

GTR Comments 11/2/10

Thank you for permitting me to speak to you today. I am speaking as past President of the American Society of Human Genetics, the largest genetics professional organization with nearly 8,000 members. We feel that the quality and accuracy of the information in the GTR are paramount.

Let me cite as an example an analogy with the Physicians Desk Reference (PDR) for pharmaceuticals. The HHS Secretary's Advisory Committee on Genetic Testing discussed a "PDR for Genetic Tests." We know that the PDR has oversight to ensure a higher level of quality and accuracy of information than one sees and hears in direct to consumer media claims. We urge the GTR to learn from the experience of the PDR and its interaction with the FDA.

The discussion of the GTR appears to be focused on the DNA tests. I would urge you to consider phenotypic tests, such as biochemical genetic analyses, so that these tests are not forgotten, and their quality and accuracy are not compromised.

Thank you.