Good Morning Lynette,

My name is Jeff Gabriel and I'm with the Coalition for CLIA (Clinical Laboratory Improvements Act) Waiver Reform, which is working to ensure more point-of-care diagnostic tests are approved by the FDA for use at the point of care. In short, the Coalition has been urging the Food & Drug Administration (FDA) to change its present process for obtaining CLIA waivers for point-of-care diagnostic tests, and has been working with the US Congress and others in this endeavor
I am specifically helping the Coalition with a grass roots effort to build support from point-of-care diagnostic test manufacturers, test users, and public health officials to urge the FDA to make changes to its 2008 Guidance document, relating to the second step of the approval process for point-of-care diagnostic tests and, at least, to coordinate our collective efforts.

Your organization could help, for example, by agreeing to send a letter to the FDA that indicates you are urging them to make the necessary changes to the draft guidance document. We would be delighted to supply you with draft language in support of such a letter. You could also send an action alert to your members, informing them of the issue and urging them to also contact the FDA in support of our effort. Again, we can supply you with everything you need to accomplish this, including draft language, names and addresses, and all other background information that you may need.

THE COALITION FOR CLIA WAIVER REFORM – The Coalition believes that point-of-care testing 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 because results are received in the exam room or at the patient bedside, speeding diagnosis and treatment decisions, and reducing instances in which patients get tested but never return to receive their results.

I'm working with James A. Boiani, founder of the Coalition and Partner with Epstein Becker Green. James' bio and contact information are here:
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In 2005, the FDA signaled its move away from CLIA's focus on equivalent performance by professional and untrained users when it published a new draft guidance that re-introduced a requirement for inherent accuracy. FDA did this by proposing a new legal interpretation of the term "accurate," which was adopted in the Agency's final 2008 CLIA Waiver Guidance. In the years that have followed, FDA has made procedural changes to improve the CLIA waiver process, leaving the substance of the 2008 Guidance intact.

By the end of 2017, the Food & Drug Administration (FDA) was required by Congress to publish revised recommendations regarding the evaluation of "accuracy" for CLIA waiver purposes to replace recommendations that are currently provided in the Office of In Vitro Diagnostics and Radiological Health's ("OIR") 2008 Guidance.

On November 29, 2017 the US Food & Drug Administration (FDA) published two draft guidance documents to help manufacturers of in Vitro diagnostic (IVD) devices apply for and receive Clinical Laboratory Improvement Amendments (CLIA) waivers [Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices; Draft Guidance for Industry and FDA Staff] and [Recommendations for Dual 510(k) and CLIA Waiver by Application Studies; Draft Guidance for Industry and FDA Staff]. As stated, these draft documents were mandated by Congress as part of the 21st Century Cures Act, which was signed into law in December 2016, and part of which directed the FDA to make substantive changes to FDA's present 2008 guidance for obtaining CLIA waivers for IVDs.

Comments on FDA's draft guidance documents are due January 29, 2018. The Coalition is leading the effort to ensure the FDA provides a correct interpretation of the definition of "accuracy" for CLIA waiver purposes and asks all interested parties in joining it in this process. The Coalition also will be filing its own comments on these draft guidance documents and it will be communicating with the FDA, congress, and others throughout the next several months to ensure a proper interpretation of the term "accuracy" as applied to the CLIA waiver process. The Coalition encourages your organization to help in this effort, including alerting your members of the issue as well as to submit your own public comments to these draft guidance documents. The Coalition will make itself available to support you in any manner possible.

Please let me know if you have any questions, concerns or comments – I'm available to discuss at your convenience and would love to speak with you about this issue.

Warm Regards,

Jeff Gabriel, Jr.

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