



**AdvaMedDx Statement for Public Meeting on Ultra High Throughput
Sequencing for Clinical Diagnostic Applications
“Harnessing Innovation in Next Generation Sequencing”**

June 23, 2011

I am Robert Di Tullio, Co-chair of the AdvaMed Diagnostics Task Force, and am here today representing AdvaMedDx. AdvaMedDx member companies produce advanced, in vitro diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and reduce overall health care costs. Functioning as an association within AdvaMed, AdvaMedDx is the only multi-faceted organization that deals exclusively with issues facing in vitro diagnostic companies both in the United States and abroad.

First and foremost, AdvaMedDx appreciates FDA’s holding of this workshop today to discuss these innovative technologies and evaluation tools to support the use of these platforms for clinical diagnostic use. High throughput capacity of next generation sequencing is already playing an important role in the life sciences. We agree that priority should be placed on finding ways to support these innovations as they will likely play an increasing role in scientific discovery as well as in clinical applications into the future.

FDA’s efforts today show a commitment to considering new and flexible approaches as the science rapidly evolves in order to meet public health needs and support diagnostic innovation. The technology breakthroughs of the U.S. medical technology industry have produced products that improve lives around the globe, while playing a critical role in American research and development and the economy.

The potential of these technologies is incredible, from novel biomarker discovery, to expanding our understanding of gene expression, to wider applications supporting personalized medicine. As we have already seen, next generation sequencing platforms are already helping us to have a better understanding of new emerging infectious diseases and potential new discoveries and targeted treatments for patients, especially those with rare diseases for which we had little to draw from in the past. These technologies will likely continue to play a powerful role in delivering on the promise of personalized medicine for patients.

AdvaMedDx supports a flexible, risk-based approach to regulation of all diagnostic tests. Regulatory oversight should be commensurate with risk—this includes considering not just how a test is used clinically, but also the availability of alternatives, experience of the user/site of service, and the risk of illness, misdiagnosis, or delay in care if a test is not available. Furthermore, it also includes considering factors that reduce or mitigate risk such as analytical characteristics of the methods and validity of the results obtained, peer-reviewed literature and other scientific information, general and special controls, and consensus standards. We believe that the development of standards will be foremost important in establishing the safety and effectiveness of next generation genomic sequencing technologies in clinical use in light of the breadth and depth of data generated by these systems.

A risk-based approach can best support the public health while assuring timely access to innovative diagnostics. In light of the growing number of novel technologies paving the future of personalized medicine and physicians' ability to provide better and more targeted care for their patients, a modernized risk-based approach allows focused priorities and resources on important regulatory issues while supporting introduction of safe and effective diagnostics to improve health care. We believe this approach fits well with OIVD efforts to implement innovative ways to improve the review process for *in vitro* diagnostics.

As mentioned, we believe the development of standards will be key to the regulatory process and FDA review of next generation sequencing technologies for clinical use. We support efforts of groups, such as the Clinical Laboratory and Standards Institute, which are working to address standards to evaluate the performance of these platforms. FDA, along with industry, academia, and other stakeholders, must work together as expediently as possible to develop and make best use of needed standards that will support the confidence of results and overall innovation in the field. A regulatory model must be adopted for analytical validation that assures performance of the system and relies on such consensus standards in the field. In this way, we can support the public health and not promote insurmountable barriers to the adoption and commercialization of these new technologies in the clinical diagnostic realm. As these efforts are critically important, FDA recognition and application of these standards will also be important in order to support a transparent and efficient pathway for premarket review that supports innovation.

We look forward to the scientific interchange today. Again, we appreciate the Agency's holding of this meeting and willingness to hear from experts in the field and consider scientific tools and new approaches for use in the regulatory process that will promote innovation.