



Association of Pathology Chairs

Promoting Excellence In Academic Pathology

100 West 10th Street, Suite 603, Wilmington, DE 19801
Tel: 302-660-4940 Email: info@apcprods.org Web: www.apcprods.org

April 5, 2021

President

Lydia Howell, MD

President-Elect

Dani Zander, MD

Past President

Barbara Ducatman, MD

Secretary-Treasurer

David Roth, MD, PhD

Councilor-at-Large

Michael Laposata, MD, PhD

Chair, Advocacy Committee

Debra Leonard, MD, PhD

**Chair, Graduate Medical
Education Committee**

Karen Kaul, MD, PhD

**Chair, Leadership
Development & Diversity
Committee**

Amyn Rojiani, MD, PhD

**Chair, Practice & Management
Committee**

Chen Liu, MD, PhD

Chair, Research Committee

Nitin Karandikar, MD, PhD

**Chair, Undergraduate Medical
Education Committee**

Jennifer Baccon, MD, PhD

Chair, Senior Fellows Group

Fred Sanfilippo, MD, PhD

Chair, PRODS Section

Scott Anderson, MD

Chair, UMEDS Section

Robin LeGallo, MD

Chair, PDAS Section

Kristen Kolb

Executive Director

Priscilla Markwood, CAE

The Honorable Rand Paul
United States Senate
167 Russell Office Building
Washington, DC 20510

Dear Senator Paul:

The Association of Pathology Chairs (APC) represents the leadership of academic clinical laboratories, who play a critical role in supporting care and research for patients treated by academic medical centers throughout the U.S.

APC endorses the Verified Innovative Testing in American Laboratories (VITAL) Act, which would codify current federal regulations that place oversight of laboratory developed tests (LDTs) under the Clinical Laboratory Improvements Act of 1988 (CLIA) administered by the Centers for Medicare and Medicaid Services (CMS).

For years, the Food and Drug Administration (FDA) has sought authority to regulate LDTs, conflating issues associated with commercially sold proprietary tests with tests developed and performed within clinical settings that already are regulated by CLIA. The VITAL Act will finally clarify the regulatory oversight of LDTs and stop the uncertainty for clinical laboratories created by the FDA.

We are grateful for the remedies proposed by the VITAL Act that would: 1) define laboratory developed tests as a medical service; 2) settle the issue that regulatory authority rests with the Centers for Medicare and Medicaid Services (CMS) (under CLIA), not with the FDA, for LDTs; 3) initiate a public meeting process to update or modernize the CLIA program; and 4) call for a report from HHS on the utilization of LDTs during the COVID pandemic.

The issues associated with FDA regulation of clinical LDTs were made tragically apparent by the COVID-19 pandemic. In the critical earliest days of the outbreak, academic clinical laboratories with expertise, resources and accreditation under CLIA to perform SARS-CoV-2 diagnostic testing were restricted by the FDA from performing those tests. Priceless weeks were lost when academic clinical laboratories could have been engaged to rapidly expand testing, to provide the needed information for contact tracing to help control community spread, and to aid understanding of disease epidemiology. Awaiting the FDA's Emergency Use Authorization (and still living under it) is entirely antithetical to the safe and innovative practice of laboratory medicine by academic pathologists (highly-trained physicians), and their clinical teams, under CLIA regulation.

We look forward to working with you on this most important issue. If you have any questions, please email Priscilla Markwood, APC's Executive Director, at pmarkwood@apcprods.org.

Sincerely,

Lydia Pleotis Howell, MD
President, Association of Pathology Chairs