

United States Senate

WASHINGTON, DC 20510

May 12, 2011

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Madame Secretary:

It is our understanding that the Department of Health and Human Services (HHS) is considering whether to designate Vascularized Composite Allografts (VCA) as organs, or tissue. We agree with the Association of Organ Procurement Organizations (AOPO), and the American Society of Transplant Surgeons (ASTS), that the Organ Procurement and Transplantation Network (OPTN), in concert with the United Network for Organ Sharing (UNOS), is best suited to address the challenges associated with VCA. As such, we write to request that HHS classify VCA as organs and move forward with the appropriate and necessary regulatory guidance under the Health Resources and Services Administration (HRSA).

In recent years, the medical community has experienced enormous breakthroughs in VCA. Full face, hand, arm, larynx transplants have the capacity to transform the lives of those suffering from debilitating injuries, disabilities, and diseases. To meet these growing needs, and as a result of tremendous advances in science and medicine, more VCA transplant programs are being developed and VCA transplants are becoming a more common therapy.

The OPTN is tasked with the responsibility of developing and operating a national computer system by which donor organs are allocated among all candidates who are listed within the national matching system. This structure has been developed over many years of systematic, comprehensive review and oversight, and it maintains broad support from the transplant community. By designating VCA as organs, this existing foundation and infrastructure for allocation, scientific data collection, review and reporting, can be applied more quickly to ensure all individuals, both civilian and military, in need of life altering VCA transplant procedures receive the same consideration as those who receive kidneys and other organs.

We believe VCA should be designated as organs, and allocation should fall under the purview of the OPTN, which is regulated by the Health Resources and Services Administration (HRSA). We appreciate your consideration and look forward to working together towards a resolution in this matter.



John Boozman



John Kerry



Jon Kyl

Sincerely,



Carl Levin



Chuck Grassley



Debbie Stabenow

Secretary Kathleen Sebelius
VCA Transplants
P. 2



Mark Warner



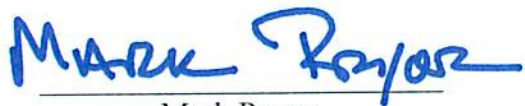
James Inhofe



Barbara Mikulski



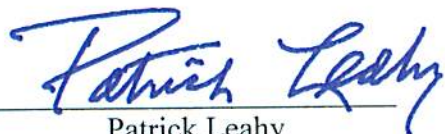
Robert Casey



Mark Pryor



Frank Lautenberg



Patrick Leahy



Jon Tester



Mary Landrieu



Sherrod Brown



Ben Cardin
