

March 13, 2003

TO: Carol Bigelow
CDC
cgb7@cdc.gov

FROM: George B. Vaughan, Ph.D
President and CEO

RE: Summary of my remarks to the committee during "Public Comments" during CLI Advisory Committee Meeting, March 12-13, 2003.

Thank you Mr. Chairman. My name is George Vaughan. I am here as a provider representing both HealthcheckUSA and also our recently formed Trade Association, appropriately named with the acronym, DATA. I wish to comment on both these organizations as Direct Access Testing applies to each.

First let me comment on HealthcheckUSA . I am the founder and president of this company which has been in this business and survived since 1987, which to my knowledge is longer than any other company doing business in this arena. Our mission statement includes the words "health awareness" and "prevention of disease" which includes "Direct-to-consumer Laboratory Testing". For years we had little competition and worked in a vacuum. It has only been in the past few years that there has been a groundswell of companies, laboratories, and hospitals offering Direct-to-consumer Laboratory Testing and we are now labeled as "Direct Access Testing". This is good as I can finally respond in three word what I do. Perhaps in the near future we will even have a SIC code.

I can appreciate that the term "Direct Access Testing" is here being used in the context of laboratory testing, but at HealthcheckUSA, it actuality includes all consumer ordered tests that relate to risk assessment and prevention, for example, sonar heel scans for detection of osteoporosis, sonar Carotid Artery Screens, Pulmonary Function assessments, EKGs as well as laboratory test. The consumer in most instances are "well" persons who would otherwise not have had these test. But there are other market drivers. (1) Many of our customers are referred by their physician to come to us for laboratory work for purposes of convenience and cost savings. (2) Many of our customers are referred by physicians to get a complete blood profile before coming in for an annual physical so that the physician will have information to review with their patient at the time of visit. (3) Many of our customers are Medicare patients who would rather pay cash for a laboratory test than risk that their referring physician did not furnish correct CPT codes for reimbursement and in turn would be balance billed. (4) Many of our customers

are part of a corporate wellness screening. (5) Now we are seeing a rise in request from insurance companies who want to offer screening services to their customer base realizing the cost savings by catching pathologies before becoming a diseased state.

In 15 + years of business, we have never had a complaint from a physician- only praise. And from consumers, I could line the walls with letters thanking us for our service. Such response is very gratifying when knowing you are helping people.

Secondly, let me address the recent formation of our trade organization, DATA. This was formed by a group representing six DAT organizations in the US as a response to the growth in the industry. Our purpose is two-fold. (1) To provide some internal criteria amongst our members in light of recent unethical business practices which always seem to crop up in a new industry so that consumers will know that member organizations adhere to a set of standards. And (2), to have a voice from the provider side of DAT to respond to the handling of legal issues. Our goal will be that its member organizations meet criteria which we are assembling which may include truth in advertising, pre- and post-test counseling on certain tests as genetic testing and HIV testing, confidentiality, dealig with "panic" values, etc. I might suggest that this organization may be a conduit to interact with this committee. As a final comment, we invite all legitimate DAT organizations to belong and if they contact me, I can include them in our next meeting.

Thank you.