bias on the part of the PHS which, while consistent with PHS' mission, is inconsistent with sound public policy and, in many cases, inconsistent with the best interests of our patients.

In the final analysis, transmission of disease can only be prevented by isolation of the infected individual or vaccination of the unexposed. If the goal is to reduce the risk of transmission (as the title of the Draft Guidelines suggests), the only way to fully accomplish the Draft Guidelines' objective is to "isolate" (prohibit the use of) organs from recipients when infection is suspected or documented in the donor. We do not believe that this should be goal of these guidelines and strongly object to the message that the very title of this document sends to the public. Our experts suggested "Guidelines for better characterizing the risk for unintentionally transmitting HIV, HBV and HCV disease via solid organ transmission" as the title; however, this was rejected by the interagency review process.

***Executive Summary***

This tone is continued in the Executive Summary (page 9), which frames the reduction of disease transmission resulting from transplantation as a "critical patient safety and public health issue. Such events can result in serious illness and death…'' These statements are one sided. In fact, the consequences of *known* disease transmission-- which is by far the most common scenario in clinical practice --rarely results in serious illness or patient death. *Unintended* donor disease transmission occurs much less frequently than many other health problems in this country that are not characterized as "critical patient safety and public health issue[s]."

The Executive Summary continues along a similar vein, noting, "[T]he transplantation of HBV or HCV infected donors is accepted medical practice *in narrowly defined situations*". (Emphasis added.) This would be much more accurate and informative if it stated that transplantation of organs from donors known to carry HBV or HCV is *routinely performed* in situations where the recipients are informed and accept the risks of the potential transmission.

Statements indicating that prophylaxis is given in these situations "to prevent transmission or reduce disease severity" (emphasis added) are also not quite accurate. In the case of transplantation of HBV positive donor kidneys or hearts, to HBV negative recipients, the available evidence, albeit weak, suggests that disease transmission does not occur, and thus many centers do not prophylax to prevent transmission or reduce disease severity. In the case of an anti-HBc positive liver being given to HBV naïve liver recipients, the evidence would suggest that transmission occurs regularly but not universally, that prophylaxis does not necessarily prevent transmission, but that it can prevent the development of hepatitis disease (in contrast to "limiting disease severity"). In this case, transmission may occur but the consequence of the transplant is that the patient's life is saved.

This conceptual confusion pervades the Draft Guidelines. Throughout this document, the term "risk of disease transmission" is used generically. However, this fails to appreciate that the risk of viral transmission does not necessarily define the risk of unwanted sequellae for that infection. For example, the risk that a liver procured from an anti-HBc positive donor will transmit HBV infection to a HBV naïve recipient is approximately 50%. However, if this is done knowingly, the risk that the recipient will develop hepatitis and complications from that transmission can be reduced significantly if prophylaxis is

used. This is precisely why the expert reviewers suggested this document and its title more thoroughly address and define the difference between intended and unintended disease transmission when it went to interagency review.

In addition, and perhaps most importantly, the Executive Summary misleadingly suggests that there are "explicit links" between the evidence and the recommendations while, in fact, there are several Category I recommendations for which there is no evidence cited, some of which directly contradict findings or other consensus gatherings. Again this misleadingly implies that these recommendations are supported by the weight of evidence, which is simply not the case.

In short, readers who do not venture beyond the Executive Summary will be left with the impression that known transmission of HBV and HCV is a rare event. They will gain no appreciation for the very important distinction between intentional and unintentional transmission, and will assume that the recommendations that follow are solidly based on sound evidence. None of these impressions would be correct.

***Donor Risk Assessment***

- **Donor Risk Assessment, Recommendation #1**. We agree that a thorough donor history is important in establishing the presence of risk factors that might be associated with a poor transplant outcome. We note, however, that the Category IB recommendations in this section are based on literature that did not include potential solid organ donors and the incremental benefits of taking such a history when combined with blood serology testing has not been confirmed to add benefit.

- **Donor Risk Assessment, Recommendation #4**. This recommendation – that the father and mother of a pediatric donor be interviewed about "behaviors that may have placed them at risk for acquiring infections that may have been transmitted to their child"— is an extraordinary intrusion that only will add distress to the family at the time of death of a child. Since this meddlesome recommendation is classified as "Category I", it is likely to be incorporated into policy, to the detriment of scarce pediatric donors and their families.

- **Donor Risk Assessment, Recommendations #5 and #6.** Data regarding the definition and acquisition of pediatric donor historical risk factors are even more scarce, which makes a strong category 1B recommendation stating "Children with any risk factors associated with increased probability of HIV, HBV, or HCV should be identified as having an increased probability of infection", inappropriate and misleading. A decrease in the shrinking pediatric donor pool would significantly alter organ availability and increase the already high mortality for children waiting for transplants.

***Donor Screening***

- **Generally**. We strongly believe that the Donor Screening section is extremely problematic.

- **Donor Screening, Recommendation #1**. This recommendation appears to refer to blood (serum) test screening for HIV, HBV and HCV only and should be modified to make this clear (i.e. Modify "Screening tests" to read "Blood Screening tests.")

- **Donor Screening, Recommendation #2.** The addition of living donor screening language occurred during interagency revisions and after the expert and review groups provided input. All of the outside experts objected to the inclusion of this recommendation and pointed out that strong recommendation for donor screening with NAT testing no more than 7 days before the transplant procedure is not based on any data whatsoever. In fact, at a recent consensus conference organized by the ASTS, the American Society of Transplantation (AST), the National Association of Transplant Coordinators (NATCO) and the Association of Organ Procurement Organizations (AOPO) at which members of the PHS were present, a clear consensus was reached that no evidence-based time frame has been defined in which living donor screening should be performed. Importantly, this consensus group declined to issue a specific guideline regarding the timing of living donor testing other than to state that all living donors should be screened for HIV, HBV, and HCV. The group specifically concluded that there should not be any specific policy in this regard since there is no evidence available at this time to support one. The inclusion of this in the Draft Guidelines constitutes a policy recommendation that we strongly oppose.

- **Donor Screening, Recommendations #3, #4, and #5**. The Draft Guidelines appear to suggest that serum screening should be performed for all deceased donors (Recommendation #1) and then establish different requirements for HIV and HCV (NAT or "best available" test for all deceased donors)(Recommendations #3 and 4) than for HBV (NAT or "best available" test required for only certain deceased donors)(Recommendations # 5 and 6). The reasons for the distinction between HBV and HIV/HCV requirements for NAT or "best available" testing are unclear to us. Even more importantly, all of the recommendations for NAT or "best available" testing for deceased donors are characterized as Category IB recommendations. Category IB recommendations are characterized in the Executive Summary as strong recommendations based on low or very low quality evidence or strong recommendations "based on accepted clinical practices." In fact, the evidence review (see pages 71-75), indicates that the evidence regarding NAT and "best available" testing is of such low quality that a "level of evidence" could not be specified. In fact, an opposite conclusion was reached after a recent joint consensus conference of transplant infectious diseases experts (see **Am J Transplant**. 2010 Apr;10(4):889-99). After estimates of incidence rates of HIV, HBV and HCV in the donor population, it was concluded that NAT in addition to serologic testing of the routine deceased organ donor was not warranted and would lead to increased organ wastage. Accordingly, the Recommendations for Further Research section in the Evidence Review identifies the need to "Assess the validity of screening test results for HIV, HBV and HCV in relevant populations". We feel that, absent these validation studies, it is imprudent and potentially costly, to recommend use of NAT or "best available" testing; at this stage, there is no creditable evidence (weak or strong) that suggests compliance with these recommendations will actually "reduce the transmission of disease".

Moreover, to the extent that NAT or other additional testing may be appropriate in some cases, the ASTS does not believe that the "best available" test standard is useful. No evidence review or guideline is necessary to reach the platitude that we should use the "best available test". The critical (and considerably more complex) issue is which test is "best". The Draft Guidelines do not address the timing constraints of deceased donor transplantation or the various accuracies of the currently available tests—which are just two of the myriad of factors that may be involved in determining which test is "best." Since this standard is so vague, we are concerned that it will be interpreted by government regulators and payers in the future as meaning NAT testing is mandatory. Most importantly, due to the added time to run these tests, more organs may be lost.

- **Donor Screening, Recommendations #7, #8, and #9**. These recommendations do not appear to be based on data analysis of expert opinion, but rather address issues of public policy unrelated to disease transmissionf that are beyond the scope of the Draft Guidelines.

***HBV-Infected Donors and Transplantation***

- The introductory paragraphs of this section are confusing regarding anti-HBc IgG and HBV infected donors. The evidence is that the presence of anti-HBc IgG does not necessarily mean the presence of transmissible HBV infection, regardless of whether the donor will be donating a liver. The possibility that an anti-HBc positive donor may harbor transmissible virus in some cases suggests that the liver recipient will have negative consequences if the virus is present, while recipients of kidneys and hearts are not likely to develop hepatitis or active HBV replication. For the purposes of informing potential recipients, it is preferable to define anti-HBc IgG positive donors as having the potential to transmit infection even though the data would suggest that this does not result in significant complications in recipients of hearts or kidneys from these donors. The recommendation of routine HBV-DNA assessment (qualitative) is unfounded. There is no data regarding risks of HBV transmission with low level viremia in the prior infected (HBcAb+) donor. In fact, long experience with extrahepatic organ transplantation in this population suggests that the risk is very low, if elevated at all. The recommendation for HBV NAT is unfounded. The guidelines suggest that acquisition of HBV is equivalent from the HBsAg+ donor and the HBcAb+ IgM - which is not true. The PHS is obligated to give further guidance. The document does not address total and covalently closed circular HBV DNA that is within 5% of all donors and has a very low level of transmission through extrahepatic organs. The discussion is too simplistic and does not give credence to HBV biology.

- **HBV Infected Donors and Transplantation, Recommendations #1 - #3**. Recommendations for transplantation using HBV infected donor livers are based on weak evidence (level B) comparing the outcomes with transplantation of non-infected grafts. No studies were found in the literature review comparing outcomes of latently or actively HBV infected organs with continuing to wait on the waiting list; yet, this is precisely how one would calculate "when the risk benefit favors doing the transplant" for both naïve and HBV exposed recipients. In light of the lack of evidence, we do not believe that any "strong" recommendations are warranted in

this area. Moreover, the way that these recommendations are framed again suggests a strong bias on the part of the CDC that elevates the avoidance of disease transmission against other, potentially more critical, clinical factors: We strongly urge PHS to revise the language to affirmatively state that transplantation of any organ regardless of the potential for transmissible disease *should* be considered when the risks are outweighed by the benefits. The suggestion that such transplants *may* be considered fails to place the proper priority on the clinical needs of potential transplant recipients.

- **HBV Infected Donors and Transplantation, Recommendation #6.** "Testing with HBV NAT and ascertainment of IgM and IgG anti HBc status should be considered for total anti-HBc positive donors to better evaluate the risk in the recipient post transplantation" is a vague and confusing statement for which the evidence is lacking. There is no data (characterization of this recommendation as IIB is unfounded) that evaluate whether adding anti- HBc IgM or IgG testing will better define the risk of transmission or the risk of symptomatic infection in the recipient since, as outlined above, these risks are organ dependent and variable. The cost and potential delay in tracking down these additional test results are significant and not justified in light of the lack of evidence. This recommendation should be removed altogether.

***HCV-Infected Donors and Transplantation***

- The language in this section of the Draft Guidelines is similar to that in the section addressing HBV, insofar as it suggests that transplantation of HCV infected donors into HCV infected recipients *may* be considered when the risks are outweighed by the benefits. Again, such language reflects the PHS bias placing undue emphasis on the prevention of disease transmission over other clinical concerns: We feel strongly that clinicians *should* consider transplantation of HCV infected donor organs into HCV infected recipient whenever the risks are outweighed by the benefits. Here again the Draft Guidelines include a "strong" (Category I) recommendation against transplanting HCV infected organs into naive recipients, but a "weak (Level II) recommendation regarding the transplantation of these organs into HCV infected recipients . Yet, there is stronger evidence that using HCV infected organs in HCV infected recipients does not cause harm and may be beneficial.

***Recipient Informed Consent***

We support the inclusion of guidelines recommending that potential candidates be informed of the possibility of disease transmission along with all of the other risks that acceptance of a donor organ can entail. It should be noted that providing comprehensive and accurate risk assessments delineating the major factors affecting outcome after transplantation may not necessarily result in reduced disease transmission rates; nonetheless, informed consent is where the focus should be, not on reducing the risk of disease transmission *a priori*.

- **Generally**. The recommendations regarding the risks and benefits of using donor organs carrying HBV or HCV do not take into consideration the many other donor risks impacting the success of any given transplant procedure. In most cases, where the routine serologic testing is negative,

these other, non infectious disease-related risk factors far outweigh the risks of disease transmission. Informing potential recipients of the risks of disease transmittal out of the context of a full discussion of the myriad of other risks involved likely will result in confusion and misunderstanding. We strongly recommend that the Draft Guidelines be fully revised to reflect the risk of disease transmission in the overall context of the full risks involved in transplantation.

- **Recipient Informed Consent, Recommendation #3**. We do not support the suggestion that a separate informed consent discussion should be carried out regarding the possibility of transmission of disease via vascular conduits. There is no evidence and there is no expert opinion to suggest that these need to be separate processes. In fact, separate processes might be more confusing and certainly would be logistically difficult. The point is that the candidates need to be informed that disease transmission can occur via a vascular conduit even if the organ has been recovered from a donor testing negative for HBV and HCV, because of a different donor source for the vascular allografts.

***Recipient Testing***

- **Recipient Testing, Recommendation #1**. Since all recipients have undergone prior testing assessing HIV, HCV and HBV status, we do not believe that there is any reason to re-test all recipients at the time of the transplant. Such a process will add costs and will yield minimal new information.

- **Recipient Testing, Recommendation #5**. This recommendation suggests that recipients inadvertently given HIV infected organs may not seroconvert due to immunosuppression; yet, Recommendation #4 in this section suggests serologic testing for recipients of HBV infected organs only.

***Donor and Recipient Specimen Collection and Storage***

- **Generally.** This entire section is too proscriptive and will likely become outdated very quickly as new technology is developed. It is not entirely clear if these Draft Guidelines recommend storing recipient blood samples for 10 years in addition to the OPTN policy for donors. In fact, the evidence supporting the OPTN policy for archiving deceased donor blood samples for 10 year should be re-examined since very few donor derived diseases present more than a few years after transplant. As with most of the other recommendations, this recommendation does not relate to disease transmission rates at all.

  The inclusion of living donors in the recommendation for archival storage has not been widely vetted. On the whole, we believe that this recommendation is arbitrary and unsupported by evidence and that it will result in considerable extra cost. Since, by definition, living donors are living, ascertaining their infectious status years after transplantation should be relatively easy and should not require long term storage of blood samples. And the requirement to draw living donor blood samples no more than 7 days prior to transplant (Recommendation #5) is completely arbitrary. This will pose a considerable inconvenience on both the donor and the

transplant center and is not likely to yield significantly more useful information in a cost effective manner.

- **Donor and Recipient Specimen Collection and Storage, Recommendation #7.** The recommendation to destroy all donor blood vessels retrieved from infected donors is also arbitrary and does not represent expert opinion. These grafts are often critically important and may be lifesaving or graft-saving. Thus, this is a particularly dangerous and potentially life threatening recommendation. Although there have been extremely rare cases of disease transmission reported with these grafts, the true risk is unknown. Transplant centers and OPOs are already charged with tracking these vessels, and the infectious status of the donor is already required to be included with the vessel graft information. Also , please note that destroying vascular grafts is inconsistent with item 4 under Tracking and Reporting of HIV, HBV and HCV

***Tracking and Reporting of HIV, HBV and HCV***

- **Generally**. The recommendations in this section generally should clarify whether the recommendation applies to those cases where disease transmission was known, those where it was unknown, or both. There are many other policies, bylaws and regulations that deal with issues in this section of the Draft Guidelines. In this regard, the Draft Guidelines add nothing to existing process, except to freeze policy in time. In our view, this whole section should be deleted.

- **Tracking and Reporting of HIV, HBV and HCV, Recommendation # 2.** This recommendation should be clarified to state that documentation of any new HIV, HBV or HCV infection in a naïve recipient should be reported as required by state or local authorities. This recommendation could be combined with recommendation # 6.

- **Tracking and Reporting of HIV, HBV and HCV, Recommendation # 11**. This recommendation does not distinguish between living and deceased donors. HIPPA may not allow disclosure of Personal Health Information regarding the disease status of potential living donors. We recommend that this recommendation be rewritten to exclude living donors.

- **Tracking and Reporting of HIV, HBV and HCV, Recommendation #12.** This recommendation does not relate to the risk of disease transmission as the result of transplantation and should be removed from this document.

***Recommendations for Further Research***

In our view, in light of the dearth of evidence in this area, this section is the most important part of the Draft Guidelines. Unfortunately, as currently written, the Draft Guidelines understate the evidence gaps and the lack of high quality data from which reasonable guidelines can be developed.

**POTENTIAL PUBLIC REACTION**

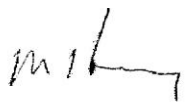
The sensationalistic media coverage of the donor HIV disease transmission cases has not had a positive effect on organ donation or transplantation. The failure of the Draft Guidelines to consider the risk of disease transmittal in the context of the overall risks of organ transplantation has the potential to contribute to public misunderstanding of the true risks involved. Such an approach fails to provide to the public or to other regulatory agencies a reasoned assessment of the magnitude of the risks or the benefits of methods aimed to address these concerns. In addition, suggesting the transplantation of HBV or HCV infected organs should be avoided without providing an evidence review assessing the circumstances that can and do justify using these organs, does not serve to clarify the complex decision-making that potential recipients and transplant programs must undertake.

But perhaps most worrisome is the liberal use of Category I strong recommendations that are not supported by the evidence or by expert opinion. We are deeply disturbed that the agency implies that the Draft Guidelines are based to a large extent on evidence, when the only evidence that exists in this area is extraordinarily weak or nonexistent. And while the Draft Guidelines purport to be consistent with expert opinion, it appears that the agency has deliberately ignored the views of the experts in the field of transplantation initially appointed to participate in the process.

These guidelines, if finalized in their current form, are likely to have significant consequences for the transplant community, which will be required to modify clinical practices to elevate the need to reduce the risk of disease transmittal over the need to address other, more serious and more common risks of transplantation. The guidelines will have a significant and ongoing impact on the cost of transplantation, which will affect third party payers (including Medicare and Medicaid) that ultimately will bear the costs of testing. But most importantly, these guidelines, if finalized in their current form, are likely to substantially and negatively impact our patients, by resulting in increased wastage of potentially life-saving organs that are in extraordinarily short supply. For all of these reasons, we urge the PHS to completely revise this document with broad representation and meaningful input from the ASTS and our other colleagues.

If you have any questions regarding these comments, please contact Kimberly Gifford, ASTS Executive Director, via email, *kim.gifford@asts.org*, or phone, 703.414.7870.

Sincerely,



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