



# National Health Council

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NIH GTR RFI Comments  
National Institutes of Health  
Office of Science Policy  
6705 Rockledge Drive, Room 750  
Bethesda, MD 20892

## Re: Solicitation of Comments on the Development of the Genetic Testing Registry

The National Health Council (NHC) supports the National Institutes of Health's (NIH) efforts to develop a Genetic Testing Registry (GTR). The NHC shares NIH's view that transparent access to the validity and usefulness of genetic tests is vital to facilitate research and to enable informed decision making by patients and others. The NHC seeks to ensure that patients have access to meaningful information on the accuracy of tests and the appropriate manner in which to interpret their results. To achieve this goal, the NHC believes it is imperative that the GTR is developed in a format that is clear and decipherable for patients.

The NHC is the only organization of its kind that brings together all segments of the health care community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 100 national health-related organizations and businesses, its core membership includes approximately 50 of the nation's leading patient advocacy groups, which control its governance. Other members include professional societies and membership associations, nonprofit organizations with an interest in health, and major pharmaceutical, medical device, biotechnology, and insurance companies.

The potential of genetic tests to transform clinical decision making and improve treatment planning for people with chronic conditions is enormous. Indeed, advances in genetic science have led to significant growth in the number of genetic tests commercially available to patients. For patients with chronic conditions, genetic technologies hold tremendous promise in driving the development of targeted therapies for disease. The NHC believes genetic tests can play a central role in eliminating the 'one-size fits all' approach to treatment. It is widely known that many drugs are effective in only a segment of the intended patient population and that the remaining patients are exposed to potentially harmful and toxic side effects with no commensurate benefit. In recognition of this, the NHC has made the development and commercialization of advanced diagnostic tests, including genetic tests, a priority policy area. We have focused on promoting policy that would improve understanding of innovative diagnostics by patients and other stakeholders and create incentives to encourage the development of new diagnostics.

As such, the NHC welcomes the NIH GTR initiative to create a centralized resource on genetic tests for the public. The NHC believes the availability of reliable, easy-to-understand information is critical to ensuring that genetic technologies are utilized fully and appropriately. In addition, we agree with the NIH that enhanced transparency would facilitate data-sharing for research and could be a powerful resource for researchers.

To ensure NIH's aim for the GTR to enable informed decision making by patients, caregivers, providers, and others is realized, the NHC believes the format of the registry must be designed with patients and their providers in mind. Today, patients have access to an

unprecedented level of information on genetic testing. However, while abundant, the information currently available to the public is fragmented, diffuse, and many times inconsistent. In addition, for those who lack expertise in this field, the information is complex and technical, thus diminishing its applicability in informing decisions. With this in mind, the NHC recommends the following:

- **NIH should supplement the GTR with public education on basic genetics and the testing process.** While a great deal of information can be found on genetics through various media, it is difficult to parse the good from the bad. A public education campaign facilitated and endorsed by the NIH would enhance the GTR's benefits to patients by providing context for viewing the information in the registry.
- **NIH should develop standardized definitions of data elements.** Today, too many important concepts in genetics are inconsistently defined by policymakers, regulatory authorities, manufacturers, and payers. Establishing clear and consistent definitions, especially with respect to test characteristics, would be an important step toward ensuring that test developers submit data that is comparable. From the perspective of the patient community, it will be vital that definitions are translated in a manner that can be understood by a novice to the field.
- **NIH should summarize evidentiary support, such as published data, systematic reviews, and practice guidelines, that are submitted in support of claims related to a test.** The NHC agrees with the NIH that the GTR will be useful if it includes information on the validity and utility of genetic tests. The submission of supporting evidence will be critical to establishing the credibility of assertions made with respect to a test's validity and utility. However, published studies and systematic reviews can be highly technical. We urge the NIH to translate such technical material to a format that is understandable for patients and their providers.

Finally, NIH has indicated that it does not plan to review information submitted to the registry, other than to implement checks against submitter error. Given the significance of NIH's undertaking in developing this registry, we urge NIH to consider additional safeguards that go beyond inadvertent errors to ensure that the information on the registry is reliable and validated. In this regard, NIH should consider:

- Establishing a requirement that any assertions with respect to a test's characteristics are supported by evidence;
- Developing quality assurance measures to help ensure the integrity of data; and/or
- Contracting with a third-party organization to validate and monitor information submitted to the registry.

The NHC is committed to ensuring that the promise of genetic technologies is realized. The NHC believes the GTR can be a significant step toward providing meaningful information to patients. As genetic technologies continue to advance and the numbers and types of tests continue to grow, people with chronic conditions will continue to be inundated with information of varying reliability. The need for a resource such as GTR will become increasingly pronounced. We urge you to develop the GTR in a format that is appropriate for all users, but in particular people with chronic conditions who will rely on the GTR to identify tests that will help them determine the best, most effective treatments.

We would like to thank you for this opportunity to share our comments. Please do not hesitate to contact Kevin Cain, our Assistant Vice President of Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0542 or via e-mail at [kcain@nhcouncil.org](mailto:kcain@nhcouncil.org). You may also reach me on my direct, private line at 202-973-0546 or via e-mail at [mweinberg@nhcouncil.org](mailto:mweinberg@nhcouncil.org).

Sincerely,



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President