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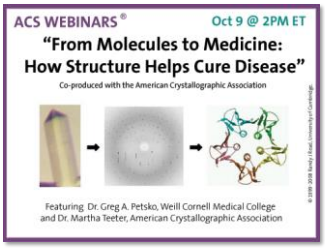

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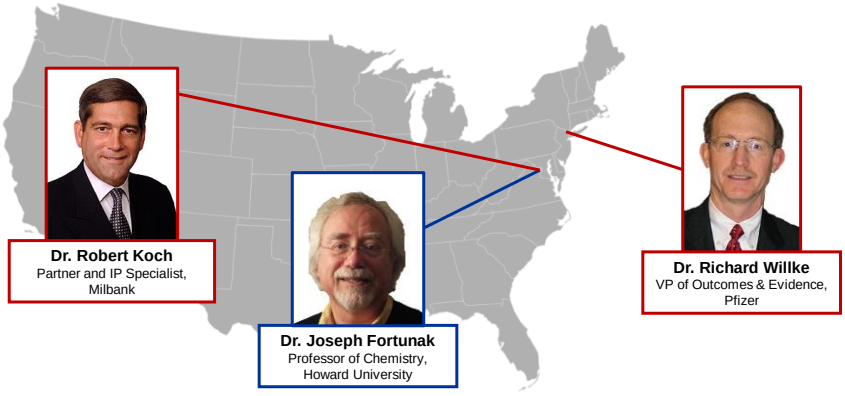

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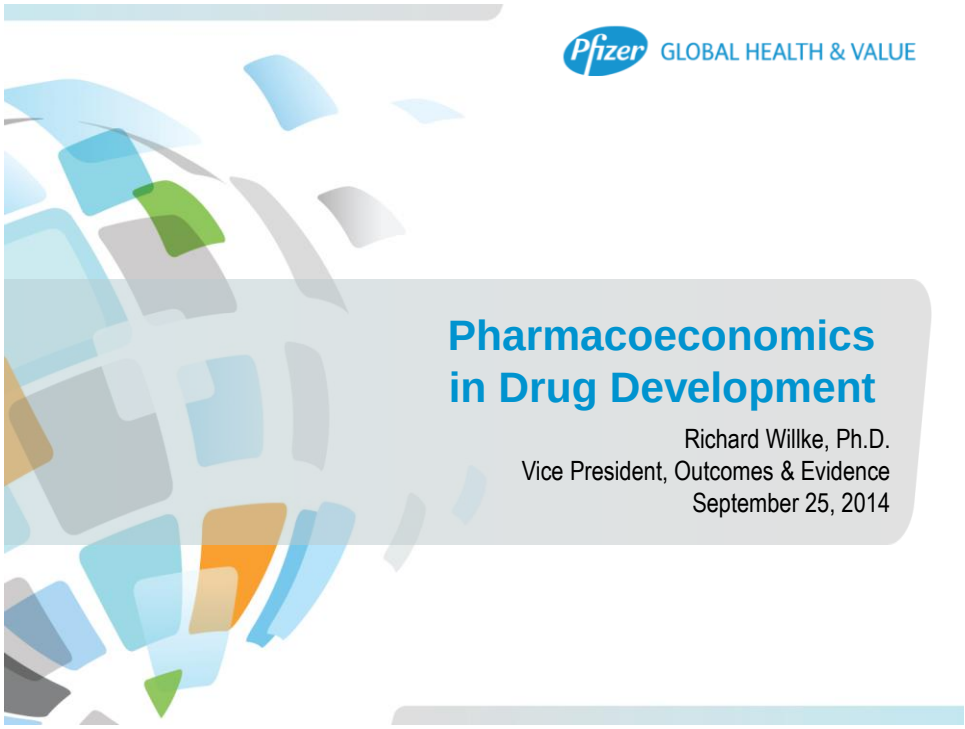

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- How patient outcomes fit into pharmacoeconomics
- The role that pharmacoeconomics plays in the drug development cycle

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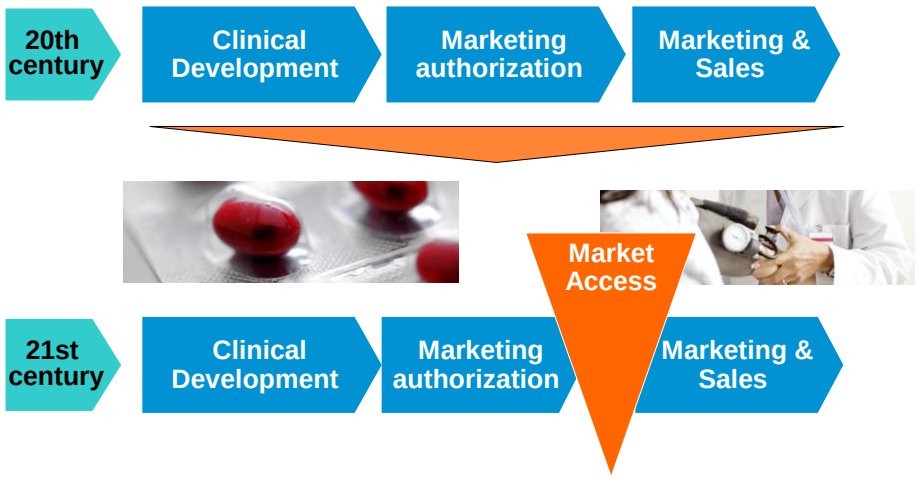
The Healthcare Environment Has Changed



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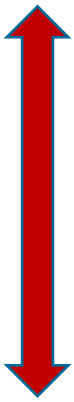
Market Access: Affected by Many Factors

Medical



Regulatory approval

Comparative effectiveness/relative effectiveness

External health system environment

Health technology assessment

Pharmacoeconomic evaluation

Conditional reimbursement

Pricing & cost containment

Economic

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Where is Pharmacoeconomic Evaluation Relevant?

There are 4 Archetypes of Payers

★ **Negotiations-driven markets** (France, Italy, Spain): National pricing and reimbursement agencies with specific requirements, often lengthy negotiations process.

★★★ **HTA-driven markets** (UK, Neth., Canada, Australia): Quantitative, formalistic approach driven by health economics.

★★ **Free pricing markets** (USA): Independent insurance companies and payer entities, laws of market economics are most relevant here. Pharmacoeconomic evaluation used by some payers.

★ ***Non-reimbursed markets*** *(emerging markets): Still need to price products and get government approval.*

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Pharmacoeconomics and the Basic Elements of Measuring Value

Cost: How does the new product affect overall treatment costs?

Budget Impact

Benefit: What's the net health benefit from the new product, compared to others?

Comparative effectiveness

Cost-benefit (aka cost-effectiveness) ratio:

What's the cost per additional unit of health? Is the patient or society willing to pay that much for the new product?

Value for money

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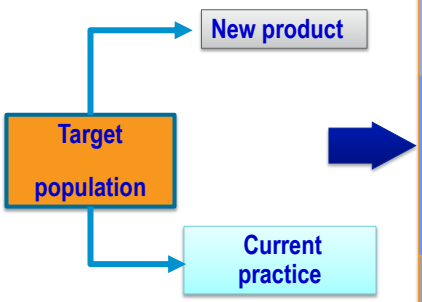
Pharmacoeconomic Evaluation Parameters



Patient benefits	effectiveness survival quality of life patient preferences
Direct costs (impact on health resource use)	hospital care outpatient care primary care medication long-term care
Indirect costs	lost productivity time lost from usual activities social costs (eg. caregiver time, childcare)

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How is Cost-effectiveness Judged?

- **Cost-Minimization**
  - Reducing overall treatment costs is always good, as long as outcomes are no worse
  - Most common situation is when drugs go generic, so choosing generic drugs over branded drugs in the same class usually reduces treatment costs
- **Cost-effectiveness**
  - Within disease
    - Reasonable cost per "endpoint improvement" , e.g., cost per stroke avoided, compared to other therapies
    - Varies by disease
  - Across diseases
    - Pharmacoeconomic endpoint is "quality-adjusted life-year" (QALY); can be used in any disease
    - Choose therapies with a reasonable cost per quality-adjusted life year saved
    - In the UK, "reasonable" means less than £20,000 - £30,000 per QALY
    - In the US, "reasonable" is more like $100,000 per QALY, though it's not specifically set by most payers and can vary by condition

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Audience Survey Question

Which of the following countries was the first European country to establish pharmacoeconomic guidelines?

- Belgium
- The Netherlands
- Portugal
- Germany
- France

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Pharmacoeconomic Guidelines Around the World

COUNTRY-SPECIFIC PHARMACOECONOMIC GUIDELINES

	Published PE Recommendations	PE Guidelines	Submission Guidelines
Africa	South Africa *2010*		
America- Centre and South		Brazil *2009* Cuba *2003* México *2008*	
America-North	United States *2009*	Canada *2006*	
Asia	China Mainland *2011*	Taiwan *2006* South Korea *2006*	Israel *2010* Thailand *2008*
Europe	Austria *2006* Denmark *1997* Hungary *2002* Italy *2001* Russian Federation *2010* Spain *2010*	Baltic (Latvia, Lithuania, Estonia) *2002* Belgium *2008* France *2004* Germany *2009* Ireland *2010* The Netherlands *2006* Norway *2012* Portugal *1998* Slovak Republic *2008* Sweden *2003*	England & Wales *2008* Finland *2009* Poland *2009* Scotland *2007*
Oceania		New Zealand *2007*	Australia *2008*

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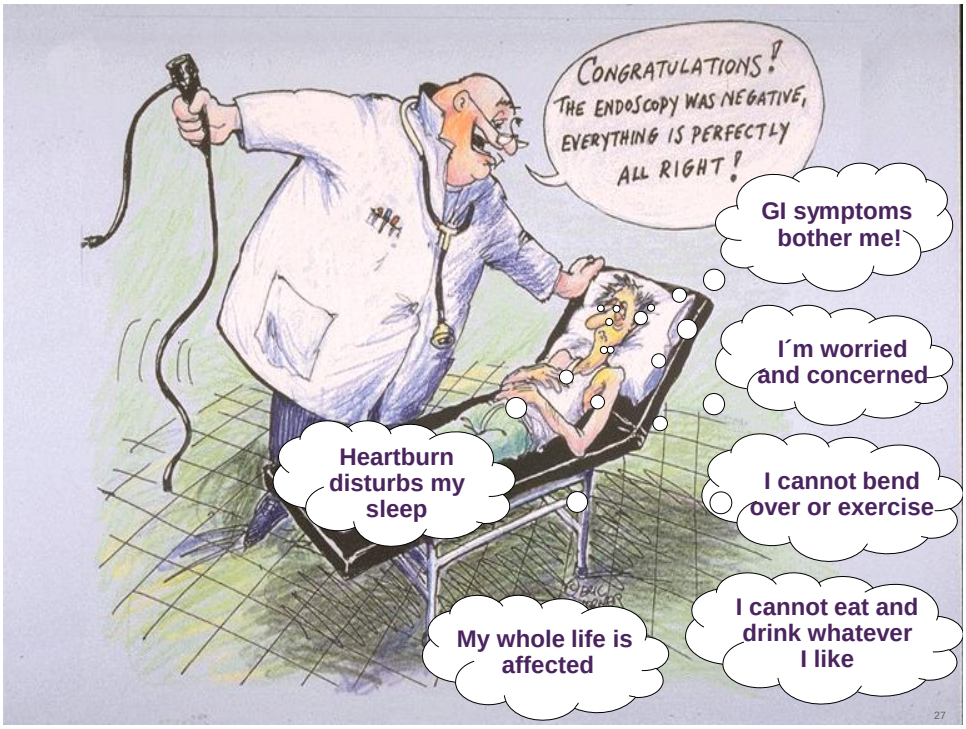
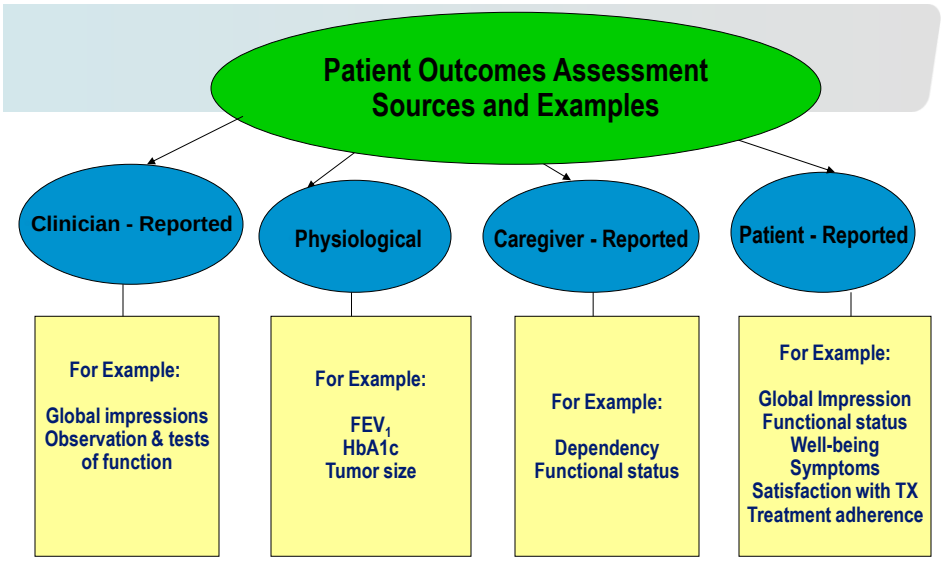

CONGRATULATIONS! THE ENDOSCOPY WAS NEGATIVE, EVERYTHING IS PERFECTLY ALL RIGHT!
GI symptoms bother me!
I´m worried and concerned
I cannot bend over or exercise
I cannot eat and drink whatever I like
My whole life is affected
Heartburn disturbs my sleep
27


Patient Outcomes Assessment Sources and Examples
Clinician - Reported
Physiological
Caregiver - Reported
Patient - Reported
For Example:
Global impressions
Observation & tests of function
For Example:
FEV1
HbA1c
Tumor size
For Example:
Dependency
Functional status
For Example:
Global Impression
Functional status
Well-being
Symptoms
Satisfaction with TX
Treatment adherence

Health-Related Quality of Life (HRQL)

A person's *subjective* perception of the impact of health status,

including disease and treatment,

on

physical, psychological, and social functioning and well-being

(Leidy, Revicki, Geneste, 1999)

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Patient-Reported Outcome Study Methods

With what?	• Validated questionnaires • "Generic" or disease-specific instruments
In Clinical Trials	• As a primary or secondary endpoint • Tested for clinically meaningful differences due to treatment • May be included in drug labeling
Other sources	• Electronic medical record • Disease-specific patient registry • On-line surveys

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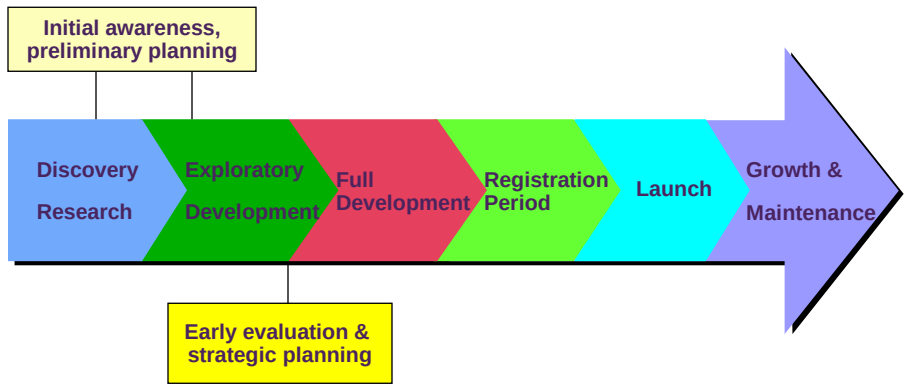
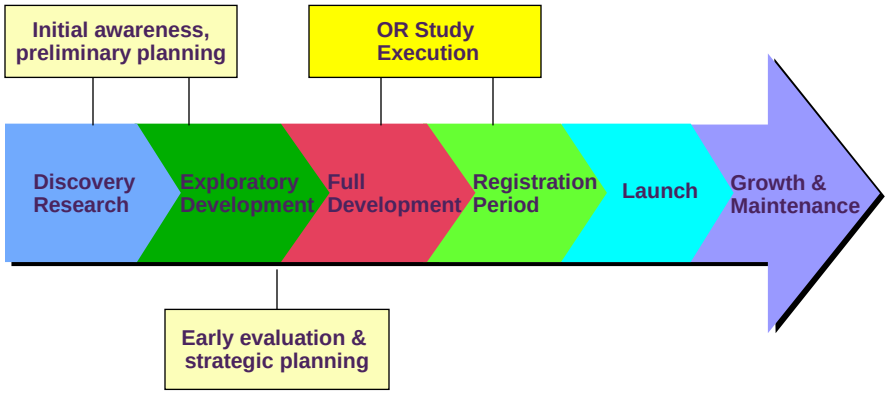
Terminology Note: "Pharmacoeconomics" is an aspect of the broader field of "Outcomes Research"; sometimes the terms are used together or interchangeably

Outcomes Research and the Product Cycle



Outcomes Research and the Product Cycle



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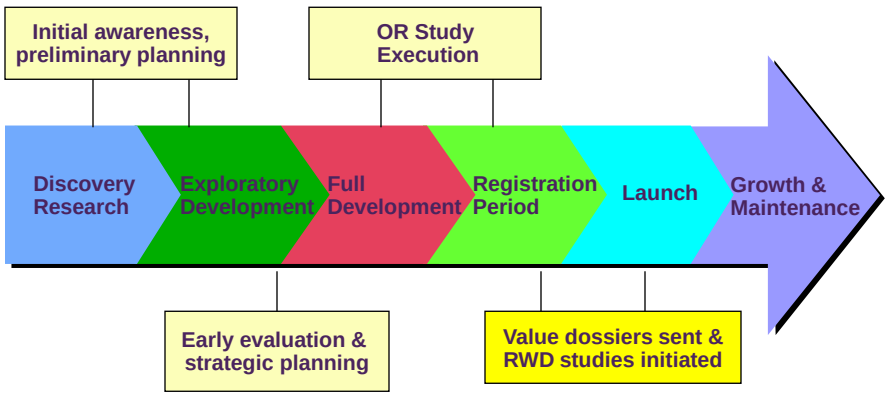
Outcomes Research and the Product Cycle



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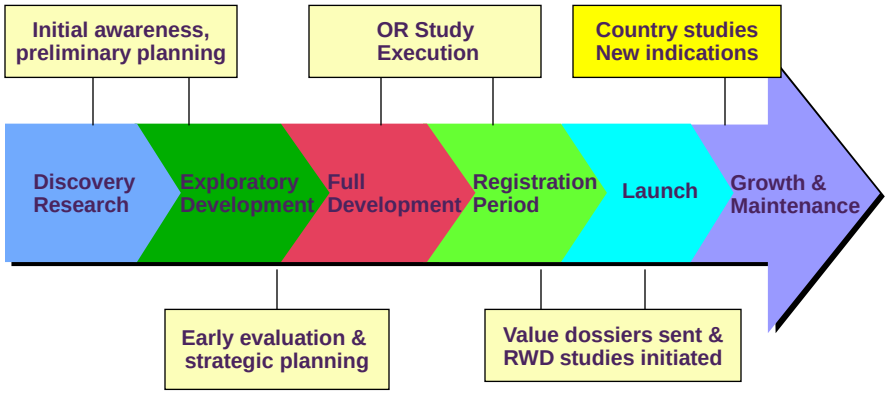
Outcomes Research and the Product Cycle



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HEOR Evidence-Generating Tools

Pre-launch

- Early economic models for price-efficacy
- PRO instrument development and RCT use
- Burden of illness studies with real world data
- RCT-based HE analyses
- Full economic models (Cost-effectiveness/ Budget Impact)
- Indirect/mixed treatment comparisons
- Dossiers

Post-launch

- Phase 4 prospective studies with HE components and/or analyses
- Registry and EMR design and analysis
- Comparative effectiveness research with real-world data
- Studies done in partnership with payers
- Employer studies/models

and more…

Can be used in preparation for P&R negotiations

Can be used to support pull-through, responses to new market issues, and P&R reviews

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Summary

- Pharmacoeconomics measures the "value for money" brought to society by drug treatments, drawing its methods from health economics more broadly
- Patient benefits, including quality of life benefits, from treatment must be scientifically captured, both to properly assess value and to better communicate treatment effects to patients and physicians
- Payers across the world are increasingly using pharmacoeconomic results in their reimbursement decisions
- Pharmacoeconomic work is done during all parts of the drug development cycle and helps inform product development strategy

What You Will Learn

I. IP Considerations in New Drug Development

II. Most Important IP Policies Affecting New Drug Development

III. How IP Protection and Enforcement Decisions Are Made

I. IP Considerations in New Drug Development

- Patents
- Trademarks
- Trade Dress
- Trade Secrets
- Copyrights

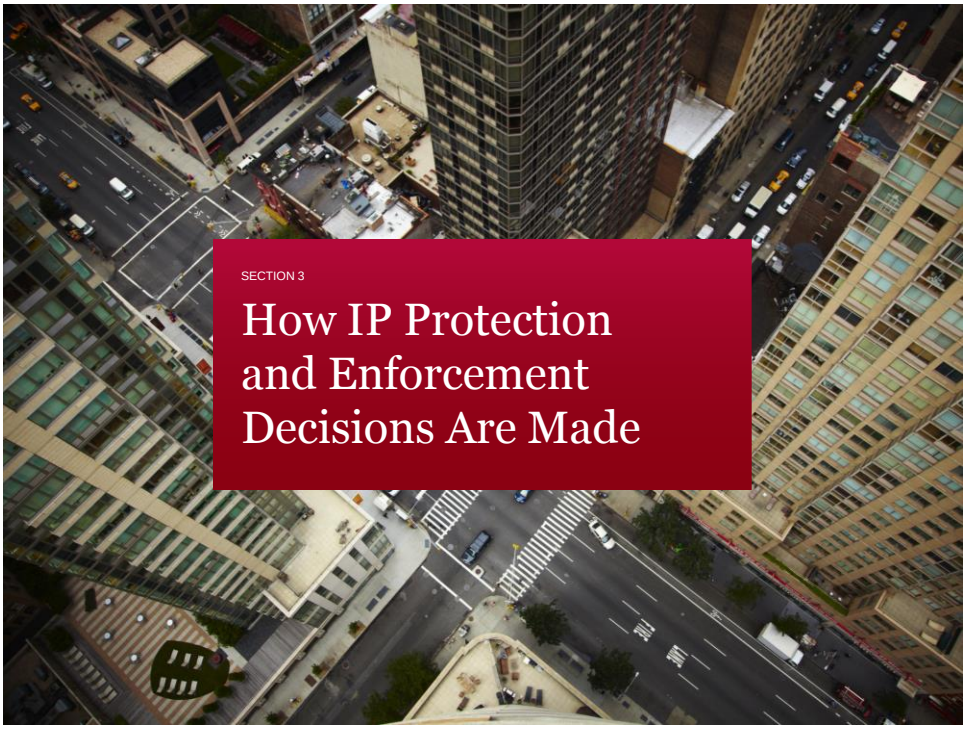
II. Most Important IP Policies Affecting New Drug Development

- IP Landscape
  - U.S.
  - Europe
  - Asia
  - R.O.W.
- Pharmacoeconomics
- Regulation
  - U.S.
  - Europe

Audience Survey Question

Are you familiar with patent enforcement under Hatch-Waxman?

- No
- Heard of it
- Somewhat familiar
- Very familiar



III. How IP Protection and Enforcement Decisions Are Made

A. Innovator

B. Generics

C. Biotechnology

A. Innovator Drug Companies

- Sophisticated IP Departments
  - Patent
  - Trademark
  - Marketing & Advertising
- Focus on Patent Consideration
  - Compounds
  - Compositions
  - Methods
  - Structure
  - Dosage Requirements
  - Treatment Protocols

A. Innovator Drug Companies

- Portfolio Development
- Patent Timelines
  - Normal 20 year term
  - Term Extensions
  - Improvement patents

B. Generic Drug Companies

- Hatch-Waxman Timeline
- Sophisticated IP Management
  - Most in-house
  - Combinations with Outside Counsel

C. Biotechnology Companies

- Only 40 years old
- Many Startups
  - Outside Patent Counsel
  - Innovative, Creative, Risk Takers
  - Reliance on Big Pharma for Drug Development

Hatch-Waxman Act

- 1984 Drug Price Competition and Patent Term Restoration Act
- Amended Federal Food Drug and Cosmetic Act
- Governs generic drug product's entry into the market place
- Designed to protect the interest of the innovator drug companies while increasing the availability of generic drugs

NDA

- An innovator company must file a New Drug Application with the FDA to obtain approval to market its product
- NDA includes:
  - Full reports of investigation showing the drug is safe and effective
  - List of components of the drug
  - Description of methods facilities and controls used for producing the drug
  - Samples of drug and manufacturing components
  - Labeling information
  - Patent Information

Orange Book

Patents listed in an approved NDA are published in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations*

Purple Book

Newly created list under new regulations for Biosimilars

ANDA

- A manufacturer seeking to market a generic version of an FDA approved drug can file an abbreviated new drug application (ANDA)

- "Safe Harbor" under Hatch-Waxman Act to conduct research to develop information for an ANDA submission

ANDA

Applicant relies on safety and effectiveness finding of FDA for the innovator drug if generic product is therapeutically equivalent to Orange Book listed drug

A. Pharmaceutically equivalent

B. Bioequivalent

ANDA Certifications

- Applicant must make one of following certifications:
  1. There are no patents listed for the drug
  2. The patents listed for the drug are expired
  3. The patents listed for the drug will expire on a particular future date
  4. The patents listed for the drug are invalid or will not be infringed by the generic drug

Patent Infringement Litigation

For certification of invalidity or non-infringement

- ANDA applicant gives notice to NDA holder within 20 days
- Statutory act of infringement under Hatch-Waxman

Patent Infringement Litigation

- Litigation to be filed by NDA holder within 45 days of Notice Letter
- Results:
  a) 30 month stay of FDA's approval of ANDA
  b) 180 day period of exclusivity
     – *i.e.,* FDA cannot approve any subsequently filed ANDA's
     – period begins on date ANDA files begins to market the generic product

Settlements

1. Highly Controversial in recent years
2. Must be reported to Federal Trade Commission and Department of Justice
3. Pay for Delay – Antitrust Challenges

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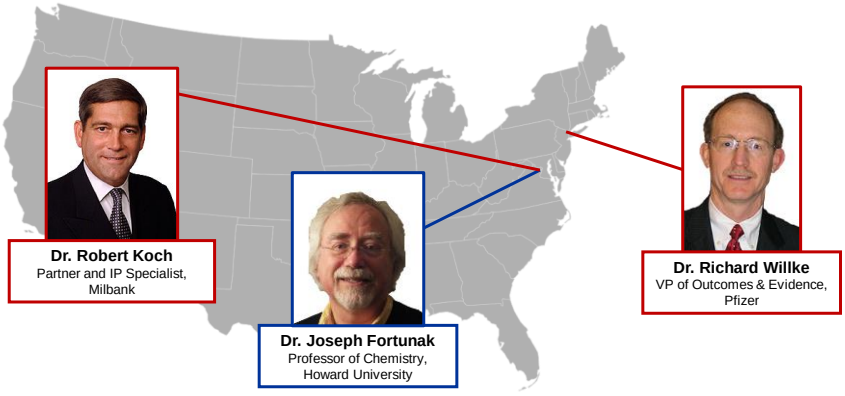

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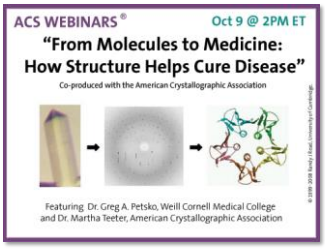

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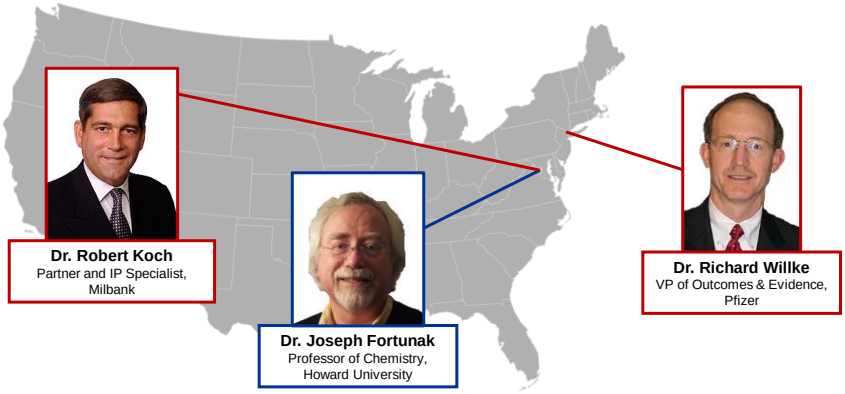

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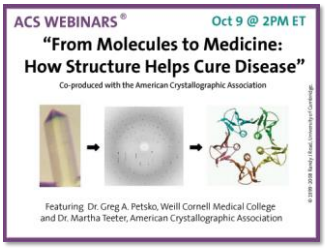

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