

December 16, 2021

The Honorable Janet Woodcock, MD  
Acting Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock,

As leaders in the national organ donation and transplant system, we write to you today to share our concern over reports of disruptions to the routine supply of certain critical organ preservation solutions. Without your urgent action to alleviate this shortage, availability may be greatly reduced or cease altogether. This is of great concern to the combined organ donation and transplantation community, as use of these solutions is essential to ensuring transplantation can continue in the U.S. These solutions are used during cooling and transport of the organ to reduce cellular injury and maintain organ viability prior to implantation.

Two suppliers of these solutions, Belzer® UW Cold Storage and Belzer® MPS –Machine Perfusion Solution have recently reported tightening market conditions, including prior distribution interruptions in June of this year. In a November 3, 2021, 506J notification filed with the FDA, manufacturer Bridge to Life Ltd. formally reported the impending shortages, notifying the United Network for Organ Sharing (UNOS) the following week that they would begin equitably allocating these solutions. Bridge to Life has estimated the supply is sufficient for 4-6 weeks of continued distribution in this manner. Concerns for supply and distribution following this interval then remains in serious question.

In the short term, our organizations are advising members to identify contingencies for conservation in ordering and stocking the products they use, consider alternatives to current solutions, consider when best to utilize machine perfusion of donor organs, and avoid purchasing additional quantities beyond reasonable needs to avoid further strain on market conditions.

However, given the threat this impending shortage poses to the continuation of donation and transplant nationwide, we urge the FDA to conduct an urgent review for U.S. clearance of the existing global supply of organ preservation solutions, including from Canada and Europe.

We thank you for your consideration of this request. Our organizations stand ready to support you in our shared goal of preventing any severe or lasting effects that may affect our collective efforts to provide lifesaving transplants for patients in need.

Sincerely,

/s/ Matthew Cooper

Matthew Cooper, MD, FACS  
President, United Network for Organ Sharing

/s/ A. Osama Gaber

A. Osama Gaber, MD, FACS, FAST  
President, American Society of Transplant Surgeons

/s/ John Gill

John Gill, MD, MS  
President, American Society of Transplantation