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Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
RE: Docket No. 2006D-0347 (for IVDMA Draft Guidance)

Dear FDA:

I am writing to express our appreciation to you for soliciting our comments regarding the IVDMA Draft Guidance issued on September 7, 2006. We applaud your critical path initiative and respect your commitment to public safety. MDV is a 23 year old investment firm with expertise in the funding of innovative start-up companies. We have a special focus on supporting companies in molecular diagnostics and personalized medicine with particular interest in the areas of oncology, cardiology, immunology and neuroscience. As a result, we have a perspective on the key issues that face innovative diagnostic companies and the consequences of the IVDMA Draft Guidance as it relates to investment and company construction in the diagnostics field.

Our gravest concern is that the Draft Guidance document could significantly impact the incentives for laboratories and young companies to develop sophisticated and innovative new tests. This is of particular concern given the promise of these tests, which includes: advancing personalized medicine, improving health outcomes, lowering the cost of healthcare, and reducing adverse events. Many of the laboratories and young companies developing the innovative diagnostics with the most promise are small and entrepreneurial. In order to make the benefits to healthcare a reality, these laboratories and companies need access to capital that firms like MDV provide. Historically, diagnostic companies have faced a difficult environment for fundraising. Indeed, the funding of diagnostics has lagged significantly behind the funding for the medical device and biopharma sectors. The uncertainty and potential burdens that the Draft Guidance document implies are making an already difficult fundraising climate even worse.

While the FDA has been made aware of the concerns of other constituencies, we would like to share with you the specific fears of innovative companies. The Draft Guidance creates tremendous ambiguity and regulatory uncertainty. For instance, it is not clear

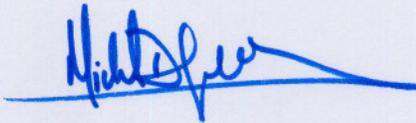
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
Docket No. 2006D-0347  
Page 2 of 2

what types of laboratory services will be subject to regulation by the FDA as IVDMIA. Furthermore, if laboratory services are subject to regulation by the FDA as an IVDMIA, it is not clear what the level of regulation will be. Finally, the FDA has not clearly defined an IVDMIA and has not laid out a regulatory path. Consequently, innovative companies and investors are unable to calculate the costs of compliance with the Draft Guidance.

MDV has already seen the repercussions of this uncertainty in our portfolio companies. Specifically, our companies are now budgeting scarce resources, time, and staffing in order to plan for multiple contingent regulatory scenarios. This is particularly problematic since it stacks the playing field in favor of large existing organizations who have the resources for dedicated regulatory staffs. Ironically, these firms are not the source of molecular diagnostic innovation. We are concerned that the FDA's good intentions may result in unintended consequences that may "kill the goose that is laying the golden eggs."

While the consequences of the current IVDMIA Draft Guidance have been frustrating to existing innovative companies and a possible deterrent to future investment, we are confident that the collaborative atmosphere the FDA provides can address these concerns. We believe that a reasonable course of regulation that is not unduly burdensome yet preserves the quality of science will help make the promise of molecular diagnostics a reality. Patients deserve no less.

Sincerely,



Michael D. Goldberg  
General Partner  
Mohr Davidow Ventures