

## The Case for Pharmacogenetic Testing Fact Sheet

Clinical studies and recent healthcare industry research enumerate compelling facts in support of pharmacogenetic testing and analysis at the point of care.

The data points below are drawn from reports in a range of areas including Adverse Drug Events (ADEs), genetics, prescription medications, adherence and medical specialties.

Roughly **75% of the U.S. population** does not metabolize medications normally<sup>1</sup>

**Genetics can account for 20-95% of the variability** in an individual's response to drugs<sup>2</sup>

**2.2 million severe Adverse Drug Events (ADEs)** occur in the U.S. every year<sup>3</sup>

ADEs:

- Are the **fourth leading cause of death** in the U.S.<sup>3</sup>
- Account for approximately **\$3.5 billion in extra medical costs annually**<sup>4</sup>

**Medicare fined three-quarters of eligible hospitals** for re-admissions in 2014<sup>5</sup>

As many as **33% of all potentially clinically significant drug interactions, one of the possible causes of ADEs, are caused by drug-gene and drug-drug-gene interactions** and may be missed by drug-drug interaction analysis alone<sup>6</sup>

FDA guidance:

- Drug-gene interactions should be considered **similar in scope to drug-drug interactions**<sup>7</sup>
- **More than 100 medications known to have drug-gene interactions** require FDA warnings on the labels, with recommendation for pharmacogenetic testing prior to use<sup>7</sup>

Drug related problems, such as non-adherence, sub-optimal prescribing, drug administration and diagnosis could cost the U.S. **as much as \$290 billion per year**<sup>8</sup>

**Cytochrome variants impact more patients** than common genetic disorder testing (for conditions such as breast cancer, cystic fibrosis, Downs syndrome, psychiatric, cardiac, pain)<sup>9</sup>

One-size prescribing can lead to treatment failures and a high cost of care. For example, **cancer drugs are ineffective in an average of 75% of patients**<sup>10</sup>

## Medical Specialties:

**Cardiology** - The FDA has included pharmacogenomic information in the labels of **16 cardiology and hematology drugs**<sup>11</sup> Nine of these drugs are processed through the body's highly variable CYP450 pathways.<sup>11</sup>

**Geriatrics** - **40% of individuals over 65** take five or more medications.<sup>12</sup> One out of five elderly Americans take medications that "may adversely affect coexisting conditions"<sup>13</sup>

**Pain** - Persistent pain impacts 116 million adults and **costs the U.S. \$560-\$635 billion annually**<sup>14a</sup>; most pain medications (opioids) are metabolized by CYP450 enzymes, thus patients with variations to these genes are at an increased risk of ADEs or treatment failure<sup>14b</sup>

**Psychiatry** - Reduced metabolic function is associated with an **increased risk of adverse effects in patients taking antidepressants**<sup>15</sup>

## References

- <sup>1</sup> Villagra D, Goethe J, Schwartz HI, Szarek B, Kocherla M, Gorowski K, et al. Novel drug metabolism indices for pharmacogenetic functional status based on combinatory genotyping of CYP2C9, CYP2C19 and CYP2D6 genes. *Biomarkers in medicine*. 2011;5(4):427-38. Epub 2011/08/25. doi: 10.2217/bmm.11.32. PubMed PMID: 21861665; PubMed Central PMCID: PMC3225004.
- <sup>2</sup> Belle DJ and Singh H. Genetic Factors in Drug Metabolism. *Am Fam Physician*. 2008 Jun 1; 77(11);1553-1560.
- <sup>3</sup> Lazarou J, Pomeranz, BH, Corey PN. Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-analysis of Prospective Studies. *JAMA*. 1998 Apr; 279 (15):1200-1205.
- <sup>4</sup> U.S. Center for Disease Control and Prevention; *Journal of the American Medical Association*
- <sup>5</sup> Rau J. Medicare Fines 2,610 Hospitals In Third Round Of Readmission Penalties [Online News Service]. *Kaiser Health News*; 2014 [cited 2014]. Available from: <http://kaiserhealthnews.org/news/medicare-readmissions-penalties-2015>
- <sup>6</sup> Verbeurgt P, Mamiya T, Oesterheld J. How common are drug and gene interactions? Prevalence in a sample of 1143 patients with CYP2C9, CYP2C19 and CYP2D6 genotyping. *Pharmacogenomics*. 2014;15(5):655-65. Epub 2014/05/07. doi: 10.2217/pgs.14.6. PubMed PMID: 24798722.
- <sup>7</sup> [www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM337169.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM337169.pdf)
- <sup>8</sup> Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease. A NEHI Research Brief - August 2009: NEHI; 2009.
- <sup>9</sup> Cystic Fibrosis Foundation; [www.BreastCancer.org](http://www.BreastCancer.org); National Down Syndrome Society; Genelex14K+ patients and hundreds of published reference papers; Administration on Aging, CVS Pharmacy; Wall Street Journal / Medco Health Solutions; Centers for Disease Control.
- <sup>10</sup> [www.personalizedmedicinecoalition.org/sites/default/files/files/Case\\_for\\_PM\\_3rd\\_edition.pdf](http://www.personalizedmedicinecoalition.org/sites/default/files/files/Case_for_PM_3rd_edition.pdf)
- <sup>11</sup> Table of Pharmacogenomic Biomarkers in Drug Labels Silver Spring, MD: FDA; 2013 [cited 2014 2/14/14]. Available from: [www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/ucm083378.htm](http://www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/ucm083378.htm)

<sup>12</sup> Qato DM, Alexander GC, Conti RM, Johnson M, Schumm P, Lindau ST. Use of prescription and over-the-counter medications and dietary supplements among older adults in the United States. *Jama*. 2008;300(24):2867-78. Epub 2008/12/26. doi: 10.1001/jama.2008.892. PubMed PMID: 19109115; PubMed Central PMCID: PMC3934884.

<sup>13</sup> Lorgunpai SJ, Grammas M, Lee DS, McAvay G, Charpentier P, Tinetti ME. Potential therapeutic competition in community-living older adults in the u.s.: use of medications that may adversely affect a coexisting condition. *PLoS One*. 2014;9(2):e89447. doi: 10.1371/journal.pone.0089447. PubMed PMID: 24586786; PubMed Central PMCID: PMC3934884.

<sup>14a</sup> Institute of Medicine Committee on Advancing Pain Research, Care, and Education. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*. Washington, DC: National Academies Press; 2011.

<sup>14b</sup> Smith HS. Opioid Metabolism. *Mayo Clin Proc*. 2009;84 (7):613-624. PubMed PMID: 19567715.

<sup>15</sup> Ingelman-Sundberg M, Sim SC, Gomez A, Rodriguez-Antona C. Influence of cytochrome P450 polymorphisms on drug therapies: pharmacogenetic, pharmacoeconomic and clinical aspects. *Pharmacol Ther*. 2007; 116:496-526.