

Congress of the United States
Washington, DC 20515

November 7, 2013

The Honorable Gene Dodaro
Comptroller General of the United States
441 G Street, NW
Washington, DC 20548

Dear Mr. Dodaro:

We are writing to request that the U.S. Government Accountability Office (GAO) conduct a study of current federal activities that impact the field of regenerative medicine. Understanding what current government initiatives affect regenerative medicine and whether these efforts are being appropriately coordinated is an important first step toward developing appropriate regenerative medicine policies.

Regenerative medicine aims to resolve unmet medical needs by addressing the underlying causes of disease. It employs a variety of therapeutic strategies to augment, repair, replace or regenerate cells, tissues or organs in order to restore or establish function. A 2006 report from the U.S. Department of Health and Human Services (HHS) entitled "2020 – A New Vision – A Future for Regenerative Medicine" stated that "virtually any disease that results from malfunctioning, damaged, or failing tissues may be potentially cured through regenerative medicine therapies." However, the HHS report also raised concerns about the absence of a coordinated federal approach to support regenerative medicine.

Many individual institutes within the National Institutes of Health, as well as numerous other federal departments and agencies, are involved in regenerative medicine policy and funding. Given the federal budget crisis, it is imperative that we invest limited resources as effectively as possible. We believe there needs to be a comprehensive assessment of activities related to regenerative medicine to highlight successes, identify duplicative efforts or areas where greater efficiency can be achieved, and evaluate how best to focus resources on those areas that could address significant unmet medical needs.

We specifically request that the GAO address the following issues:

1. Research Funding -- How are federal dollars for regenerative medicine research being spent, and where and how could federal investment yield better results? Is there an overall research strategy within the federal government? How are research priorities determined? What agencies are involved in funding for regenerative medicine research, and are those agencies coordinating their efforts internally and with each other? Is there duplication of federal research spending? Are agencies evaluating the effectiveness of different regenerative medicine initiatives and which ones have led to measurable outcomes and improvements in quality of care for patients? Are agencies following appropriate standard procedures for public notice and input?

2. Barriers to Innovation -- What federal policies and programs are designed to support development of regenerative medicine products and related technologies? Are these programs integrated with research policies? Has the federal government identified and analyzed barriers to successful development of regenerative medicine products? If so, what steps have been taken to reduce these barriers?

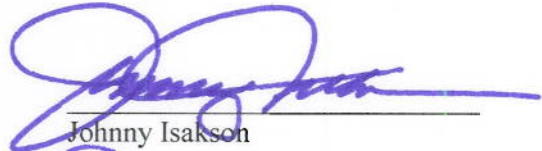
3. Coordination among federal agencies -- What mechanisms exist for coordination of federal agency funding and other policies regarding regenerative medicine? How effective are these mechanisms? What federal entity or agency is best suited to coordinate federal efforts?

Thank you for your cooperation and attention to this matter. We urge you to complete this study and analysis in a timely manner.

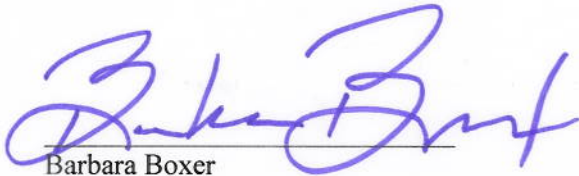
Sincerely,



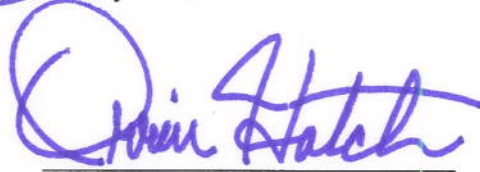
Tom Harkin



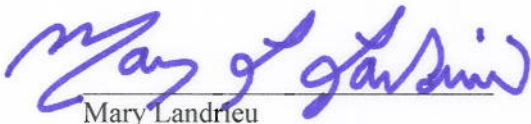
Johnny Isakson



Barbara Boxer



Orrin G. Hatch



Mary Landrieu



Lamar Alexander