



Archived Policy Statement

Comments on behalf of the Board of the Genetic Alliance Secretary's Advisory Committee on Genetics, Health and Society

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February 11, 2008

Thank you for the opportunity to comment publicly on your report on oversight for genetic tests. Thank you, too, to the Task Force and the working group—your efforts have been generous and enormous.

I speak on behalf of the board of directors of Genetic Alliance. I know you received and considered our 18 pages of comments, so I will not belabor them here. I will call out seven important concerns for us, then move to a more global view of your task and product.

1.) The first step to improving oversight of genetic testing is through enforcement of existing regulatory authority under the CLIA program and applying the available funding resources to provide for additional personnel, consultants, and training and to provide the mandated level of transparency of CLIA labs under the current statute. In addition, it is important to take action on the identified interim steps within the agency's discretion to implement immediately the necessary steps for proficiency testing enhancements for genetic testing, e.g., PT expansion, incentives for PT reference controls, training of inspectors, and adding to the list of regulated analytes.

2.) It is clear that mandatory genetic test registration, including all tests across the risk continuum, to provide all stakeholders with information would greatly improve oversight. Making test performance characteristics and reference information, including analytical and clinical validity, publicly available should increase confidence and improve the appropriate utilization of genetic tests. We also believe that the registry should be housed at, and managed by, a federal agency such as the FDA or NIH to offer needed capacity and independence. It will also allow the first assessment of harms through adverse-event reporting.

3.) We agree that more public resources should be committed to fill in "gaps in the extent to which analytical and clinical validity data can be generated and evaluated for genetic tests." We support the establishment of a laboratory-oriented consortium for sharing information regarding method validation, quality control, and performance issues. We believe any such undertaking must prioritize based on clinical need, availability of information, and appropriate resource allocation.

4.) To maximize benefits and minimize harms, a public/private consortium of stakeholders should be created to assess the clinical utility of genetic tests, including the establishment of evidentiary standards and increasing the number of systematic reviews.

5.) We agree with the SACGHS report's concern over the FDA exerting regulatory authority over clinical decision-aids.

6.) Direct-to-consumer access to testing must be carefully regulated to ensure the public's safety.

7.) HHS must convene relevant HHS agencies, as well as the interested stakeholders, to provide further input into the development of a risk-based framework for the regulation of LDTs. In addition, HHS must take the leadership role in coordinating the activities of the federal agencies under its auspices for the benefit of public health.

More important than these concrete recommendations, however, is the overall place of genetic tests and testing in the integration of genetics into medicine, and further, into prevention and wellness. We recommend that HHS take a broad and enlightened view of the landscape. We are at the dawn of a new age, and innovation, development, oversight, and delivery of genetic services in a coordinated manner is critical to advancing human health. Genetic testing is a disruptive innovation, and this is a critical time for the development of new paradigms. We must avoid applying old models and methods to new technologies. HHS can require that federal agencies work with one another to achieve the best possible solutions. Human health is no place for politics and turf battles. Excuses such as “the burden is too great” and “it is too difficult” are unacceptable in the realm of health.

We, the entire genetic testing community, have dialogued a great deal over the past year. I believe we have achieved a great deal in understanding each other's issues. It is time now to engage one another in meaningful and landmark solutions, novel partnerships, and collaborative models. As you deliberate over the next two days, you are representatives of the millions of individuals who are suffering, sick, and dying. Not an easy task. You must keep them before you—they are your loved ones, your neighbors, your friends. You cannot offer answers or opinions from your silo or your own self interest today. You must push the boundaries regardless of your company, profession, university, constituency—and represent what is best for the public, both in this country and beyond. Before you speak, don't think of your “position” but instead of the greater good to be gained. Focus on the intended consequences, not on the unintended ones. This is not a zero-sum game, and while the status quo will be destabilized in the short term, we will all win in the long term.

Finally, it is a decade since your previous committee made important recommendations that have been left to history unimplemented. Regardless of the Secretary's response, we, as a community, are now further enlightened by your work and have a responsibility to one another and the world community to strive for solutions that will release the incredible potential of biomedical research. We must all remain engaged, in dialogue with one another, seeking to

tell the truth, to discover new pathways together. We have a historic opportunity—let's commit to measuring our responses, products, and actions against the greater good.

On behalf of those who wait for treatments and therapies, thank you.