OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

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BY ELECTRONIC MAIL
Claudia Cohn, MD, PhD
Chair, Advisory Committee on Blood and Tissue Safety and Availability
Office of Infectious Disease and HIV/AIDS Policy
U.S. Department of Health & Human Services
330 C Street, S.W.
Suite L100
Washington, D.C. 20024

RE: Fifty Sixth ACBTSA Meeting, Written Public Comment – November 17, 2022 Meeting

Dear Dr. Cohn,

On behalf of the Organ Procurement and Transplantation Network (OPTN), thank you for the opportunity to offer comment on the proposed Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) recommendations to remove the statutory National Institutes of Health (NIH) research criteria for HIV-positive donor to HIV-positive recipient organ transplants performed under the HIV Organ Policy Equity (HOPE) Act in advance of the Committee's November 17, 2022, meeting.

We are pleased to reiterate our support for the removal of the statutory "NIH Research Criteria" for all organs as first communicated in an October 21, 2022 letter to HHS Secretary Becerra[1]. As noted in our initial letter, the data show these transplants are safe, effective and have the potential to expand the pool of eligible organ donors. We also support removing the IRB requirement for kidney and liver transplants.

We do have concerns with the proposed oversight that would direct the OPTN to develop policies requiring:

1. OPTN organ-specific variance for each organ other than kidneys and livers
2. Additional organ-specific candidate criteria and transplant program requirements analogous (but not "identical") to the NIH Research Criteria developed specifically for the unique patient safety and outcomes monitoring characteristics of transplants other than kidneys and livers in HIV patients
3. Additional organ-specific OPTN outcomes monitoring for candidates of organs other than kidneys and livers on the Waiting List and recipients following transplantation

[1] Matthew Cooper, OPTN President to Xavier Becerra, HHS Secretary, October 29, 2021.

4. Each center/institution must have an IRB-approved protocol that will include measures of outcomes and safety
5. When multiple organs are transplanted simultaneously, the default approach will be to use the guidelines of the organ with more conservative policies

We believe that the current model of the HOPE Act, based on the existing NIH criteria, is appropriate for continued research oversight of non-kidney or liver transplants. In addition, we believe that the OPTN structure and outcome data collected is sufficient in its current state to provide oversight for all organs. The OPTN favors keeping the status quo for non-kidney and non-liver organs if the clinical research and IRB requirements remain rather than creating and implementing new policies, criteria, and models that currently exist elsewhere.

We also hypothesize that the continued IRB requirement for other organs, including thoracic organs, will keep barriers in place that have resulted in the limited number of transplants done for HIV positive heart donors to HIV positive recipients. Removing the NIH Research Criteria and the IRB requirement for only kidneys and livers is likely to perpetuate inequities and disparities between HOPE Act organ program development and negatively impact access to organs for HIV infected recipients in need of a non-kidney or non-liver transplant. Further, HIV-positive individuals may be precluded from access to less common transplant types, such as solitary pancreas or vascular composite allografts not addressed in this proposal, as current experience to guide the development of research criteria and appropriate data collection is limited.

The current structure requiring formal protocol development and IRB approval by transplant programs is limiting in the context of the small number of non-kidney or liver transplants that are likely to be done at any one program. Maintaining an active program-specific research program for a very small number of transplants is not an effective use of transplant program resources and is not likely to generate sufficient data to provide a meaningful analysis of outcomes beyond individual case reports or limited series. In the two years since the HOPE Act variance was expanded by the OPTN to include all solid organs, only two programs have sought additional approval and only a single heart transplant has been done.

We feel that lack of program participation is a barrier to patient access and limits life-saving transplantation opportunities for a disadvantaged patient group.

As with any policy change, ending the HOPE Act transplant allocation variance and allowing HOPE Act transplants to occur as a component of standard OPTN policy will prompt standard OPTN assessments of the impact of the policy change. The OPTN would continue to monitor HOPE Act transplant activity, outcomes, and safety using the existing OPTN data and safety structures for at least five years. We believe this approach is in the best interests of the patients we serve.

We would also ask that the ACBTSA consider any potential unintended consequences of shifting the NIH-analogous functions for non-kidney and non-liver organs to the OPTN. Assuming this important and multifaceted role, would require additional resources and expertise to be successful. The proposed 15-month timeline would need to be extended to

account for all steps in the OPTN policy development and implementation processes. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through federal government Office of Management and Budget (OMB) approved data collection forms and therefore subject to its approval process under the Paperwork Reduction Act of 1995. We would welcome further discussions on how to best proceed to effectively and safely expand access to transplant under the HOPE Act.

We appreciate the extraordinary efforts of the ACBTSA in evaluation of these complex questions.

Sincerely,

Jerry McCauley, MD, MPH
President, OPTN Board of Directors