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BECKER  
GREEN

Attorneys at Law

James A. Boiani  
202.861.1891  
jboiani@ebglaw.com

May 17, 2016

VIA FEDEX

The Honorable Lamar Alexander  
The Honorable Patty Murray  
Committee on Health, Education, Labor and Pensions  
428 Senate Dirksen Office Building  
Washington, DC 20510

Re: FDA Device Accountability Act, S.1622

Dear Chairman Alexander and Ranking Member Murray:

The undersigned organizations are writing to express their support for the FDA Device Accountability Act, S.1622, and to urge the Committee to advance its passage into law using all means at your disposal. If enacted, S.1622 will help foster advances in medical technologies that have the potential to provide patients with better and more affordable health care that patients deserve.

For example, Section 4 of the bill would establish a timeline for FDA to work with stakeholders in developing new guidance for evaluating “CLIA waivers” for diagnostic tests. Under law, many healthcare facilities, including the vast majority of physician offices, urgent care centers, and community health clinics that are crucial centers of patient care, can only use point-of-care tests that receive a CLIA waiver from FDA. Point-of-care testing, which provides results to medical professionals while a patient is in the exam room, can speed diagnosis and treatment and greatly benefit the public health. So, to gain the full public health benefits of point-of-care testing, FDA must have a good process in place for evaluating CLIA waivers.

Unfortunately, the current process for CLIA waivers is not working as well as it should. In particular, FDA’s current recommendations for evaluating the accuracy of CLIA waived tests, which are included in a 2008 guidance document, have discouraged development of new point of care testing, and delayed access to many tests for infectious diseases and other serious health conditions.

Section 4 of the bill would require FDA to re-evaluate and revise its recommendations through its Good Guidance Practices, which provides an opportunity for input from patient advocacy groups, physician groups, test manufacturers, and other stakeholders. Section 4 has broad support amongst stakeholders, and FDA has agreed the legislation is appropriate. Having this directive and timeline for developing guidance set in law will help ensure that there is



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discussion and implementation of reforms that will benefit patients within a reasonable time frame.

The other proposals in the bill with regard to Central IRBs and Least Burdensome Standards also enjoy broad support amongst stakeholders because of the potential they bring to speed the study and approval of beneficial new medical devices. For that reason, we are asking that you take whatever measures are necessary to move forward S.1622.

We appreciate your efforts to improve healthcare for Americans, and stand ready to assist in any way we can to advance legislation that can improve point-of-care testing and medical device development. Should you have any questions, please contact James Boiani, Esq., General Counsel, Coalition for CLIA Waiver Reform at [jboiani@ebglaw.com](mailto:jboiani@ebglaw.com) or 202-861-1891.

Very truly yours,

Coalition for CLIA Waiver Reform  
Advanced Medical Technology Association  
Infectious Diseases Society of America  
National Coalition of STD Directors  
Abbott  
Alere Inc.  
Becton Dickinson & Company  
BioFire Diagnostics, Inc.  
ChemBio Diagnostic Systems, Inc.  
Roche Diagnostics  
Sekisui Diagnostics, LLC  
Spartan Bioscience Inc.  
TearLab Corporation

cc: The Honorable Richard Burr, US Senate  
The Honorable Al Franken, US Senate

