

Exagen Diagnostics, Inc. Statement for FDA Public Meeting on IVDMIAs

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Hello. I am Dr. Caroline Popper, and I am a medical doctor serving as a senior regulatory advisor for Exagen Diagnostics, Inc™. I appreciate the opportunity to respond on behalf of Exagen™ to the draft guidance entitled, “In Vitro Diagnostic Multivariate Index Assays,” issued on September 7, 2006. Overall, Exagen is pleased with this document and supports the FDA’s thinking in regulating IVDMIA. We welcome the FDA’s efforts to protect public health via reasonable regulatory oversight and we offer our thoughts and perspective on some of the issues raised and questions asked.

Exagen, founded in 2002 in Albuquerque, New Mexico, discovers, designs, validates, manufactures and commercializes small sets of genomic markers to provide prognostic and diagnostic kits for commercial laboratory testing and for use in clinical trials for drug development.

Exagen is currently developing a number of products that fall under the Food, Drug, and Cosmetic Act (the “Act”) and FDA regulations, including premarket review in the case of Class II and Class III devices. During the past year we have been working closely with the Office of In Vitro Diagnostics as we are pursuing regulatory review of the first of several products in the coming months.

We understand that new technologies giving rise to new more complex marker sets challenges conventional diagnostic regulatory paradigms and believe that reasonable oversight to protect public health is appropriate.

Like the FDA, we also feel IVDMIA that utilize data from an IVD assay, which is then manipulated via a simple or complex algorithm to produce a final result intended to help diagnose, cure, mitigate, treat or prevent disease, is indeed a medical device, and therefore should be regulated by FDA. We hope that as the FDA seeks a regulatory framework for IVDMIA that the agency takes a “least burdensome approach,” thereby facilitating regulatory oversight while not impeding commercialization of new technologies.

It is also important to note that not all IVDMIA assays are equal. The agency should take into consideration that the intended use of new IVDMIA products varies considerably. As such, they may warrant a variety of regulatory approaches.

We agree with the statement in the draft guidance, “that most IVDMIA’s will be either Class II or Class III. As an example, any device intended as an indicator of a patient’s risk of cancer recurrence may be a Class II.” The IVDMIA which provides another data point to the physician without dictating treatment is not relied upon by the physician as the sole decision point in diagnosis or selection of therapeutic options.

Exagen does request that clarification be given as regulations are developed regarding the definition and regulatory status of IVDMIAs. On page 3 of the guidance document under the section about the “Definition and Regulatory Status of IVDMIAs”, there is a sentence which reads, “Even if a laboratory or other IVDMIA manufacturer...”. Exagen recommends clarification of this ambiguous statement. It is clear that IVDMIA applies to laboratories. However, Exagen does not believe that manufacturers seeking pre-market review under the Act for interstate commerce fall under this guidance.

Clearly, this is a very exciting time for science and medicine, where the promise of many more new discoveries and IVDMIA products lie on the horizon from many companies. Given that laboratories and IVDMIA manufacturers are in the early stages of discovery, development, and validation of IVDMIA products, it is important that FDA guidance and regulations supports the degree of innovation we have seen in recent years.

We look forward to continued discussion and the opportunity to offer our thoughts as the FDA works for final regulations in the months ahead.

Thank you.