

## **OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC)**

### **Meeting Summary**

**March 1, 2022**

**Conference Call**

**Ricardo La Hoz, MD, FACP, FAST, Chair**  
**Lara Danziger-Isakov, MD, MPH, Vice-Chair**

### **Introduction**

The Ad Hoc Disease Transmission Advisory Committee met via Citrix GoToMeeting teleconference on 3/1/2022 to discuss the following agenda items:

1. Open Session: FDA Presentation on Xenotransplantation

The following is a summary of the Committee's discussions.

#### **1. Open Session: FDA Presentation on Xenotransplantation**

The DTAC received a presentation from the FDA on the regulatory oversight of xenotransplantation products. The OPTN has no purview over xenotransplantation but as an interested party the DTAC thought a review of the science and efforts to date would be helpful.

#### Summary of discussion:

The DTAC appreciated the opportunity to get an overview of this important work from the FDA, given the implications for the organ transplant field in the future. A DTAC member asked about collaboration and engagement within the transplantation community – it was clarified that there is an international xenotransplantation community group that the FDA has been collaborating with. Within the Transplantation Society (TTS), there is collaboration ongoing. Another member asked about bacterial/fungal infections of concern in potential xenotransplants, and the level of immunosuppression recipients of xenotransplants would require. The presenter clarified that there are a lot of questions about the level of immunosuppression required; it is worth noting that the genetic modification of the animals occurs to decrease the amount of immunosuppression needed to maintain the transplant.

Another member asked about the level of oversight and the evaluation of outcomes as they relate to recipient characteristics. Because outcomes may be closely tied to recipient characteristics, it is especially important to think through the evaluation of outcomes. Right now evaluation is focused on survival, given the early stages of this process. The DTAC also discussed the impact of inbreeding depression on the genetic population. Most of the animals are cloned due to the genetic modifications, and it may be difficult to sufficiently provide the necessary number of animals to fully address the number of people waiting for a transplant currently. The presenter noted this is something the Center for Veterinary Medicine to consider.

### **Upcoming Meetings**

- March 28, 2022

- April 5, 2022

## Attendance

- **Committee Members**
  - Gerry Berry
  - Kelly Dunn
  - Charles Marboe
  - Gary Marklin
  - Lara Danziger-Isakov
  - Sarah Taimur
  - Ricardo La Hoz
  - Stephanie Pouch
  - Sam Ho
  - Ann Woolley
  - Raymund Razonable
  - Dong Lee
  - Jason Goldman
  - Michelle Kittleson
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **UNOS Staff**
  - Courtney Jett
  - Cole Fox
  - Anne McPherson
  - Sandy Bartal
  - Emily Womble
- **FDA Staff**
  - Judith Arcidiacono
- **CDC Staff**
  - Pallavi Annambhotla
  - Ian Kracalik
  - Sridhar Basavaraju
  - Rebecca Free