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August 2, 2010

Dr. Francis Collins
Director, National Institutes of Health
c/o Genetic Test Registry RFI Comments
National Institutes of Health
Office of Science Policy
6705 Rockledge Dr.
Room 750
Bethesda MD 20892

Dear Dr. Collins,

As you have highlighted in the Request for Information (RFI) regarding the proposed NIH Genetic Test Registry (GTR), the rapid growth of the genetic testing/molecular diagnostic industry makes it challenging for consumers, health care providers, and payers to stay current on the level of evidence for specific genetic tests. DNA Direct supports the efforts of the NIH to develop a Genetic Test Registry. We would use such a registry to further our goals of developing and providing test appropriateness tools for consumers, providers and payers.

DNA Direct has had significant experience in this area that we would like to share with the NIH. With our recent acquisition by Medco, I believe there is an opportunity here for a strong public/private partnership between our two organizations.

As you know from our early meetings together, DNA Direct was founded in 2005 with the mission "to bring the power of personalized medicine to patients, providers and payers — reducing health risks, preventing disease, and better targeting therapies."

In order to develop our web-based tools to aid patients, providers and payers in the appropriate use of genetic tests, we first developed a genetic test database that has evolved over time to a catalog of over 700 molecular diagnostic tests that represent the most common tests on the market across all medical subspecialties and ICD9 categories. The tests were identified through a combination of public databases (GeneTests and AMP), the internet, test menus of laboratories, and claims data on 15 million lives. Our catalog includes most of the data fields proposed by the GTR, including evidence of analytical validity, clinical validity, clinical utility, and a review of ethical/legal/social issues.

DNA Direct will be presenting an abstract on the "Development and Use of Our Genetic Test Catalog for Payers and Providers" at the upcoming NCHPEG 13th ANNUAL MEETING on Sept 24th. To date, our Genetic Test Catalog and related products have been used to inform over 1,500 health care providers about test use and appropriateness on nearly 200 unique genetic tests. We will review and report on our experience developing the catalog and implementing its use by payers and health care providers.

In addition, our informational products on test appropriateness include consumer education and decision support programs, utilization management tools, and point-of-care physician education.

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Several health plans and hospitals routinely use our services. As a result, we have significant experience in understanding the data needed by consumers, health care providers, and payers on genetic testing.

We believe in public/private partnerships, and would be delighted to share our experience in developing our genetic testing catalog, and determine ways to work with the GTR to advance public awareness and understanding of appropriate genetic testing.

Sincerely,

Ryan Phelan
President and Founder