United States Senate Special Committee on Aging
July 27, 2006

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Leading scientists and clinicians predict that the widespread adoption of DNA testing technologies will bring revolutionary improvements to long-term health, medication safety and efficacy. This will open an era of personalized medicine, thereby fulfilling the promise of the Human Genome Project. Accelerated adoption of existing, yet underused, pharmacogenetic DNA drug reaction testing, combined with evidence-based drug interaction software, is the most important existing opportunity to personalize and improve U.S. senior healthcare. The routine use of this technology by physicians leads to evidence-based prescribing practices that could save thousands of lives every year, lead to improved quality of life for many senior citizens, and save money. (See attached DNA and Adverse Drug Reactions Fact Sheet.) The ability of consumers to purchase DNA Drug Reaction Testing directly is an important force driving the adoption of this life-saving technology.

> "…the incorporation of pharmacogenetics into clinical medicine is likely to have a great effect on public health in the near future."
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> Yoseph Caraco, MD NEJM 351; 27 2004

Direct to Consumer DNA Testing

Many DNA tests, including paternity, DNA drug reaction, nutritional genetic, and some medical genetic tests are currently available directly to the public. Purchasing these tests directly, bypassing their physicians, is the only way patients have to control the entry of this information into the healthcare records system. In many instances, direct ordering of the tests also saves consumers money. It is important for citizens to continue to have this right, given the sensitivity of genetic information and the lack of confidence people may have in the ability of the healthcare records system to protect their privacy.

Until the mid-1990s, most parentage testing was ordered by doctors or lawyers. When the testing became available direct-to-the-public there was concern voiced that this would be problematic. By now tens of thousands of people have obtained the benefits of DNA parentage testing, at lower cost and in the privacy of their homes, without the development of significant problems.

Need for Interpretive Services

All DNA testing requires appropriate reporting and interpretation services in order for consumers to take action based on test results. In DNA Drug Reaction Testing the lack of appropriate interpretive software has, until recently been a major barrier to the adoption of the testing by the medical community. The many combinations of interacting genotypes and changing medication regimens require complex, evidence-based software such as GeneMedRx. Recently introduced by Genelex, GeneMedRx is a genetics-enabled drug interaction software program created by physicians for physicians to help them apply DNA Drug Reaction Testing results. Trained personnel, whether pharmacogenetic experienced physicians, certified nutritionists, genetic counselors, or trained client service personnel need to be available to consumers. Currently, laboratories providing DNA testing appear to be doing a reasonable job of providing these services and are not providing results in a fashion that could be harmful to patients. As the field

grows it will be important to ensure that the level of information provided to clients and their providers continues to improve and remains at a high level.

DNA Testing Regulation

Since the commercialization of DNA testing began two decades ago, the development of quality standards and comprehensive quality assurance programs has been widespread throughout the disparate public and private sector enterprises producing and using DNA test results. In 1992, for example, the American Association of Blood Banks Parentage Testing Committee initiated the first comprehensive quality program available for DNA testing by inspecting and accrediting DNA parentage testing laboratories.

Medically used DNA testing is covered by CLIA (clinical laboratory improvement act) regulations. The development of CLIA regulations that address DNA Testing as a specialty is a welcome natural evolution of the regulatory process. Most testing is done as "home brew" which means the test has been validated to CLIA standards by the testing laboratory. These tests are not subject to FDA regulation. The FDA is becoming involved by the approval of DNA testing instruments and reagent kits which are regulated as medical devices. DNA testing is designated as high complexity by CLIA. The growing availability of FDA approved DNA tests allows it to be performed in lower complexity settings. It is not appropriate for academic research laboratories to perform medical genetic testing for patients without being CLIA licensed.

Nutritional Genetic Testing

Recently Nutritional Genetic Testing has become available to the public over the internet, through multilevel marketing organizations and retail stores. These tests are designed to help people personalize their diet and supplement programs in order to reduce the incidence of dietary and life-style induced risk factors that over a period of decades can lead to major disease.

Although sometimes criticized by academics scientists as being premature, nutritional genetic testing is proving useful to clients by helping them make the long-term behavioral changes required to optimize health. As the testing results in the development of individualized programs it tends to improve compliance and permits clients to resist the many fads that permeate the nutrition and weight loss fields.

> "…for people who are already overweight, the public health interventions aimed at the general population are not a complete solution. …public health needs to also seek new approaches—such as considering genetic factors in risk factor assessment and intervention design – to more thoroughly address this complex problem…"
> *CDC (US Centers for Disease Control and Prevention) 2005.*

Currently, most of this testing is done in CLIA licensed laboratories, even though it may not be subject to CLIA regulation. It is important that as the field grows and new players enter the market place, that current truth in advertising and other consumer protection legislation is adhered to.

Genelex Company Background

Since starting in 1987, Genelex has become a world leader in direct-to-consumer DNA testing by commercializing proven but generally unavailable tests. Throughout the 1990s Genelex was recognized as a pioneer in forensic and paternity DNA testing. In 2000 the company entered the field of personalized medicine with the first launch of direct-to-consumer pharmacogenetic testing for the prevention of adverse drug reactions. In 2002 Genelex was the first to launch nutritional genetic testing in the U.S. In 2005, with the launch of the genetics-enabled GeneMedRx drug interaction software, Genelex began providing the first comprehensive personalized prescribing program available.

Genelex has been accredited by the AABB Parentage Testing Committee in DNA parentage testing since 1992, the American Society of Crime Laboratory Directors Laboratory Accreditation Board from 1998 to 2003, is Washington State Medical Test Site No. MTS-3919 CLIA No. 50D0980559 and has contributed to the validation of National Institute of Standards and Technology (NIST) Standard Reference Materials.