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### **ACLA Responds - Genentech Citizen Petition**

WASHINGTON, D.C. – The American Clinical Laboratory Association (ACLA) will soon release a comprehensive response to the December 9<sup>th</sup> citizen petition filed with the federal Food and Drug Administration (FDA) by Genentech which if adopted would have a chilling effect on innovation and patient care while stifling the promise of personalized medicine. The petition seeks to require all clinical laboratory developed tests (LDTs), which are currently regulated by the federal and state governments, to be under additional regulation by FDA. Alan Mertz, President of ACLA, said “Genentech’s call for FDA to impose a new, unnecessary regulatory framework on all LDT’s is ill-informed, unsubstantiated, and will threaten individual patient care and public health preparedness”.

LDT’s have a long history of advancing patient care as safe and effective laboratory services. Millions of these tests have been ordered by health care providers for their patients with few if any problems documented. The Genentech petition provides no substantive evidence on the need for additional oversight. On the contrary, reckless statements are made about the value and effectiveness of many specific LDT’s, including some that are standard-of-care in medicine, without any acknowledgement of the significant body of evidence that supports the analytic and clinical validity of many of these tests. Extensive information in the form of peer reviewed journal articles, presentations and abstracts supporting clinical validity, medical decision impact, platform technology, assay development, and clinical trials is readily available from the companies’ web sites on many of the specific products labeled “unsubstantiated” in the petition. <sup>1,2</sup>

The Genentech petition is ill-informed and additional FDA oversight is not needed. All health care related laboratory tests are already either cleared by the FDA or are performed in a laboratory regulated under the Clinical Laboratory Improvement Amendments (CLIA) by the Centers for Medicare and Medicare Services—or both. In addition, clinical laboratories that perform genetic tests must meet the most stringent level of CLIA regulatory oversight, often are also regulated by states, and most have additional oversight through laboratory accrediting bodies. Laboratory developed tests are validated to ensure their safety, accuracy and reliability before they are used in the first patient’s care. These tests meet otherwise unmet medical needs because of the rapidity of updating testing parameters and information being provided to clinicians. These testing services enable timely inclusion of the most up to date medical research and innovations to be used in patient care. This is in contrast to FDA-approved medical device kits, which often undergo such extended reviews that by the time FDA clears a new assay, it is no longer relevant to the current medical circumstances. Today’s FDA approval process essentially freezes medical innovations it regulates to the time the test application is submitted for approval.

The foreseeable negative consequence for the individual patient’s care if FDA regulates LDT’s is real. Clinical laboratory tests advance personalized medicine by distinguishing those individuals who likely will benefit from the right drug and dose, given at the right time from those patients with the same diagnosis likely to receive no benefit. When developed in the laboratory, under federal

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<sup>1</sup> <http://www.oncotypedx.com/HealthcareProfessional/Publications.aspx>

<sup>2</sup> [http://hermarkassay.com/reclassify\\_her2\\_status.aspx](http://hermarkassay.com/reclassify_her2_status.aspx)

oversight by CLIA, these tests can be quickly modified to take advantage of new, critically important developments in this rapidly advancing field of genetic testing and personalized medicine. Genentech's call for FDA pre-market review and post-market surveillance of these laboratory developed tests would have a chilling effect on this essential rapid innovation in genetic testing by subjecting it to an additional layer of regulation and driving away the investment needed to validate and employ test modifications.

There are many examples of tests initially developed in the laboratory that have provided major positive healthcare breakthroughs, especially in infectious disease and cancer. AIDS has been transformed from a deadly disease to a manageable chronic disease in large part because of laboratory developed tests for the diagnoses and management of HIV. Because the AIDS virus mutates so rapidly, there are over 20 FDA-approved antiviral drugs for HIV treatment and over 50 more in development. LDT's have been essential in rapidly incorporating new information for this individualized therapy. LDT's allow treatment to move from a "one drug suits all" approach to providing the right treatment to the right patient at the right time. LDT's also played a critical role in the nation's public health defense by allowing for the identification of SARs, Avian Flu, and West Nile Virus. LDT's have been and should be allowed to continue to be rapidly developed to meet new and menacing disease challenges within the congressionally established regulatory framework.

If all laboratory testing was subject to FDA regulations, testing for rare and low-volume tests for genetic diseases – such as Spinal Muscular Atrophy, Gaucher disease, Tay Sachs disease, and Canavan disease among many others - could be removed from CLIA labs' menus and no longer be available to parents of children afflicted with these diseases. These well established and medically important tests, because of small populations for clinical trial testing, would not be able to meet FDA requirements, and with limited markets could disappear.

Requiring FDA regulation of LDT's will needlessly place a huge burden on FDA staff and resources. The November 2007 Report, "FDA Science and Mission at Risk" acknowledged that "[t]he lack of new science capability/capacity places the FDA mission at risk for those many products at the leading edge of innovation. This compromises not only the public health mission since the Agency cannot effectively regulate products built on emerging science, but it also hamstring the Agency's ability to support innovation in the industries and markets that it regulates."

To allow for this 21<sup>st</sup> century healthcare revolution to continue, ACLA has proposed a regulatory model that builds on interagency coordination between CMS and FDA, provides a publicly transparent test registry, is consistent with principles of least burdensome regulation, fills all the identified regulatory "gaps", avoids overlapping and potentially conflicting requirements and allows for a participatory approach that draws on the expertise of industry stakeholders. The model also would establish "ongoing extramural collaborations [to assure] that innovations are understood by FDA science and regulatory staff – giving the agency more time to "play catch-up" as they are now doing with genomics" consistent with the November 2007 report noted above.

21<sup>st</sup> Century disease challenges require 21<sup>st</sup> century solutions and expertise – let us approach the promise of personalized medicine with a commitment to regulatory balance that will allow this new dawn of medicine to continue and not place needless burdens on a now thoughtfully regulated industry. Or as the FDA Mission report concludes: "This is not simply "new science," but represents the coming wave of "new medicine" and the need for "new regulatory scientists".

ACLA represents local, regional and national clinical laboratories throughout the United States