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TO: Cathy Fomous  
SUBJECT: Genetic Testing Registry

It is a privilege to be invited to give comments on the plan to develop a Genetic Testing Registry (GTR). I have read many, but not all, of the comments made prior to the November 2 Public Meeting. As a nonprofessional I learned much from those comments.

I am particularly impressed with all of the suggestions from A/Prof Julie McGaughran President, The Human Genetics Society of Australasia (HGSA) and A/Prof Paul McKenzie President, the Royal College of Pathologists of Australasia. On page 2 of their communication, as a consumer of the projected GTR information, I especially appreciated their statement:

“A recent report published by the National Health and Medical Research Council, Australia’s peak body for supporting health and medical research, outlines the regulatory frame work for genetic tests . . . . The report also outlines potential ethical, social and legal implications of DTC [direct-to-consumer] testing in detail, which include potential psychological and medical risks to consumers from receiving adverse results in the absence of genetic counseling and concerns regarding the scientific validity and potentially misleading claims of some DTC genetic tests. A centralized Registry would go some way in preventing potential misuse and misapplication of genetic tests.”

I also appreciated the thoughts expressed by Joanna Mountain, Senior Director of Research on behalf of Anne Wojcicki, Co-founder and President of 23andMe. However, I do have a concern about the statement in a bulleted paragraph on page 2 under “Variants of Unknown Significance”: “Consumers of genetic tests will find the GTR most helpful if the GTR is capable of communicating that some tests may produce results where accuracy cannot be evaluated or health significance is unknown.” I would hope that if that suggestion is accepted, it will be clear that statement applies only to specific tests, so that the consumer will not interpret it as applying across the board.

In other letters that I read, there is considerable concern that the data in GeneTests and GeneReviews not be abandoned. I feel sure that is not your intent, but reassurance of some sort is apparently needed by the professionals who use those resources. My question is, are those data presented usable and understandable by consumers?

As a consumer, I think the GTR will contain, of necessity, many terms with which I will not have familiarity. I hope that as the GTR is developed, terms will be identified and placed in a Glossary with definitions as understandable as possible to a lay public.

Thank you for the opportunity to present my thoughts.

Polly Liss