



**Personalized Medicine Coalition Public Statement
General Comments on LDT Framework**

January 9, 2015

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Good afternoon FDA staff and members of the public:

My name is Amy Miller. I am the executive vice president of the Personalized Medicine Coalition. The Personalized Medicine Coalition (PMC) represents innovators, scientists, patients, providers and payers. PMC promotes the understanding and adoption of personalized medicine concepts, services and products to benefit patients and the health system.

We thank FDA for the opportunity to speak here today.

Personalized medicine is an emerging field that uses diagnostic tools to identify specific biological markers, often genetic, that help determine which medical treatments and procedures will work best for each patient. By combining this information with an individual's medical records and circumstances, personalized medicine allows doctors and patients to develop targeted prevention and treatment plans. When efficiencies are introduced, such as providing the right treatment to the right patient at the right time, overall costs decrease.



It is fair to say that no other issue in personalized medicine policy has garnered more interest over the last decade than the questions of if, when and under what circumstances FDA would actively regulate laboratory developed tests. We now have a proposal to consider and improve.

While some of our members actively oppose FDA's regulation of lab tests, stating that device regulation was not designed to fit laboratory medicine, and some of our members actively support it and want the framework implemented as quickly as possible, arguing that many important tests are now unregulated, the Coalition is committed to improving this framework so that personalized medicine can advance and improve the quality of patient care, thus reaping system cost saving.

We contend that FDA's proposed framework for regulating laboratory developed tests is a good start. PMC is pleased by the high level of engagement that FDA has had with stakeholders, and we encourage FDA to continue that engagement.

As many have pointed out though, two large, critical pieces of the framework are missing:

- first, guidance on LDT risk-classification, and
- second, harmonization between the CLIA program for laboratory inspections and FDA's manufacturing regulations.



PMC recommends releasing these two documents in draft before finalizing the framework, since most of the regulatory structure is predicated on the risk-classification of LDTs. Furthermore, releasing all of these documents as a draft package will allow for a more robust examination of FDA's vision that could lead to more specific potential improvements to it, thus better serving patients and the public.

FDA is currently collecting public comments on the draft framework and has stated that it only intends to issue another draft for public comment if the changes are substantial. We argue that the two missing pieces, risk-classification and FDA-CLIA harmonization, are substantial enough to warrant further review and the issuance of another draft.

To encourage thoughtful review of the proposed second draft, we suggest that FDA outline the substantive comments received from stakeholders and the agency's responses to those suggestions. A clear articulation of why a suggestion was accepted or rejected would greatly aid stakeholders as they work with the agency.

While FDA is likely to receive tremendous pressure to finalize the guidance documents and start actively regulating LDTs, we urge the agency to take the time necessary to get it right. Future investment in the field depends on clear, reasonable guidelines, which are in our power to develop now, not at some future date.



In conclusion, we request that FDA issue draft guidance documents on LDT risk-classification and FDA-CLIA harmonization, along with an updated draft of the two existing framework documents and an explanation of why substantive comments received from stakeholders were accepted or rejected by FDA. FDA should again engage in public outreach activities like those that have occurred over the last few months.

Thank you for the time to speak with you and we look forward to working with you on these issues.