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DNA testing pioneers since 1987







# DNA Today

ADDRESSING THE DNA TESTING NEEDS OF MEDICAL PROFESSIONALS AND PATIENTS SINCE 1987.

youScript
Personalized Prescribing System

## New Look, New Brand, & New Pharmacists

After more than a decade, the medical and insurance communities are beginning to embrace DNA-based analysis as a powerful tool in selecting and optimizing pharmaceutical treatments. Genelex has been a consistent front-runner in these technologies.

GeneMedRx and our drug sensitivity tests are combining under our new **YouScript™** brand. Over the next few months, you'll notice changes in our informational materials and a major upgrade to our services.

For those who haven't taken advantage of GeneMedRx, our new **YouScript™** Personalized Prescribing System is a comprehensive, long-term solution for safer, more targeted prescribing. Most patients taking a series of drugs have genetic variations that affect their ability to process those drugs – to either eliminate or activate them. This includes most classes of routinely prescribed drugs, over-the-counter medicines, many herbal preparations, and some dietary supplements and foods. Cytochrome P450 testing detects those genetic variations.

**Tyler Mamiya & Paul Verbeurgt**

Now, whenever a major or significant drug-drug or drug-gene interaction risk is noted, **YouScript™** will generate a medication advisory report including potential alternative drug or dosing recommendations based on the patient's DNA test results and overall medication regimen.

To bring more clarity to the prescribing process, we have a new team of clinical pharmacists: Paul Verbeurgt and Tyler Mamiya. They are busy analyzing patient medication regimens, DNA test results, and recommending specific actions to help improve prescribing outcomes. They are available to help prescribers, patients, and other pharmacists understand specific cases and to guide users in getting the most out of the **YouScript™** system.

We're celebrating the evolution of our state-of-the-art personalized prescribing services. We encourage you to join in the excitement, and the opportunity to improve patient care, by taking advantage of our new services today!

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# Personalized Prescribing in Action: Case Study

**You don't need genetic information to benefit from YouScript™!**

A 62-year-old male doctor's health conditions included hyperlipidemia, erectile dysfunction, dental caries, and insomnia. His daily medications consisted of aspirin, Lipitor, chlorhexidine mouth rinse, and Viagra as needed. For sleep, he took valerian root, melatonin, and Benadryl. He regularly consumed coffee and energy drinks, and took several over the counter medications: fish oil, coenzyme Q10, niacin 1000 mg, and L-carnitine. For knee pain, he used Voltaren gel (purchased in Mexico) and ibuprofen 400-600 mg daily as needed. He had no known drug allergies.

An ophthalmologist instructed him to start taking red yeast rice, curcumin powder, grape seed, and Wobenzyme. Soon after adding the supplements to his daily regimen, the doctor began to experience muscle aches, pains, and flu-like symptoms.

Unfortunately, the ophthalmologist had advised the doctor to take substances that interacted with the prescribed medications he was taking.

……..*Continued on next page*

# Identifying Twins: DNA Straight Talk

Some may not see the value in knowing the difference between identical and fraternal twins, but to the parents of twins, it can matter a great deal. It's a part of their children's identity. Unfortunately, according to a new study, a fair number of parents were misinformed due to a common misconception that twins who gestate in separate placentas are fraternal. Actually, 25-30 percent of identical twins have separate placentas and amniotic sacs. A 2004 survey among members of the American College of Obstetricians and Gynecologists found that 81 percent of doctors were under this misconception. This new study, published in the journal BJOG this past February, showed 14.7 percent of the 1,302 parents of same-sex twins were misinformed that their twins were either identical or fraternal. The type of twins was confirmed through DNA testing, which may be a lesson learned for the future. With the availability, accuracy, and simplicity of DNA testing, the "rule of thumb" no longer need apply.

**"I think there are a lot of parents who just want to know. A lot of parents finding out later on felt they just didn't know their own children."**
**-Abi Fisher,**
**an author of the study**

*http://www.nytimes.com/2012/03/06/health/research/study-finds-twins-can-easily-be-misclassified.html*

The interactions were severe and the symptoms resembled the early signs of rhabdomyolysis.

If either the doctor or the ophthalmologist had utilized **YouScript™** before starting the herbal medications, they would have caught the following interactions:

- Red yeast rice contains the compound lovastatin which is in the same class of drugs as Lipitor. The subject was already on high-dose Lipitor. This combination alone could have caused the adverse reactions described. This combination is not advised.

- Levels of red yeast rice may be increased up to 150% by grape seed because grape seed inhibits CYP3A4. Levels of Lipitor might also be increased, but to a lesser extent. This interaction could also help explain the patient's adverse reaction.

- Clinical studies show that co-administration of niacin and lovastatin increases the risk of rhabdomyolysis. The lovastatin product insert recommends no more than 20 mg daily when niacin levels exceed 1 gram per day – however, because the patient was taking lovastatin in a non-standardized form, it is unknown how much he was truly receiving.

Once the doctor stopped taking the drugs and herbal preparations recommended by his ophthalmologist, the problems resolved.

You don't need a patient's genetic information to benefit from **YouScript™**. It is a powerful algorithm-based program that can help patients and practitioners predict clinically significant drug interactions *before* they happen. **YouScript™** predictions are based on clinical studies and the most up to date expert opinions in the field.

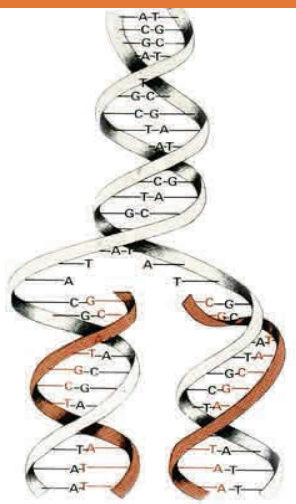
## Healthcare Provider? Ready to Make Personalized Prescribing Part of Your Pharmacy or Practice?

Contact Genelex at **800-523-3080** and ask for a Medical Accounts Specialist. We can help you take the guesswork out of prescribing at no cost to your patients or your practice.

## Patient? Is Personalized Prescribing Right for You?

Contact Genelex at **800-523-3080** or visit **www.HealthandDNA.com**.

## DID YOU KNOW?



**More than 50% of the most commonly prescribed drugs are processed by enzymes whose levels vary due to genetic factors. This genetic variability is a leading cause of adverse reactions.**

**There are over 2 million severe adverse drug reactions every year.**

**Every day more than 5,000 Americans have an adverse drug reaction serious enough to require hospitalization.**

**In 2001, the direct healthcare costs associated with adverse drug reactions were estimated at $177 billion.**


# FDA Reaffirms Plavix Black Box Label Decision

The US Food and Drug Administration (FDA) is standing by its original decision to update the Plavix label with pharmacogenetic information. A meta-analysis published last year in the Journal of the American Medical Association, led by Michael Holmes of the University College of London, raised questions about whether the label changes were premature.

**"The FDA was right in updating the Plavix label."**
**-Larry Lesko,**
**former FDA CDER Director**

The CYP2C19 enzyme converts Plavix into its active form. Pharmacogenetic testing identifies the amount of the enzyme a person creates and assigns a value ranging from *poor* to *rapid* metabolizers. The FDA updated the label to emphasize that pharmacogenetic tests could help guide therapeutic strategies, with the black box advising doctors to "consider alternative treatment strategies" in *poor* metabolizers.

Holmes *et al* argued the labeling decision, stating "evidence of small-study bias" in the data collected by the original meta-analysis. His counter-analysis of four large studies, plus six randomized trials, failed to identify any significant associations between CYP2C19 genotypes and Plavix effectiveness in terms of cardiovascular events and bleeding.

According to Lawrence Lesko, former director of the Office of Clinical Pharmacology at FDA's Center for Drug Evaluation and Research, emerging data has shown that the FDA was right in updating the Plavix label. He noted that two other meta-analyses, published before the Holmes *et al* study, found that *poor* metabolizers were at heightened risk for cardiac events.

## Questions? Comments?

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