

FOR IMMEDIATE RELEASE

The Coalition for CLIA Waiver Reform Welcomes Four New Members

WASHINGTON, DC, October 13, 2017, -- The CLIA Waiver Coalition, an organization dedicated to ensuring FDA provides an improved CLIA Waiver reform process, has welcomed four new members to the growing list of entities seeking common sense reform to the Food & Drug Administration's CLIA Waiver Guidance, including Basil Leaf Technologies; the Convenient Care Association; the National Association of Worksite Health Centers; and the Urgent Care Association of America.

Point-of-care testing ("POCT") is a cornerstone of patient care, and in coming years, will play an increasingly important role in improving patient outcomes and the public health at large. Roughly 80% of POCT facilities are so-called "Certificate of Waiver" laboratories, which include physician offices, health clinics, urgent care centers and other points of care.

In 2008, FDA published guidance rejecting Congressional standards and limiting development of new CLIA-waived diagnostic tests for nearly a decade. In 2016, Congress responded by directing FDA to propose new policies in the form of updated guidance reinterpreting the meaning of "accurate" as part of 21st Century Cures. The law gives FDA until December 2017 to publish draft guidance, and until December 2018 to finalize that guidance following public comment.

The Coalition for CLIA Waiver Reform is dedicated to removing unnecessary impediments that are preventing patient access to innovative CLIA-waived point-of-care tests, and preventing providers from giving their patients the best care.

About the New Members

Basil Leaf Technologies was organized in March 2013 to develop interactive, consumer-level products that empower individuals to monitor and improve their personal health.

The Convenient Care Association (www.ccaclinics.org) The Convenient Care Association was established in 2006 and serves as the National Trade Association for Retail Health clinics. The CCA works to enhance and sustain the growth of the Convenient Care industry to ensure affordable, accessible and high-quality care for all Americans.

The National Association of Worksite Health Centers (www.nawhc.org), based in Chicago, is the nation's only non-profit organization representing and supporting public and private employer-sponsors of onsite, near-site, shared and mobile health and wellness centers.

Urgent Care Association of America (www.ucaoa.org), established in 2004 and based in Naperville, IL is a member association dedicated to advancing and distinguishing the role of urgent care medicine as a healthcare destination and support the ongoing success of its membership through education, advocacy, community awareness, benchmarking and promoting standards of excellence.

About the Coalition for CLIA Waiver Reform:

The Coalition for CLIA Waiver Reform is an organization dedicated to ensuring FDA provides an improved CLIA Waiver reform process and is looking for new partners to join us in the crusade to improve access to safe and effective CLIA waived POCT. If you would like more information on how to get involved contact jboiani@ebglaw.com.

<http://www.cliawaiverreform.org>