

Arxcel

Excellence in Prescription Benefit Management

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- Strategic analysis and solutions
- Evaluation and placement of PBMs
- Cost control initiatives
- Education in drug trends and industry events
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- Coordinate member and account communication

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- PBM auditing
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The ArxExaminer

Examining issues and trends in the prescription benefits industry

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SPECIAL TWO-PART SERIES: Examining Pharmacogenomics

New science to bring change to health plans

Year after year, millions of Americans suffer adverse drug reactions. A 1998 study published in the Journal of the American Medical Association cited 2.2 million serious ADRs in 1994 leading to 100,000 deaths. Indications are that these numbers have not changed dramatically in subsequent years.

According to the National Center for Biotechnology Information, there has been no simple way in the past “to determine whether people will respond well, badly, or not at all to a medication. Therefore, pharmaceutical companies are limited to developing drugs using a one-size-fits-all system. This system allows for the development of drugs to which the *average* patient will respond.”

But, that’s beginning to change, thanks to a new science known as pharmacogenomics.

As defined on the Pharmaco-

genomics website of the U.S. Human Genome Project (HGP), pharmacogenomics is the study of how an individual's genetic inheritance affects the body's response to drugs. The term comes

from the words pharmacology and genomics and is thus the intersection of pharmaceuticals and genetics.

Pharmacogenomics holds the promise that drugs might one day be tailor-made for individuals and adapted to each person's own genetic makeup, says HGP.

The day is coming, says HGP, when a patient will walk into a doctor's office and, after a simple and rapid test of her DNA, the doctor will be able to select one drug that will be particularly beneficial to the patient

over another that may cause a negative reaction – all based upon the particular makeup of that patient’s individual genetic makeup.

Effect on drug performance

There are three principal ways that an individual’s genetics affect drug performance:

1. METABOLISM -- Genes that are responsible for the liver enzymes that metabolize drugs vary by individual. Some people may simply not have enough of an enzyme, and in some cases, none of the enzyme at all. If they do not have any of an enzyme necessary to metabolize a drug, the drug be ineffective.

2. TRANSPORT -- Proteins produced in the liver, kidney and other tissues are responsible for transporting the drug to the appropriate area of the body. Genetic

See [Pharmacogenomics](#) next page

Pharmacogenomics is the study of how an individual's genetic inheritance affects the body's response to drugs

This article is the first of a special two-part series examining pharmacogenomics and how it will bring change to health plans sponsors and their members. The series will continue in the next issue of The ArxExaminer.

“Everyone has a PBM, everyone needs a PBM consultant.”

Pharmacogenomics, *continued*

testing can determine whether or not the person has the protein and establish whether or not the drug will be able to perform the necessary transportation.

3. TARGET -- An individual's genetic makeup will determine whether or not the target (e.g., tumor) will be receptive to the intended drug therapy.

In summary, pharmacogenomics is an exciting new frontier on the prescription drug horizon that has the potential to significantly improve the health and overall quality of life for individuals requiring drug therapy.

The challenge for health plan sponsors is determining what patient populations to target, evaluating the cost/benefit by condition or drug class, and then determining the financial responsibility for the cost of the genetic testing.



The Challenge Ahead

An example of how metabolism affects drug effectiveness is the drug **Tamoxifen**, commonly used for the treatment of breast cancer in women. However, approximately 20% of women do not have the enzyme necessary to enable them to metabolize the drug. A simple test can be performed to determine whether or not a woman possesses the enzyme. Here is the challenge: this drug test costs approximately \$300. Who should be responsible for the cost: the patient OR the health plan?

Similarly, the drug **Warfarin (Coumadin)** is used to prevent blood clots. But, too little causes strokes and/or pulmonary problems, while too much can cause life-threatening bleeding. Genetic testing may be able to establish dosing guidelines based upon an individual's ability to metabolize the drug and prevent such adverse side effects. But, again, who pays for the testing?

New drug safety law beefs up FDA

The US Food and Drug Administration (FDA) gained new powers under a bill President Bush recently signed into law. The law is designed to ensure the safety of millions of Americans who use prescription drugs. It renews for five years programs to collect fees from drug and medical device manufacturers.

These fees account for about 25 percent of the FDA's overall budget, defraying the cost of reviewing products that need agency approval.

The legislation shifts more of the FDA's attention from experimental drugs pending approval to those already on the market, and gives the agency more power to act when problems emerge. It also authorizes the FDA to require drug companies to do further study on the safety of medicines, and if needed, to mandate new label warnings when problems do appear.

The new law gives the FDA the power to fine companies to ensure compliance with those new authorities, and requires companies to publicly release results of all clinical trials of their drugs' performance.

The FDA would also be able to impose penalties for violations. The penalty for misleading direct-to-consumer ads would be at least \$250,000 and up to \$1 million for multiple violations.

An additional piece of the law authorizes the HHS secretary to require a Risk Evaluation and Mitigation Strategy for drug and biologic



Mission Statement: We offer expert counsel, analysis and solutions that control prescription benefits to ensure quality pharmaceutical care that improves the health of our clients and their members.