

March 5, 2007

HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket #2006D-0336 and Docket #2006D-0347

Dear Sir/Madam:

My name is Sandy Gordon and I suffer with a horrible rare disorder called Trimethylaminuria. I co-founded The Trimethylaminuria Foundation (TF) a few years back because it took me 10 years and my life-savings to get a diagnosis, and I wanted to work to ensure that the journey would not be as difficult for those who would come after me. However, it is still a rocky road and lives are still being devastated in 2007. I am sure that you're aware that it is extremely difficult for those living with rare disorders to get an early diagnosis and that the financial toll is devastating; but do you know that it affects entire families, entire communities? Therefore, I write to encourage the FDA to reconsider sanctioning the IVDMA or ASR Draft Guidances currently under review. We caution that forcing laboratories to function under both these new guidelines and the existing Clinical Laboratory Improvement Amendments of 1988 (CLIA) will significantly cut down on the ability to produce new, effective testing methods and will eliminate much of the progress made in early detection and treatment of a plethora of diseases and disorders.

In our work, we look to assist patients who live with Trimethylaminuria and the effect of not having access to testing and diagnosis is one of the compounding factors that can derail a family. The ability to move forward is reliant on accurate and effective diagnosis. This disorder is rare, and it is important that laboratories are able to innovate and generate effective testing. But the Draft Guidances may create an unnecessary web of regulation and also potentially significantly slow the process of producing new technologies for any condition. The result is that uncommon disorders like Trimethylaminuria will continue to be sidelined, without the attention and dedicated research necessary to improve the lives and diagnosis of suffering patients.

Even if laboratories wanted to continue developing new tests for rare diseases under the proposed Draft Guidances, the task itself could become too expensive. When the process for a new test to come to market is difficult and arduous, testing for rare diseases will be pushed to the curb, as will all of us living with these conditions. In such a dense regulatory environment, it may no longer be cost effective for laboratories to innovate in an area that affects a lesser number of people. But to those people, that innovation is critical and life-altering.

We must keep it going, and we can.

Thank you for your consideration. If you need any further information, please feel free to contact me.

Sincerely,
Sandy Gordon
Director and Co-founder