

Personalized Medicine

A Legal and Business Perspective

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Benefits of PGx

- **Addressing pharma productivity crisis**
 - Faster/lower cost clinical trials
 - New uses
 - Drug rescue
 - Product differentiation
 - Dominating niche markets
- **But, market size may decrease**
 - Little incentive to invest in PGx applications of approved drugs

Outlook

- **Progress will need:**
 - Biomarkers
 - Diagnostics
 - Bioinformatics
 - Clinical trial design
 - Drugs or biologicals
- **Will affect balance of power of players in therapeutics world**

Patents

- **Extremely important for therapeutic products**
- **Market exclusivity carefully managed**
- **PGx applications may lengthen exclusivity term**

Patents

- Thicket of granted patents
- ~ 6% of drug/diagnostic/biotech patents are related to personalized medicine
- High growth rate
- Freedom of action concerns

Patents

- **SNP consortium approach**
- ***Integra v. Merck***
- **Bargaining position depends on patent position**

FDA Guidelines

- **“Pharmacogenomic Data Submissions” issued March 2005**
- **Of much symbolic value**
- **Addresses concerns that FDA might misuse submitted data**

FDA Guidelines

- Data to be submitted with IND, NDA/BLA, and/or supplements
- Submission required for known valid biomarkers, but voluntary for exploratory/research data
- Exploratory data will not be used for regulatory decision-making
- Gaming concerns

PGx and tort liability

- “failure to test” theories not yet successful
- “duty to warn” of known potential side effects
 - *Cassidy v. SmithKline Beecham*
- Current medical practice standard
- Law will be changing with PGx advances

PGx and Forensics

- **CYP2D6 polymorphism exonerated parents in fluoxetine poisoning case**
- **CYP2D6*4 homozygous genotype linked to methadone death**

PGx and Privacy

- **Genotyping might include too much predictive information**
- **Access by employers/insurers to genetic information**
 - ADA
 - HIPAA

Conclusion

- **Personalized medicine is here**
- **Biotech companies need to carefully plan patent portfolios**
- **Pharmaceutical companies should routinely think pharmacogenomically**
- **Patients need to protect their confidentiality**