



**PDC**  
PHARMACY®  
QUALITY IS OUR FOCUS  
pdcpharmacy.com

**Serving the Intellectually and Developmentally Disabled and Behavioral Health Communities**

**[www.pdcpharmacy.com](http://www.pdcpharmacy.com)**

# Our Purpose:



## **Our Mission Matters**

To provide innovative solutions for service organizations through consultative, administrative and pharmaceutical services that promote efficiency.

## **Who Do We Serve**

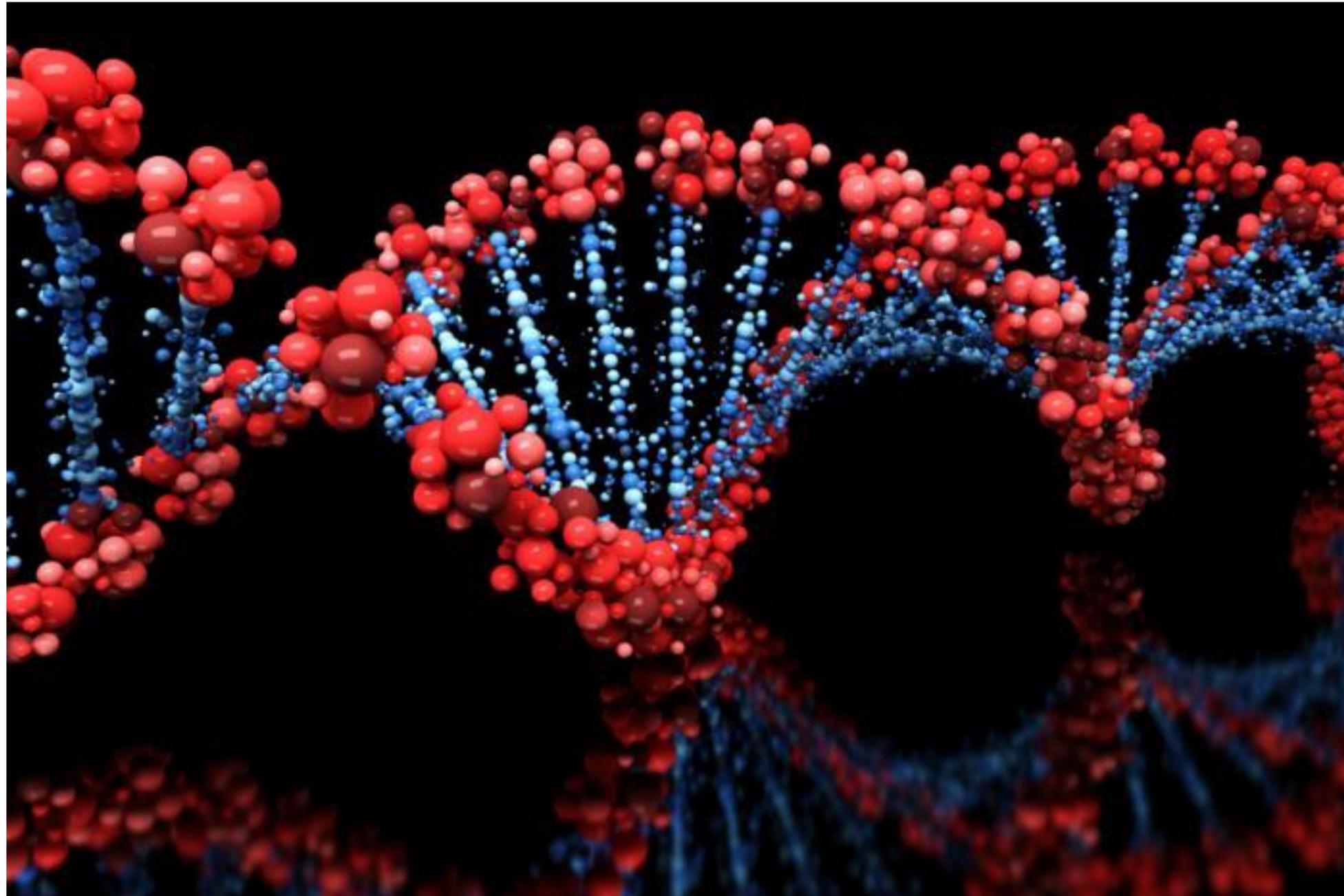
We provide specialized pharmacy services to the Intellectually and Developmentally Disabled and Behavioral Health Communities.

## **Founded by Non-Profit**

PDC Pharmacy was established in 2000 as a subsidiary of our non-profit parent provider, Passavant Memorial Homes (PMH), a Pennsylvania based human services provider with nearly 125 years of experience.

# Pharmacogenomics

## Where We Are Headed



# What is Pharmacogenomics?

- **Pharmacogenetics**

- Genetics variation to be considered in response to the drug/environmental substance

- **Pharmacogenomics**

- Discovery of new therapeutic targets and interventions and clarify the collection of genes that determine drug behavior and sensitivity

# What is Pharmacogenomics?

- Personalized medicine, targeted therapies, biomarkers, and pharmacogenomics: the next frontier of medicine is becoming part of clinical care.
- Pharmacogenomics correlates gene expression (e.g., the translation of RNA and DNA data to create proteins such as hormones, enzymes, and receptors) and polymorphisms (e.g., genetic variations) to an individual patient's drug response, both from an efficacy and toxicology standpoint.

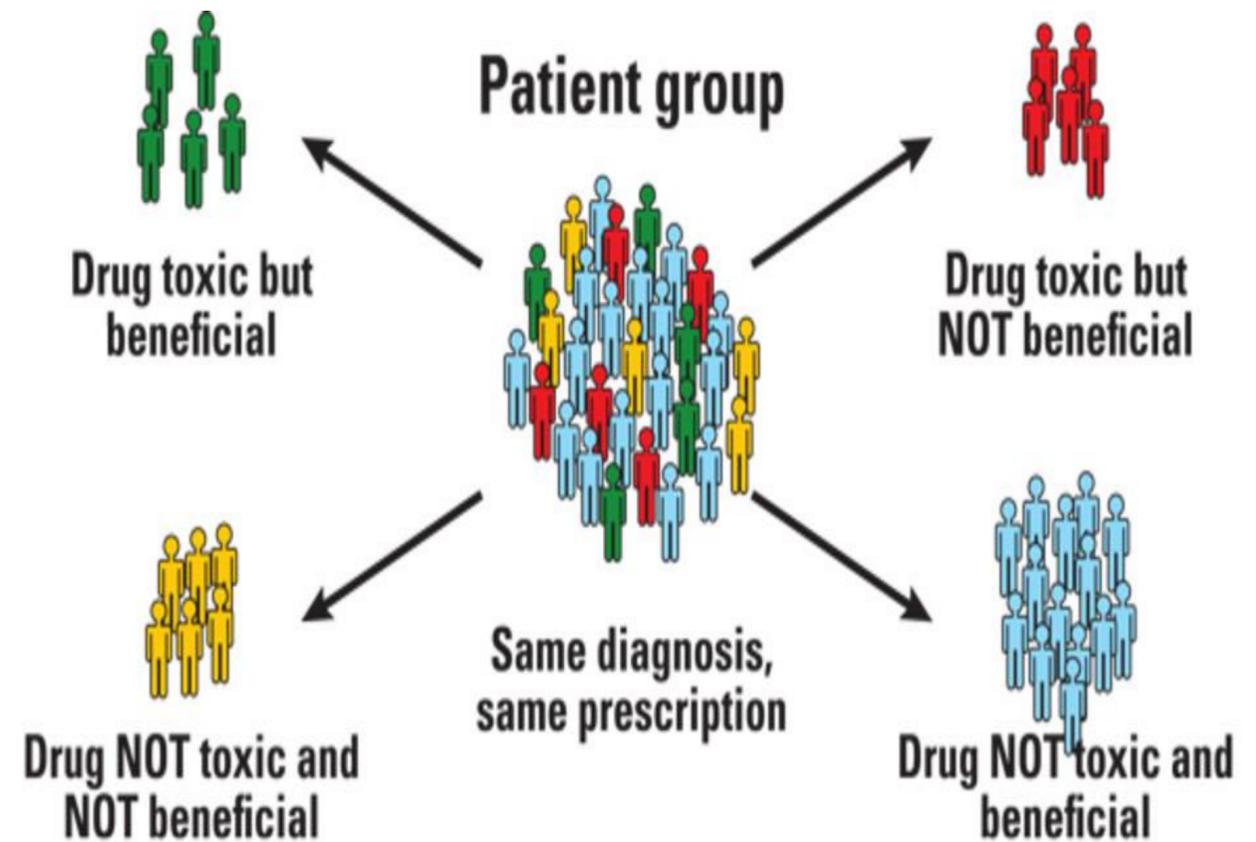
# What is Pharmacogenomics?

- The goal of pharmacogenomics is a “personalized medicine” approach to predict drug response and to tailor drug therapy according to a patient’s genetic makeup, thereby maximizing efficacy while minimizing toxicity or adverse effects.
- With over 11 million potential single nucleotide polymorphisms (SNPs) or variations at a single position in a DNA sequence, there are numerous variations in the human genome that can affect the way humans react to drugs.

# What is Pharmacogenomics?

- **Anticipated benefits of pharmacogenomics**

- Pharmacogenomics has the potential to provide tailored drug therapy based on genetically determined variation in effectiveness and side effects
- More powerful medicines
- Better, safer drugs the first time
- More accurate methods of determining appropriate drug dosages



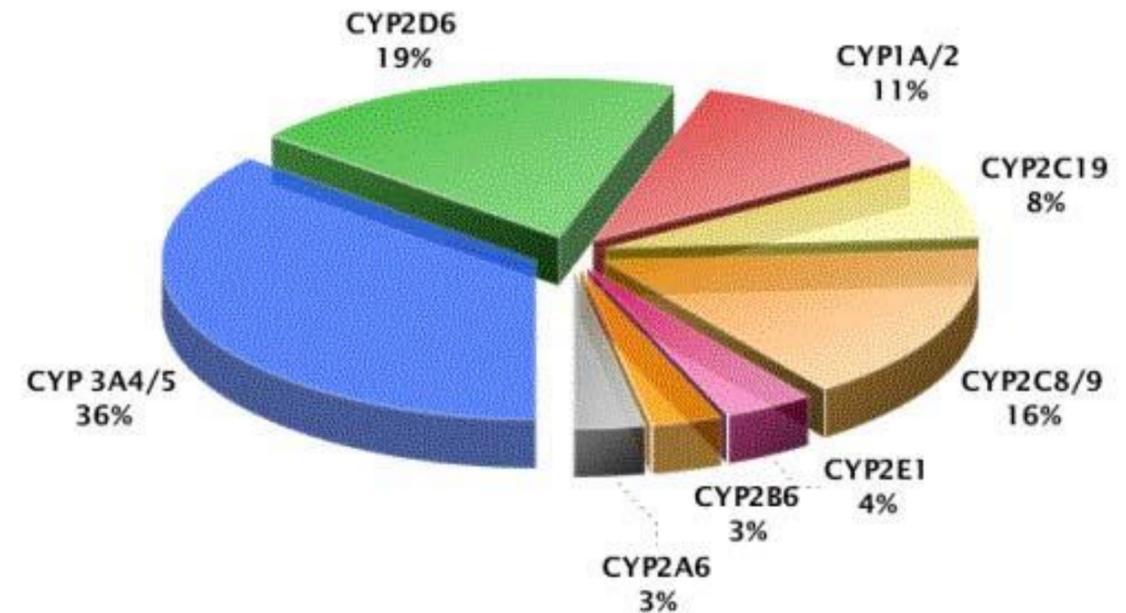
# Pharmacogenomics History

- One of the earliest applications of pharmacogenomics was the ability to look at variations of the cytochrome P450 (CYP) system enzymes.
- CYP enzymes make up the major enzyme group that performs oxidative biotransformation of drugs in the body.
- Genetic differences affect the activity of these enzymes, increasing or decreasing drug levels in the body, resulting in varying adverse effects among patients.

# Pharmacogenomics History

- Loss-of-function or gain-of-function polymorphisms can occur, resulting in an increased or decreased number of gene copies that code for CYP enzymes. This, in turn, may increase or decrease the amount of drug metabolized.
- Many new drugs can be evaluated to see how well CYP enzymes will metabolize them.

Proportion of Drugs Metabolized by P450 Enzymes



Adapted from: Wrighton SA et al. Crit Review Toxicology 1992;22:1-22.  
Kashuba and Bertino. Mechanisms of drug interaction. In Drug Interactions in Infections Diseases. Humana Press. 2001.

# Benefits of Pharmacogenomics

- Pharmacogenomics allows researchers and practitioners to better predict how an individual patient will respond (or not respond) to a drug.
- The knowledge of which patient may benefit most from a given drug and which patient may endure significant toxicity from a given drug has some very obvious benefits.
- Pharmacogenomic testing can also identify patients for enzyme differences which can improve drug monitoring and selection.

# Benefits of Pharmacogenomics

- In addition to decreasing cost, patients can benefit from genomic testing (also known as genetic testing) by discontinuing therapy with drugs deemed ineffective according to their genetic makeup and by taking preventative measures against predisposed diseases.
- For example: The use of pharmacogenomics can help decrease the cost of healthcare by lowering the number of adverse drug reactions, number of failed drug trials, and the time for new drug approvals.



# Limits of Pharmacogenomics

- The process of determining gene variations and their relations to drug response is complex and not nearly completely determined for every instance
- Pharmaceutical manufacturers may find barriers to entry to create multiple pharmacogenomic products
- Healthcare providers require additional education; this is still a very new process that many are not aware of or familiar with

# Summary

- The FDA provides guidance for including pharmacogenomics biomarkers in drug labeling.
- The labels of drugs that contain pharmacogenomic information may include data on: drug exposure, clinical response variability between patients, genotype specific dosing, mechanism of the drug, polymorphic drug targets, and genetic predispositions relating to the medication.
- The FDA also provides a table of approved drugs that contain pharmacogenomics data in their product labeling

<http://www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/ucm083378.htm>

# For Consideration

- A barrier of pharmacogenomics is identifying a single gene variation and trying to determine its relevance to drug response.
  - This is a time-consuming process and is especially difficult when multiple genes or factors influence a given patient's response.
- Patients with a particular genomic makeup may not benefit from specific treatments, leaving them few or no alternatives.
- Ethical and legal concerns can also arise from results of genomic testing.
  - Patients who get tested may have results that affect family members
  - Patients may even be denied treatment if their genes put them at a predisposition to have a reduced effect.

# Cost Savings

- The positive impact of pharmacogenomic testing (which may be expensive) on the overall cost of health care may not be realized at the start.
- Pharmacogenomic testing is credited for cost savings due to a decreased number of adverse drug reactions, number of failed drug trials, time it takes to get a drug approved, length of drug therapy, and the quantity of medications needed to treat a patient's disease state.
- The overall impact on cost-of-care continues to be measured as the availability of pharmacogenomic testing expands.

# Message from Clinical Director

Thank you for the opportunity to research and share these exciting developments in sequencing of genes as it relates to drug therapy.

I had an instructor in pharmacy school that told us about a specific enzyme used in metabolizing specific anesthesia drugs. The problem is that you didn't know you lacked the enzyme until you couldn't wake up. Wouldn't it be nice to know ahead of time?

With the onset of genomic sequencing we have the ability to evaluate the sequence, specific to the drugs. For those individuals that we service, that are non verbal, unable to voice side effects, or the success or failure of a drug, this is, in my opinion, life changing. There is a plethora of information regarding this now. On the next slide you will find a list of just a few sites you might visit.

Cheryl Olson, RPh  
Clinical Director of Operations - PDC Pharmacy

# Additional Resources

<https://www.genome.gov/27530645/faq-about-pharmacogenomics/>

<http://mayoresearch.mayo.edu/center-for-individualized-medicine/drug-gene-testing.asp>

[https://www.pharmacist.com/sites/default/files/files/mtm\\_integrating\\_pharmacogenomics.pdf](https://www.pharmacist.com/sites/default/files/files/mtm_integrating_pharmacogenomics.pdf)

<http://www.isdbweb.org/documents/file/4d8a0226ababd.pdf>

<https://www.sutori.com/story/a-brief-history-of-pharmacogenomics--rZrnL6ncN47jbbVUK6cE2UaL>