

December 19, 2022

The Honorable Xavier Becerra, Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: Biomarker Research in Organ Transplantation

Dear Secretary Becerra and Ms. LaSure:

We are writing on behalf of the American Society of Transplantation to share our desire for continued advancement of biomarker research in the area of organ transplantation. The continued development of testing in this area provides the opportunity to develop less invasive testing through the use of molecular biomarkers such as gene expression profiling (GEP) and donor-derived cell-free DNA (dd-cfDNA). Both biomarkers are molecular diagnostic tests that are examples of precision medicine tools currently used to detect organ rejection in heart, kidney, and liver transplantation.

As advocates for our patients, we believe that the further study of molecular biomarkers is important in order to optimize the management of transplant recipients. From a clinical perspective, these non-invasive diagnostic tools can provide valuable and timely information that may help optimize immunosuppression in our patient population. Without molecular biomarkers, we rely primarily on biopsies to determine if subclinical or early rejection is occurring in transplant recipients. Biopsies are more invasive and expose patients to additional and unnecessary risks. From a quality of life perspective, molecular biomarkers have the potential to be safe, simple, quick, and non-invasive alternatives to biopsy in appropriate heart and kidney transplant patients with minimal loss of work hours and the opportunity to understand whether treatment for rejection has been successful. More recently, GEP is now available in liver transplant recipients to monitor immunosuppressive therapy, in particular the potential to assist with minimization of therapy which may be able to improve long-term health outcomes.

We believe there is a continued need for advancement in the area of biomarker

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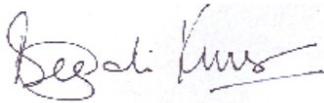
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research including further defining the optimal use of currently available biomarkers. The ability to recognize molecular changes as an advanced cue to complications or illness has great value across the field of medicine, not just the field of transplantation. We believe there is still much to be learned in how to best capture and utilize this information to benefit our patients and recognize potential complications earlier and encourage continued research and exploration in utilizing molecular biomarkers. We see biomarker research as a valuable opportunity to address a *significant* unmet need in the field of transplantation and to improve overall patient care.

Sincerely,

A handwritten signature in black ink, appearing to read "Deepali Kumar". The signature is fluid and cursive, with a horizontal line at the end.

Deepali Kumar, MD, MSc, FRCPC, FAST
President

A handwritten signature in black ink, appearing to read "Richard Formica". The signature is cursive and includes a long, sweeping horizontal line at the end.

Richard Formica, MD
Chair, Public Policy Committee