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Congress of the United States
House of Representatives
Washington, DC 20515

March 13, 2020

The Honorable Jose Serrano
Chair
House Appropriations Subcommittee on
Commerce, Justice, Science, and Related Agencies
Washington, DC 20515

The Honorable Robert Aderholt
Ranking Member
House Appropriations Subcommittee on
Commerce, Justice, Science, and Related Agencies
Washington, DC 20515

Dear Chairman Serrano and Ranking Member Aderholt,

I wish to submit a request for \$5 million in appropriations within the House Commerce, Justice, Science, and Related Agencies account for the National Institute for Standards and Technology (NIST) to support their congressionally directed responsibilities under the 21st Century Cures Act (Public Law 114-255) to coordinate and prioritize the development of standards for regenerative medicine and advanced therapies.

Regenerative medicine (RM) and advanced therapies offer the hope of significant public health benefits to patients with unmet medical needs. To ensure these products will be efficacious and provide consistent results when released for use as therapies or for implantation, measurements and standards for quality control, product stability, and performance testing are needed. Because of their complexity, the approach to developing and validating measurements and standards for RM and advanced therapies will be unique, and they will require a unique measurement science and measurement assurance infrastructure. Without these standards, expanding production of regenerative medicine products to a commercial and usable level would be impossible.

In December 2016, the 21st Century Cures Act (Public Law 114-255) directed the Food and Drug Administration (FDA), in consultation with the National Institute of Standards and Technology (NIST) and industry stakeholders, to “coordinate and prioritize the development of standards and consensus definition of terms...[that] support, through regulatory predictability, the development, evaluation, and review of regenerative medicine therapies and regenerative advanced therapies.” However, while Congress has provided dedicated funding to NIH and FDA through 21st Century Cures Act-related appropriations for translational research, similar funding was not extended at that time to NIST so that it could fully utilize its collective expertise for the development of standards for regenerative medicine. Fortunately, \$2.5 million in dedicated funding was appropriated in Fiscal Year (FY) 2020 for these efforts.

Building off of the FY 2020 funds, which are being used by NIST to acquire significant infrastructure, such as a lab reinnovation with modern cell processing, storage, and measurement equipment, to support measurement assurance activities nationwide, the \$5 million appropriation request in FY 2021 for NIST’s Health and Biological Systems Measurement account would provide sufficient resources for NIST to meet its 21st Century Cures Act responsibilities, including establishing a regenerative medicine assay validation and innovation core at NIST, coordinating and conducting inter-laboratory studies to improve measurement assurance, and providing continued coordination of stakeholders for efficient development and use of needed documentary

standards. This work would greatly benefit not only regenerative medicine research, development, and production across the nation but also the manufacturers and research centers in my district, including the University of California – San Diego.

Thank you for your attention to this request.

Sincerely,

A handwritten signature in blue ink, appearing to read "Scott Peters", written in a cursive style.

Scott Peters
Member of Congress